



PRATISHTA INSTITUTE OF PHARMACEUTICAL SCIENCES

(Accredited by NAAC with 'A' grade, Approved by AICTE PCI New Delhi, Affiliated to JNTUH and SBTET, TS)
Duraipally (V), Chivmela (M), Suryapet (Dist.) Telangana-508214

Website: www.pratishtapharmacy.in, E-mail: pratishta.pharmacy@yahoo.com



2.3.1: Student centric methods, such as experiential learning, participative learning and problem-Solving methodologies are used for enhancing learning experiences

The teaching-learning process is one major objective and the strength of our college. Students are given a right blend of traditional and modern methods to make learning student-centric and a rewarding experience. Experiential learning, participative learning and problem solving methodologies are well adopted to ensure the holistic development of students and facilitate life-long learning and knowledge management. a) Experiential learning 1. Practical courses (laboratory) including virtual labs are made compulsory in the online mode class activities. 2. The inclusion of Internship is developing good practices and innovative methods of learning, The traditional lecture and laboratory activities have evolved into more open ended, Internship-based experiences that help students develop additional skills and contextualize the learning of theories. 3. Each student must do a Project as part of the curriculum where the student can choose a domain of their interest and implement their innovation. The students are motivated to do industry and research-oriented projects. 4. Content beyond the experiments are assigned to the student to fill the gap between curriculum and industry requirements.

b. Participative learning 1. Industrial / field visits / internship at Industry and/or renowned institutions are mandatory. 2. Students are involving group discussion and seminar presentation on very course related topics. 3. Students are encouraged and presently made mandatory to take Online Courses offered by premier institutions of the country. 4. Each course handling conducting Quiz, Debate for the sharing of the student technical knowledge. 5. Industry projects and collaborations are undertaken to enrich students with pre-employment training. 6. Periodical Guest lectures on topics relevant to employment skills by personnel from respective organizations / industry.



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C) Problem solving methodologies

1. Each course handling faculties are giving Case Study topic – related their subject for analysis and discussion. 2. Faculties are conducting subjects of highly analytical nature, with the objective to increase problem solving capabilities, analytical thinking and logical ability. 3. Faculties are support to the students to attempt and solve problems individually and independently. 4. For the tutorial session, a class is divided into two groups and faculty members are assigned to each group separately. 5. Giving assignments and quizzes at the end of instruction of each unit. All academic activities are aimed at elevating the students' knowledge, skills and build confidence in them.

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INDUSTRIAL TRAINING

- Industrial training, where a student undertakes a period of training at an organization usually during a semester break, is an important part of preparing the student for a professional career.
- Through active involvement in preparation, the student learns about industrial demands, skill sets, and work ethics.
- Every year, students experience industrial training as per the syllabus prescribed by JNTUH and gain knowledge of various departments such as Quality Assurance, Quality Control, Tablets, Capsules, Vaccine Manufacturing, Analytical Research and Development, Clinical Research, Drug Regulatory Affairs, Hospital Pharmacy, etc. For instance, IV-year B. Pharmacy students have visited The Suven Pharmaceuticals Pvt. Ltd., located at Suryapet Ho, Suryapet-508213 (Near Sree Maruthi Vidya Nikethan, Dasai Gudem Industrial Area).





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HANDS-ONLEARNING

- B. Pharmacy, Pharm D, and M. Pharm students gain theoretical knowledge by participating in pragmatic learning within various laboratories located at the institute.
- The faculty has designed various experiments according to the syllabus assigned by JNTUH. Students gain practical awareness through live activities and handling instruments such as UV-Visible Spectrophotometry, HPLC, Dissolution, and Gel Electrophoresis, among others.

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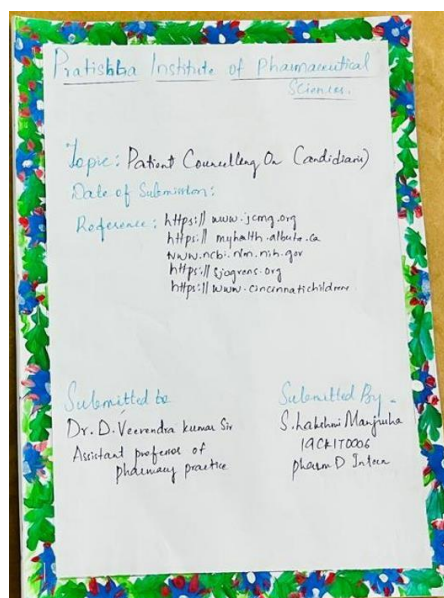
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ASSIGNMENTS

- Assignments are a crucial component of the internal evaluation process, serving as valuable learning instruments.
- Students may be given various types of assignments, including essays, literature reviews, annotated bibliographies, critical reviews, reflective journals, and case studies, depending on the needs and learning situations. These tasks are designed to help students achieve learning objectives related to specific content, concepts, or relationships. Assignments involve independent information seeking and the use of a wide range of information sources. Each semester, students are assigned two topics per subject related to their syllabus and are required to gather relevant information.
- Marks are allotted based on the completion and quality of the assigned tasks.
- Through this process, students enhance their knowledge of the topic, improve their proofreading skills, and develop presentation techniques.



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Topic: PATIENT COUNSELLING ON VARICOSE VEIN

REFERENCE: ISTG Book
MED FLIX
MED SCAPE.

SUBMISSION DATE:

SUBMITTED TO
DR. D. VEERENDRA KUMAR SIR,
Asst. Professor,
Department of pharmacy practice.

SUBMITTED BY:
Bilhabha Ramsh,
jackit0017
pharm-D saler.

Pratishta Institute of Pharmaceutical Sciences

Submitted to:
Amena Kausar
19CKT0004
Pharm D Student

Topic: Disease/Counseling
Points on Meningitis
[80 Points]

"Meningitis"

Submitted to → DR. D. VEERENDRA KUMAR SIR

Signature:

Remarks:

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PROJECTBASEDLEARNING

Project-based learning is a teaching method where students gain knowledge and skills by working over an extended period to investigate and respond to an authentic, engaging, and complex question, problem, or challenge. This approach not only provides opportunities for students to collaborate and take charge of their own learning but also teaches essential skills such as problem-solving. Additionally, it helps in developing critical thinking and time management skills, which are integral to their future.

Each year, IV B. Pharmacy, II M. Pharmacy, and Pharm D students are assigned a project under the guidance of faculty, to be completed within the academic year. Marks are awarded based on the project results, presentation, and viva-voce. The research and review articles of these projects are published by students in various national and international journals.

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LIST OF PROJECTS OF IV TH YEAR B.PHARM STUDENTS-A.Y.2023-2024

A Total of 11 projects were done under the guidance of their respective guides.

Sl.No	Name of the Superior	Roll.No	Name of the Student	Title of the Project
1	K.Sandhya Ms.Pharm	20CK1R0003	J.AKHILA	DESIGN AND SYNTHESIS OF 1,3,4 OXADIAZOLE DERIVATIVE SACTING ON INFLAMMATION
		20CK1R0010	A.ASHWINI	
		20CK1R0016	G.DIVYA	
		20CK1R0050	R.SRAVANI	
		20CK1R0077	SOUMYA DEEP MAITI	
2	SHAIKRAFIYA, M.Pharm	(20CK1R0001)	PANJALAA KANKSHA	PREPARATION AND EVALUATION OF HAIR GELS BY USING BUTEAMONOSPERMA FLOWER EXTRACT
		(20CK1R0031)	RUDRAPRADEEP	
		(20CK1R0049)	MANNEM SRAVANI	
		(17CK1R0075)	CHARALA VENUMADHAV	
		(17CK1R0059)	KAKARJALAPA VANKUMAR	
3	SHAIKSHAHEEN, M.PHARM.,	(20CK1R0008)	MAMIDI ANU	SYNTHESIS AND STUDIES OF BIPHENYL DERIVATIVES AND THEIR ANTIMICROBIAL ACTIVITIES
		(20CK1R0011)	SHAIKASMA	
		(20CK1R0014)	NARIGE BH OOMIKA	
		(20CK1R0043)	MAMIDI SHEELA	
		(20CK1R0062)	CHINNAPANGU VISHNU	
4	Y.VENKATESWARLUM, Pharm.	(20CK1R0074)	MDS AIDALAM	"SYNTHESIS AND STUDIES OF BIPHENYL DERIVATIVES AND THEIR ANTIMICROBIAL ACTIVITIES"
		(20CK1R0066)	AKSHAY HATI	
		(20CK1R0047)	CHINTHA SHOBHA	
		(20CK1R0060)	M.VINAY KUMAR	
		(20CK1R0061)	D.VINEETH	

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5	BOINAPALLI.RAMBABU M.Pharm(PhD)	20CK1R0023	PATTETIM EGHANA	FORMULATION AND INVITRO EVALUATION OF ORAL DISINTEGRATING TABLETS OF DICLOFENAC SODIUM TABLETS
		(20CK1R0033)	K RAJARAJESH WARI	
		(20CK1R0045)	SIRIKONDA SHIRESHA	
		(20CK1R0048)	DUGGESINDHU	
		(20CK1R0051)	SHAIKSULTHAN	
6	BATHINIVIJAYKUMAR M.Pharm	(20CK1R0013)	ATHRAM BHEEMRAO	DESIGN AND INVITRO CHARACTERIZ ATION OF NON- EFFERVESCENT FLOATI NG TABLETS OF GLIPIZIDE
		(20CK1R0055)	KVANDANA	
		(20CK1R0055)	DURGAMVASAVI	
7	Dr.CHANDAKAMADHU. M.Pharm, PGDCR., (PhD)	(20CK1R0030)	BASARAJU PAVANI	INFLUENCE OF CRUDE FIBRE AN LAXATIVE ACTIVITY ON DRY FRUITS
		(20CK1R0026)	KAVALI NARESHKUMAR	
		(20CK1R0076)	SUBHAMAJHI	
8	DONTAMALLA.GUNASHEELA M.Pharm(PhD) Scholar	(20CK1R0009)	GUMMAKONDA ANUSHA	FORMULATION OF GEL AND ITS UV PROTECTION STUDY OF SOME MEDICINAL FLOWE RS
		(20CK1R0032)	PADIRA PRUDVIRAJ	
		(20CK1R0044)	MALOTHSH IREESHA	
		(20CK1R0072)	AMARESHGIRI	
		(19CK1R0003)	PACHIPALA BHAVANI	
9	G.MANASAVEENAM.Pharm	(20CK1R0069)	PRITAMGHOSH	ESTIMATION OF SPF NUMBER
		(20CK1R0067)	RITWIKDAS	
		(20CK1R0006)	CH.ANAND	
		(20CK1R0071)	TOOBAAYESHA	
10	M.RAJANI.(M. Pharm)	(20CK1R0005)	THOTAAMULYA	PHYTOCHEMICAL SCREEN ING AND ANTIOXIDANT ACTIVITY ON METHANOLIC EXTRACT OF MANILKARAZAPOTA
		(20CK1R0029)	KONGALANAVYA	
		(20CK1R0042)	KANKALIS HARADHA	
		(20CK1R0052)	CH. SURYANAR AYANA	
		(20CK1R0068)	BUDDHADEVSHIT	



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11	DRYENUMULANETTEKALLUM. PHARM.,Ph.D., Professor	(20CK1R0007)	RATLAVATH ANJALI	DEVELOPMENT AND CHARACTERIZATION OF FLOATING TABLETS OF METFORMIN HYDROCHLORIDE
		(20CK1R0017)	JONNALAGADDA GOPICHAND	
		(20CKIR0023)	PERUMALLAPALLI MADHURI	
		(20CKIR0036)	MANDADIR USHMITHA	
		(20CK1R0070)	PUSULURI NAYAKANTIK ALYANBABU	

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LIST OF PROJECTS OF V TH YEAR PHARM D STUDENTS –A.Y.2023-2024

sl no.	Name of the Supervisor	Rollno	Name of the Students	Title
1	Dr.CHANDAKA MADHU M.Pharm,PGV Ph.D(Dept of pharmacology)	19CK1T0001	KOMARARAPU BHANUSANJANA	EVALUATING VITAMIN-DRUG INTERACTIONS: THE CRUCIAL ROLE OF CLINICAL PHARMACIST.
		19CK1T0010	BALKONDASAI SREEVARDHAN	
		19CK1T0014	GAJABIMKAR VAISHNAVI	
		19CK1T0017	SILBHADRA SAMAT	
2	Dr. MD.RASHEEDUD DIN, Pharm.D, ASSISTANT PROFESSOR	18CK1T0005	PEDDAPALLI HAREESH	HYPERTENSIVE PATIENTS AT A PRIMARY CARE HOSPITAL: AN ASSESSMENT OF MEDICATION ADHERENCE AND ITS RISK FACTORS
		19CK1T0007	NARAPANGU MOHANASREE	
		19CK1T0013	DONGARIS UMANASREE	
		19CK1T0016	DIPENDUSAHU	
3	Dr.Y.N.KUMAR M.Pharm, Ph.D Director	19CK1T0003	CHANDANABOINA JYOSHNA	PREVALENCE AND RISK FACTORS OF PREGNANCY INDUCED HYPERTENSION - A COMPREHENSIVE ANALYSIS IN A LOCAL POPULATION
		19CK1T0011	PASULAS ANJEEVANI	
		19CK1T0018	SUBHAJITMANNA	
		19CK1T0020	TIRTHANKAR SANKI	
	Dr.VRAJKUMAR, M.Pharm., Ph.D., PROFESSOR AND PRINCIPAL	19CK1T0004	AMENAKAUSAR	OPTIMIZING THERAPEUTIC STRATEGIES: A PROSPECTIVE ANALYSIS OF DRUG PRESCRIBING PATTERNS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND COMORBIDITIES
		19CK1T0005	NITTAKAVYA	
		19CK1T0019	SUSOVANJANA	
5	Dr. D.VEEERENDRA KUMAR Pharm.D, ASSISTANT PROFESSOR	19CK1T0006	SURAPANENI LAKSHMI MANJUSHA	A STUDY ON THE ASSESSMENT OF LEVEL OF DEPRESSION, ANXIETY AND STRESS AMONG PATIENTS WITH DIABETES MELLITUS
		19CK1T0009	PASULAPRASAD	
		19CK1T0012 19CK1T0015	NIMISHAKAVI SPOORTHIBUBAI	

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LIST OF PROJECTS OF II ND YEAR M.PHARM STUDENTS –A.Y.2023-2024

sl no.	Name of the Supervisor	Roll no	Name of the Students	Title	DEPARTMENT
1	Dr V. RAJKUMARM. Pharm. Ph.D.,	(H.T. No.21CK1S1214)	MOZNUR RAHMAN	STABILITY INDICATING METHOD DEVELOPMENT AND VALIDATION OF FENOFIBRIC ACID & PITAVASTATIN BY USING RP-HPLC METHOD	PHARMACEUTICAL ANALYSIS
2	Dr V. RAJKUMARM. Pharm. Ph.D.	(H.T. No.21CK1S1209)	BORAS ARITHA	DEVELOPMENT AND VALIDATION OF A RP-HPLC FOR THE SIMULTANEOUS ESTIMATION OF QUINAPRIL AND HYDROCHLOROTHIAZIDE INACTIVE	PHARMACEUTICAL ANALYSIS
3	Dr V. RAJKUMARM. Pharm. Ph.D.,	(H.T. No.21CK1S1205)	JATANGI MOUNIKA	ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR ABALOPARATIDE AND TERIPARATIDE IN COMBINED DOSAGE FORM BY RP-HPLC METHOD	PHARMACEUTICAL ANALYSIS
4	Dr V. RAJKUMARM. Pharm. Ph.D.,	(H.T. No.21CKIS1207)	ANKA MSAHITHI	METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF GATIFLOXACIN AND AMBROXOL IN PURE FORM AND MARKETED PHARMACEUTICAL DOSAGE FORM	PHARMACEUTICAL ANALYSIS
5	Dr V. RAJKUMARM. Pharm. Ph.D.,	(H.T. No.21CK1S1215)	MANDA DISOWMYA	RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF CIPROFLOXACIN AND DEXAMETHASONE IN EYEDROPS	PHARMACEUTICAL ANALYSIS



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6	Dr V. RAJKUMARM. Pharm. Ph.D.,	(H.T. No.21CK1S1211)	GANNOJUTH RIVENI	ANEWRP-HPLCMETHODAND IT'S VALIDATION FOR THEANALYSISOFARTESUN ATEANDMEFLOQUINEIN BULKAND PHARMACEUTICALDOSA GEFORMASPERICH GUIDELINES	PHARMACEUTICALANAL YSIS
7	G.MANASA VEENA Assistant Profes sor	(21CK1S0108)	PANDAVUL AMOUNIK A	PHYTOCHEMICAL AND ANTI-HYPERLIPIDEMIC SCREENINGOFMOLLUGOPE NTAPHYLLA	PHARMACOLOGY
8	Dr.CHANDA KAMADHU, M.Pharm.,PG DM,Ph.D	20CK1S0101	PoleKalyani	EXPLORINGTHE PHYTOCHEMICALCOMPO SITION ANDGASTROPROTECTIVE EFFECTSOE ETHANOLIC EXTRACTFROM SOLANUM INDICUMLINNLEAVESINALBI NORATS:ASTUDYOFANTI- ULCER ACTIVITY	PHARMACOLOGY
9	Dr.CHANDA KAMADHU, M.Pharm.,PG DM,Ph.D	20CKIS0108	Pindiga Uma	STUDY OF ANTI OBESITY ANDANTI-ARTHRITIC ACTIVITY OFLANTANACAMARAEXTRA CTINWISTARTALBINORATS	PHARMACOLOGY
10	DrChandraka Madhu, M.Pharm,PG DM.,Ph.D.,	(H.T.No.21CK1S0 101)	N.AMBIKA	INVESTIGATIONINTOTHE ANTIULROLITHIC PROPERTIESOFSYZYGIUMCUMI NIEXTRACTUSING AN ETHYLENE GLYCOLINDUCED MODEL IN MALEALBINORAT	PHARMACOLOGY
11	Dr Chandraka Madhu, M.Pharm, PGDM.,Ph.D.,	(H.T.No.21CK1S0 104)	KUNDENAK AVYA	THE INFLUENCE OF CRUDE FIBRE ON LAXATIVE ACTIVITYINBOTHINVITROAN DINVIVISTUDIES	PHARMACOLOGY
12	DrChandraka Madhu, M.Pharm,PG DM.,Ph.D.,	(H.T.No.21CK1S0 115)	SANIDU LISLAM	STUDYONTHE PHYTOCHEMICALSCREENIN GAND IMMUNOMODULATORYACTI VITY OF THE HYDROALCOHOLIC EXTRACTS OFMANGIFERAINDICALEAV ESINALBINORATS.	PHARMACOLOGY



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PROJECT WORK – 2023 - 2024

CHRONIC RENAL FAILURE

Chronic pathology, often known as Chronic renal failure is the end result of Persistent kidney damage and gradual loss of organ function, which results in buildup of dangerous level of fluid, electrolytes and wastes in body. This can lead to a drop in kidney function (known as the glomerular filtration rate, or GFR), which can be measured using a blood test. CKD can be graded as mild, moderate, or severe, based on the presence of certain markers in the urine. In early CKD, there is still some degree of renal function, while in the late stages, CKD is considered to be kidney failure. Chronic kidney disease is on the rise all over the world. One in ten people has some form of the disease, which is caused by a number of factors, including diabetes, hypertension, obesity, smoking, and high cholesterol.

EPIDEMIOLOGY: Chronic kidney disease (CKD) is a common condition that affects millions of people worldwide. Prevalence: According to the latest estimates by the Global Burden of Disease study, the global prevalence of CKD was 9.1% in 2019. This represents an increase from 7.2% in 1990. Age and gender: The prevalence of CKD increases with age, and is higher in men than in women. However, the incidence of end-stage renal disease (ESRD) is higher in women, possibly due to a longer life expectancy.

- Kidney disease is a condition that affects a lot of people in the United States. It's especially common in adults, and affects around 15% of adults (more than 1 in 7 adults).
- Nearly 90% of people who have kidney disease don't know they have it.
- One in three adults in the United States has a risk for kidney disease.

ETIOLOGY:

The etiology (i.e. the cause) of Chronic Kidney Disease (CKD) is complex and can be influenced by multiple factors.

Diabetes: Diabetes is a leading cause of CKD. High blood sugar levels can damage the small blood vessels in the kidneys over time, leading to kidney damage.

Hypertension: High blood pressure can damage the blood vessels in the kidneys and affect their ability to filter waste from the blood.

Glomerulonephritis: This is a condition in which the tiny filters in the kidneys (glomeruli) become inflamed and damaged.

Polycystic kidney disease: This is a genetic disorder in which numerous cysts form in the kidneys, leading to kidney damage and failure over time.

Infections: Certain infections, such as chronic pyelonephritis, can cause inflammation and scarring in the kidneys, leading to CKD.

Obstruction: Blockages in the urinary tract, such as from kidney stones, can cause damage to the kidneys if not treated promptly.

Medications: Certain medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and some antibiotics, can cause kidney damage.

Fatal organic process problems:

This will occur if the foetus' kidneys do not develop correctly within the female internal reproductive organ.

Systemic lupus erythematosus:

This is an associated degenerative condition whereby the body's system attacks the kidneys like they were foreign tissue.

Certain medications:

The overuse of bound medication, together with NSAIDs, will cause nephropathy

CKD STAGES:

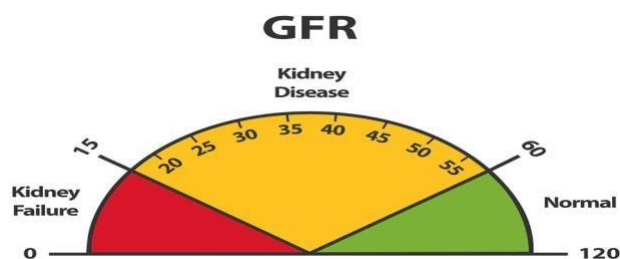


Figure1:Glomerularfiltrationrate

Doctors can determine how much kidney damage a person has by measuring their GFR (a scientific

discipline formula that employs a person's age, gender, and their blood serum creatinine level). This could be a good indicator of how well their other organs are working. The diagnostic clues that suggest kidney disease include the presence of protein in the urine, high creatinine levels in the blood, and small kidneys on ultrasound. This reflects the kidneys are slowly losing function. The increase in creatinine levels over time is a reliable indicator of kidney disease.

- **Stage1:** with 2 or high GFR ($\text{GFR} > 90 \text{ ml/min}$)
- **Stage2:** gentle CKD ($\text{GFR} = 60\text{--}89 \text{ ml/min}$)
- **Stage3A:** Moderate CKD ($\text{GFR} = 45\text{--}59 \text{ ml/min}$)
- **Stage3B:** Moderate CKD ($\text{GFR} = 30\text{--}44 \text{ ml/min}$)
- **Stage4:** Severe CKD ($\text{GFR} = 15\text{--}29 \text{ ml/min}$)
- **Stage5:** final stage CKD ($\text{GFR} < 15 \text{ ml/min}$)

CKD STAGE 1 KIDNEY FUNCTION (90-100%):

In Stage 1 CKD, the kidneys are working well and the glomerular filtration rate (GFR) is greater than $90 \text{ ml/min/1.73 m}^2$. However, there are laboratory abnormalities like protein in the urine;

evidence of structural damage to the kidneys on x-ray, ultrasound, MRI, or CT scan; or a family history of polycystic kidney disease. Patients are usually asymptomatic.

CKD STAGE 2 KIDNEY FUNCTION (60-89%):

Stage 2 or mild CKD means that the kidney function is 60 to 89 ml/min/1.73 m². Frequent urination, especially at night, high blood pressure, and urine abnormalities on urinalysis. However, most patients are asymptomatic.

CKD STAGE 3 KIDNEY FUNCTION (30-59%):

In Stage 3 or moderate CKD, the kidney function is 30-59 ml/min/1.73 m². The patient may not have any symptoms yet, or may start to experience mild ones. There may be urinary abnormalities present and the serum creatinine is elevated.

CKD STAGE 4 KIDNEY FUNCTION (15-29%):

In Stage 4 CKD, your kidney function is less than 29 ml/min/1.73 m². This means that even if you don't have any other symptoms, your kidney might not be working very well. This can cause mild, vague, or very serious problems.

CKD STAGE 5 KIDNEY FUNCTION (<15%):

Stage 5 CKD is a very serious condition with a reduced kidney function. Most patients will need dialysis or a kidney transplant at this stage can lead to life-threatening complications.

END STAGE RENAL DISEASE

End-stage kidney disease is a stage of kidney disease where the kidneys have stopped working properly and it is considered to be an advanced stage. At this point, conservative management (e.g. medications, diet, lifestyle modifications) is not enough to keep the person alive and they will need to be on dialysis or have a kidney transplant. If the disease progresses to an advanced stage, almost all of your kidney's functions are lost. There are only two treatment options available at this stage: dialysis (which includes haemodialysis and peritoneal dialysis) or kidney transplant.

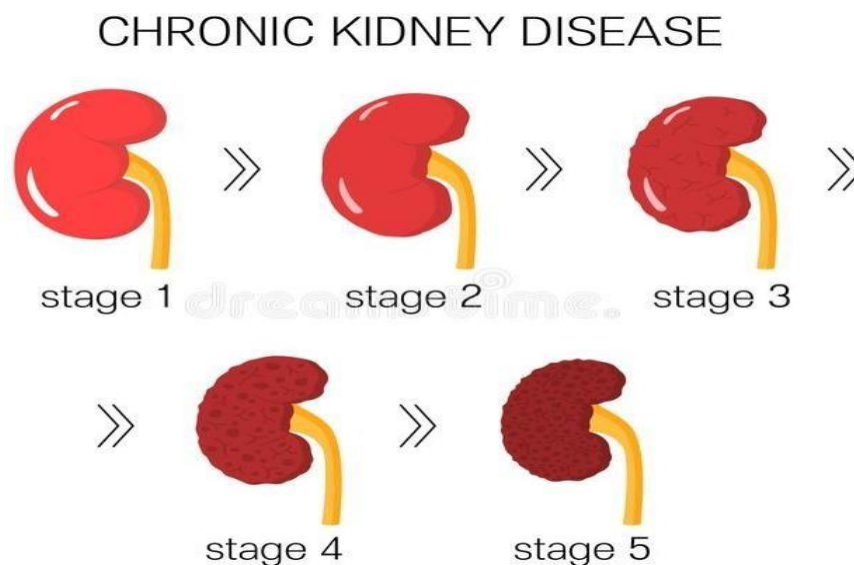


Figure2:stagesofchronickidneydisease

RISKFACTORS:

- ❖ Cigarettesmoking
- ❖ Highsteroidalcohol
- ❖ Diabetes(types1and2)
- ❖ Autoimmunedisease
- ❖ Obstructivenephropathy,similarlyasbladderobstructioncausedbybenignendocrineabnormality.
- ❖ Atherosclerosis
- ❖ Cirrhosisandliverfailure
- ❖ Narrowingofthearterythathas yoururinaryorgan
- ❖ Kidneycancer
- ❖ Bladdercancer
- ❖ Kidneystones

- ❖ Kidneyinfection
- ❖ Systemiclupuserythematosus
- ❖ Scleroderma
- ❖ Vasculitis
- ❖ Vesicoureteralreflux,thathappensoncewasteflowsbacktoyoururinaryorgan.

PATHOPHYSIOLOGY:

• While they increase the risk of kidney disease, susceptibility factors do not actually harm thekidneys. Age, low birth weight, racial or ethnic minority status, family history, and reducedkidneymassareriskfactors.

- ❖ systemicinflammation,dyslipidaemia,andlowincomeoreducation.
- ❖ Drugtherapychangethewaythatinitiationfactorscausekidneydamage.

After the start of a progression factor, the decline in kidney function accelerates. Kidney harm.Diabetes-relatedglycaemia,hypertension,proteinuria,andsmokingareprogression-relatedfactors. The majority of progressive kidney diseases have a final common pathway that leads toirreversible damage to the renal parenchyma and ESRD. Important components of the pathwayincludeglomerularcapillaryhypertension,proteinuria,andnephron massloss.

CKD, or chronic kidney disease, is a condition where the kidneys progressively lose their abilitytofilter wasteand excessfluid fromtheblood.

Pathogenesis of chronic kidney disease

Eric Wong

Once half of the total nephrons are lost, CKD progresses similarly regardless of etiology. Initial hyperfiltration activates RAAS and causes proteinuria. Angiotensin II and protein uptake at the tubules causes inflammation and fibrosis of the glomerulus and tubules. Progressive decline in GFR and systemic complications occurs.

FSGS Focal segmental glomerulosclerosis

SNGFR Single nephron GFR

RAAS Renin angiotensin aldosterone system

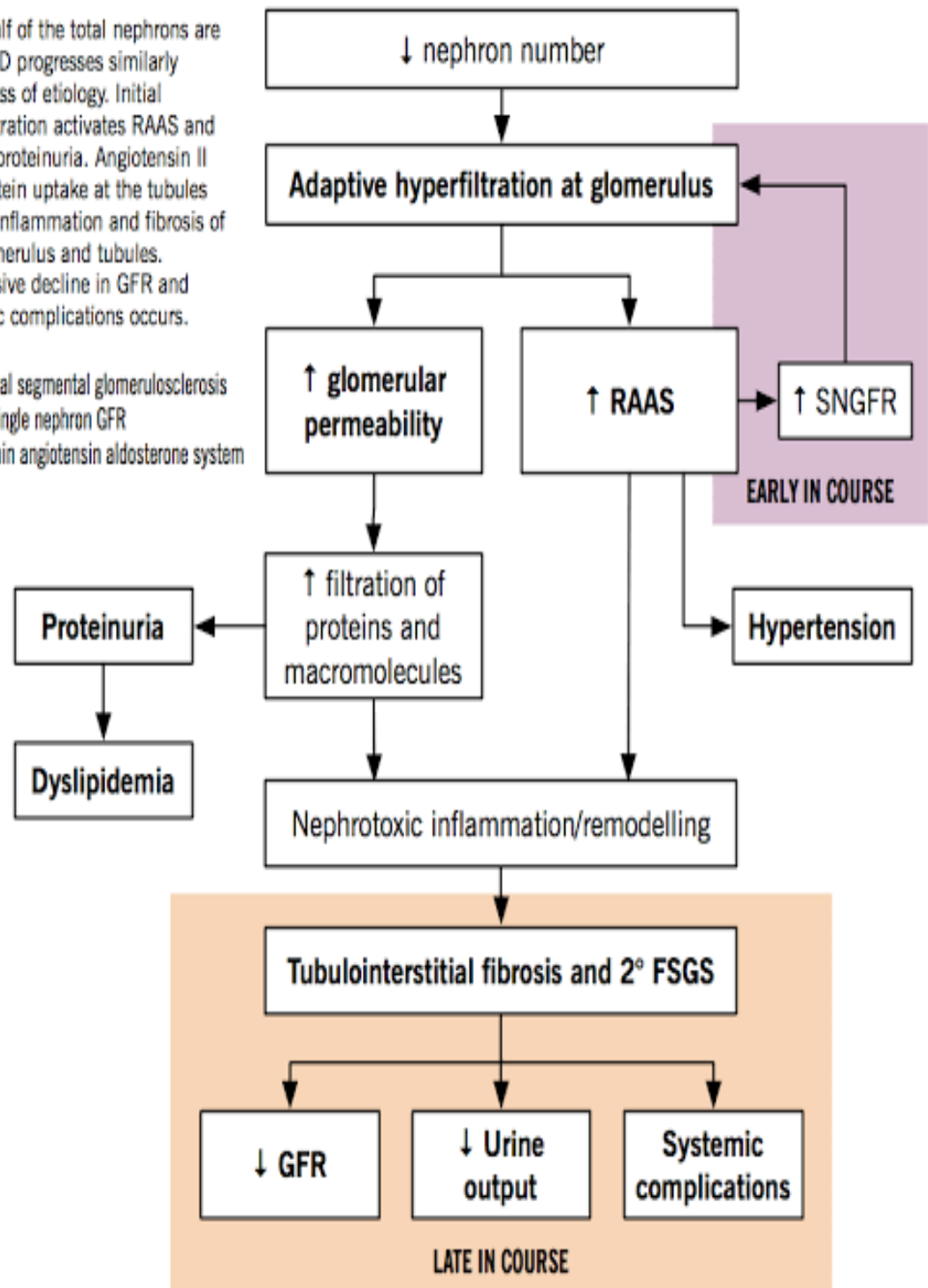


Figure3:pathogenesisofCkD

SIGNS AND SYMPTOMS

Fatigue and weakness: This is one of the most common symptoms of CKD.

Swelling: CKD can cause fluid retention in the body, leading to swelling in the legs, ankles, feet, face, and hands.

Shortness of breath: As fluid builds up in the lungs, it can become difficult to breathe, causing shortness of breath.

Urinary changes: Changes in urination, such as frequency, colour and amount may be a nearly sign of CKD.

Blood in urine: CKD can cause damage to the kidneys' blood vessels, leading to blood in the urine.

Nausea and vomiting: Waste build up in the blood can cause nausea and vomiting, as well as a loss of appetite.

Itching: As waste builds up in the blood, it can cause itching, which is usually worse at night.

Muscle cramps: Electrolyte imbalances, such as low potassium and magnesium, can cause muscle cramps.

Difficulty sleeping: CKD can cause insomnia and other sleep disturbances.

DIAGNOSIS

Chronic kidney disease (CKD) is usually a symptomless condition, but it can be diagnosed with

lab tests. However, other tests are needed to confirm that you have CKD, such as blood pressure and urinalysis.

Medical history and physical exam: The Physician will query about the health status, including any history of kidney disease, and perform a physical exam to look for signs of kidney damage.

Blood tests: Blood tests are done to measure the level of waste products, such as creatinine and blood urea nitrogen (BUN), in the blood. High levels of these waste products indicate that the kidneys are not functioning properly.

Urine tests: Urine tests are done to check for the presence of protein and other abnormalities, which can be a sign of kidney damage.

Imaging tests: Imaging tests such as ultrasound, CT scan or MRI may be performed to look at the size and structure of the kidneys.

Renal ultrasound

This non-invasive check provides footage to help your doctor ensure whether or not or not there's a blockage in the urinary tract.

Other tests:

Additional tests for CKD include:

- ❖ A kidney diagnostic test
- ❖ A bone density check
- ❖ An abdominal CT scan.

Kidney biopsy: In some cases, a kidney biopsy may be performed to examine a small piece of kidney tissue under a microscope, to help determine the cause of the kidney disease.

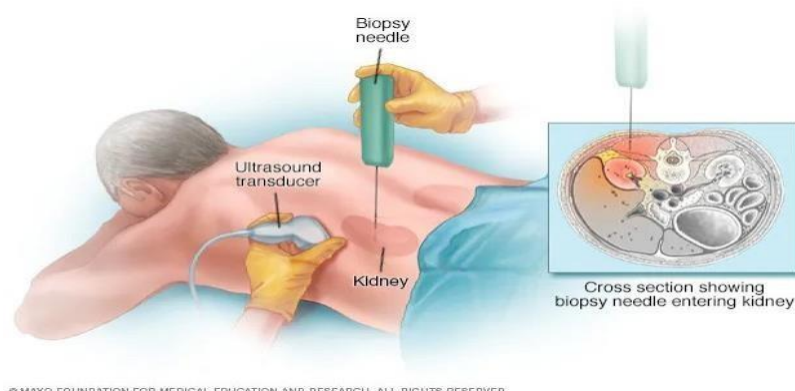


Figure 4 kidney biopsy

MANAGEMENT

Both pharmacological and non-pharmacological treatments are used to treat CKD. Depending on whether diabetes is present or not, different strategies should be used.

Pharmacological treatment:

Pharmacological treatment for chronic kidney disease (CKD) typically involves the use of medications to manage comorbidities and complications associated with the disease.

Both non-loop diuretics (e.g., thiazides) and loop diuretics (e.g., furosemide) are effective in all stages of CKD as adjunct antihypertensive therapy.

- **Furosemide can be**

used safely for management of fluid overload in all stages of CKD, including when GFR is severely reduced to $< 30 \text{ mL/min/1.73m}^2$.

1. **Blood pressure medications:** ACE inhibitors and ARBs can help to lower blood pressure in people with CKD. If your GFR falls below 25% after starting these medications
2. **Diuretics:** Diuretics help in managing fluid build-up in CKD patients, particularly those with edema or heart failure.
3. **Erythropoietin-stimulating agents:** These medications may be used to treat anemia in CKD patients by stimulating red blood cell production.
4. **Phosphate binders:** Phosphate binders may be used to lower blood phosphate levels in CKD patients, as high phosphate levels can contribute to bone disease.
5. **Vitamin D supplements:** Vitamin D supplements may be used to manage bone disease in CKD patients by promoting calcium absorption.
6. **Iron supplements:** Iron supplements may be used to treat anemia in CKD patients by providing the necessary building blocks for red blood cell production.

Non-pharmacological: the progression of CKD in people by eating a low-protein diet (0.6 to 0.75 g/kg/day) patients with or without diabetes, though the benefit is minimal.

LIFESTYLE MODIFICATIONS

Changes you make to your lifestyle may help slow the progression of chronic nephrosis (CKD).

Stop smoking

Nutrition For $\text{GFR} \geq 30 \text{ mL/min/1.73 m}^2$

Parameters:

Protein: 0.75-1.0g/kg/day (no restriction necessary)

Salt: The limit for sodium is 2.3 grams per day. That means you can't have more than 2.3 grams of sodium each day. Avoid adding salt during cooking.

Phosphate: No restriction

necessary **Fluid:** Drink water to

satisfy

thirst Increased fluid intake is not necessary

ry

Carbonated beverages: Avoidance is preferable

- Limit alcohol intake.
- Follow a healthy eating plan and reduce the amount of salt
- Follow up and treat regularly as directed by your nephrologist.

COMPLICATIONS:

CKD progresses to failure, complications can include:

Anaemia: If your kidneys don't make enough erythropoietin, this can lower your blood cell count and cause anemia. This can lead to problems like not getting enough oxygen to your vital organs and tissues.

Fluid retention: When the kidneys can't filter out too much salt from your body, it causes fluid to

build up (swelling). This can make your hands and feet swell, and it can also make your life more difficult.

Gout: Arthritis is a condition that can be caused by a build-up of uric acid in the joints. This is

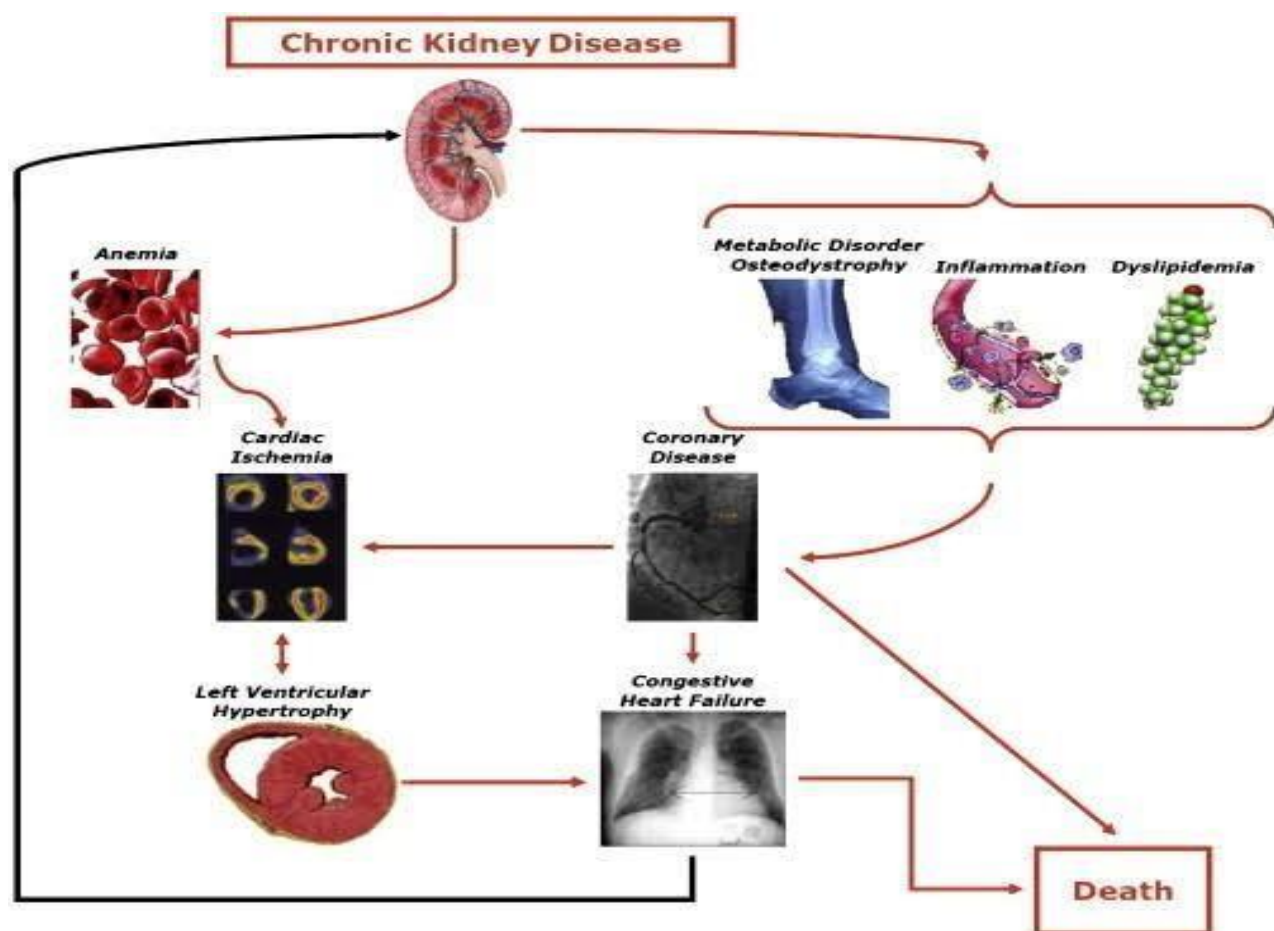


Figure 5: complications of chronic kidney disease

because uric acid is filtered through the kidneys and is linked to arthritis.

Hyperkalaemia: that is once blood metal element levels rise, presumably leading to heart injury.

Metabolic pathology, that is once acid builds up within the body

Osteomalacia: bones can become weak and break.

Pericarditis: that is once the sac-like membrane around the heart becomes inflamed

Secondary thyrotoxicosis: that is once fat-soluble vitamin, calcium, and phosphorus levels square measure out of balance.

END-STAGE RENAL DISEASE

End-stage kidney disease is a stage of kidney disease where the kidneys have stopped working properly and it is considered to be an advanced stage. At this point, conservative management (e.g. medications, diet, lifestyle modifications) is not enough to keep the person alive and they will need to be on dialysis or have a kidney transplant. If the disease progresses to an advanced stage, almost all of your kidney's functions are lost. Dialysis (which includes haemodialysis and



Figure 6: End stage kidney

peritoneal dialysis) or kidney transplant are treatment options.

Palliative care: For people who are not eligible for dialysis or transplant, or choose not to receive these treatments, palliative care can be provided to help manage symptoms and improve quality of life.

DIALYSIS

Dialysis is a way to remove waste products and excess water from your body that accumulate in kidney failure.

Dialysis also helps to keep the water level in the body correct and to correct electrolyte and acid-base balance disturbances. However, dialysis cannot replace all the functions of a normal kidney, such as making erythropoietin.

Dialysis is a process in which different substances are separated from your body by using an external machine. In dialysis, diffusible substances like medicine and metabolites are separated from your body. Dialysis includes two different procedures: peritoneal dialysis and haemodialysis.

HEMODIALYSIS

In haemodialysis, the blood is passed through a special filter or artificial kidney to remove waste products and excess fluids.

Hemodialysis is a type of treatment that is very safe, effective and comfortable. This process is assisted by a dialysis machine. A dialysis machine uses a dialyzer to remove waste and water from the blood. This is done by pumping the blood through flexible tubes. In some cases, a special treatment called heparin infusion or continuous saline flushing is done to prevent clots from forming.

. You can do hemodialysis at home four to seven times per week; you will need to do at-home treatments for fewer hours each session, you may choose to do hemodialysis at night while you sleep.

BEFORE HEMODIALYSIS

Before hemodialysis, you may have a minor surgical procedure to make it easier to get blood. To make the most of your hemodialysis treatment, stay as close to your ideal weight as possible. Your ideal weight is the weight you maintain when you don't have any extra fluid in your body. If you stick to a healthy diet and take care of your sodium levels during hemodialysis treatments, you should be able to reach your ideal weight at the end of every treatment. When your hemodialysis treatments are working and you stay close to your ideal weight, your blood pressure should be under control.

ARTERIOVENOUS FISTULA (AV FISTULA): An AV fistula is a medical procedure that connects an artery and vein in your arm. This makes it easier for doctors to give you dialysis treatments. AV grafts are also often used in AV fistulas.

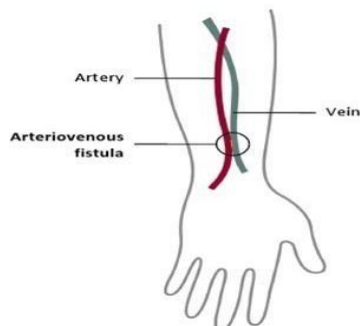


Figure 7: Arteriovenous fistula

ARTERIOVENOUS GRAFT (AV GRAFT): These grafts are soft and hollow, and they help the connected artery and vein to grow larger. This makes it easier for your body to get blood and oxygen, and it also helps the flow of blood in and out of your body quickly.



Figure 8: Arteriovenous graft

If dialysis needs to happen quickly, your provider may use a catheter (thin tube) to access a vein in your neck, chest, or leg. The dialysis machine is a special filter that helps to remove extra fluids and waste products from the blood. This helps to make the blood more purified and healthier. The dialysate (special solution) is prepared by the machine, and it helps to make the

blood even more purified. The dialysis machine is about 20 inches long and 5 inches wide. It has a clear plastic cylinder that holds thousands of tube-like hollow fibres. Each tube is made of synthetic semi-permeable material. These hollow fibres are connected at the top and bottom of the cylinder, and they form the "blood compartment." Blood enters the blood compartment at one end and exits at the other end after being purified.

- The machine cleans the blood and then sends it back to the body.
- Each hemodialysis session lasts about four hours and is done 3 times a week.

Purification Of Blood in Dialyzer

In hemodialysis, blood is taken from a patient through a vein and passed through a dialysis machine. The dialysis solution flows around the machine's hollow fibers, called dialysate. In hemodialysis, blood is taken from a patient through a vein and passed through a dialysis machine.

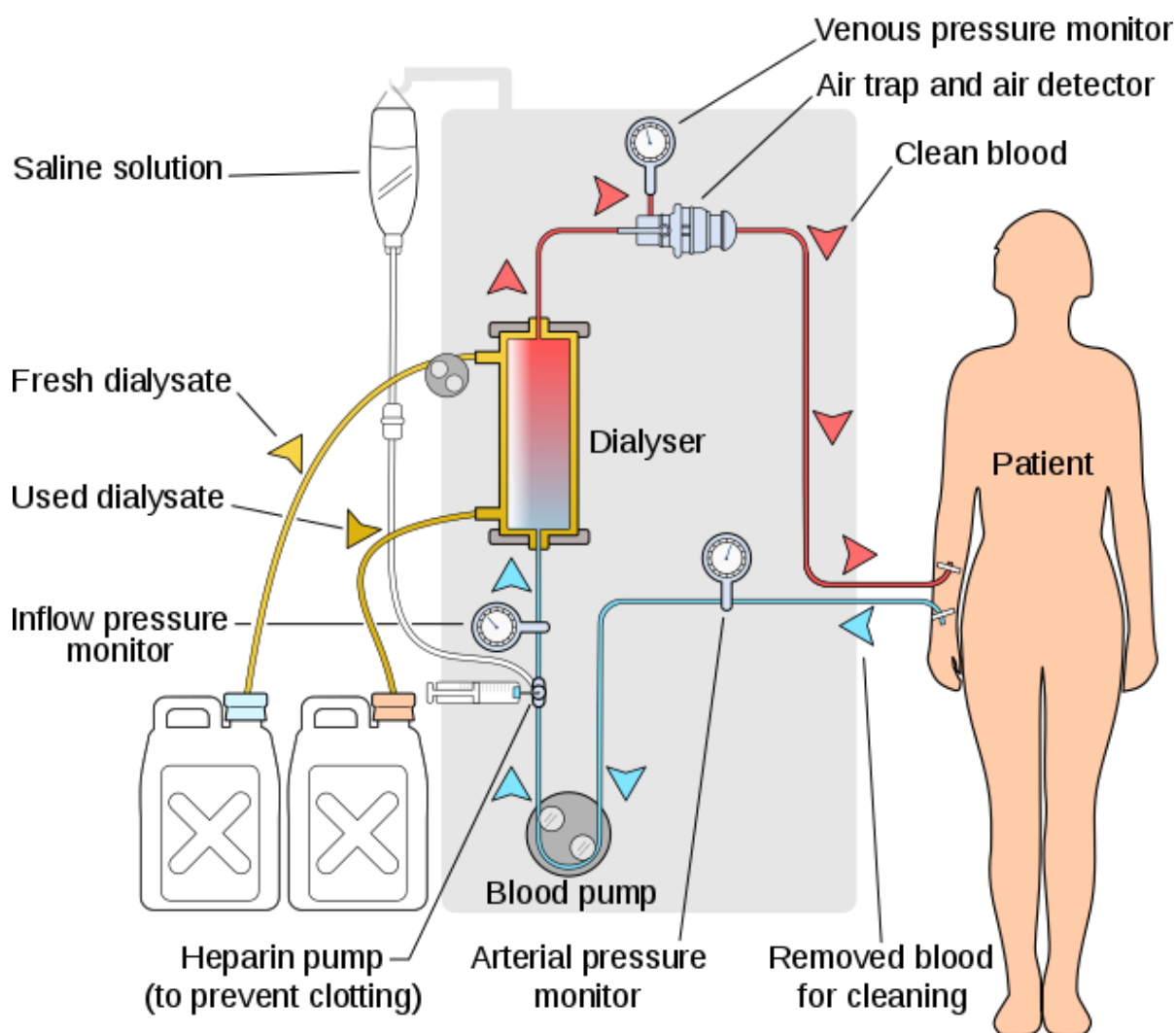


Figure9:PurificationofbloodinDialyzer

Every minute, 300 ml of blood and 600 ml of dialysis solution flow in opposite direction through the hollow fibers that separate the blood and dialysate compartments in a dialyzer. The semi-permeable membrane of the hollow fibers allows waste products and excess fluid to be removed from the blood, while the dialysis solution with toxins and fluid from the blood flows out. Four hours of treatment with hemodialysis results in a significant reduction of blood urea and serum creatinine levels, the removal of excess fluids, and correction of electrolyte levels.

COMMON PROBLEMS DURING HEMODIALYSIS:

Some common problems during hemodialysis include low blood pressure (hypotension), nausea, vomiting, muscle cramps, weakness, and headache. These problems may be avoided by taking appropriate measures before the dialysis session, such as checking the patient's blood pressure and blood volume status. Weight gain between sessions should be monitored, and serum electrolytes and haemoglobin levels should be checked as well.

PERITONEAL DIALYSIS

Peritoneal dialysis is a type of dialysis that is used to treat people with kidney failure. It is very popular and effective, and it is the most common way that dialysis is done at home. In order to control weight gain between dialysis treatments, it is important for patients to keep their fluids and salt intake restricted.

Peritoneal dialysis is a type of dialysis that is not normally used to detoxify. It is only about 10-25% as effective as haemodialysis, and it is only a little more effective than forced diuresis. It is also time consuming, requiring 24 hours for successful completion as opposed to the 2-4 hour cycles of haemodialysis and haemoperfusion. The only advantage to peritoneal dialysis is that it does not require anticoagulation.

The peritoneum is a layer of tissue that lines the inside of the abdominal cavity. This membrane helps to keep waste products and toxins in the blood away from the body. Peritoneal dialysis is a process of purifying blood through the membrane.

PROCEDURE

Peritoneal dialysis works on the same principle as hemodialysis, which allows the diffusion of toxins from the mesenteric capillaries across the peritoneal membrane into the dialysate dwelling in the peritoneal cavity. A stylet catheter is placed at the bedside or the surgical insertion of a Tenckhoff catheter is performed, and dialysate fluid is instilled. 1 to 2 Liters of fluid is exchanged each hour.

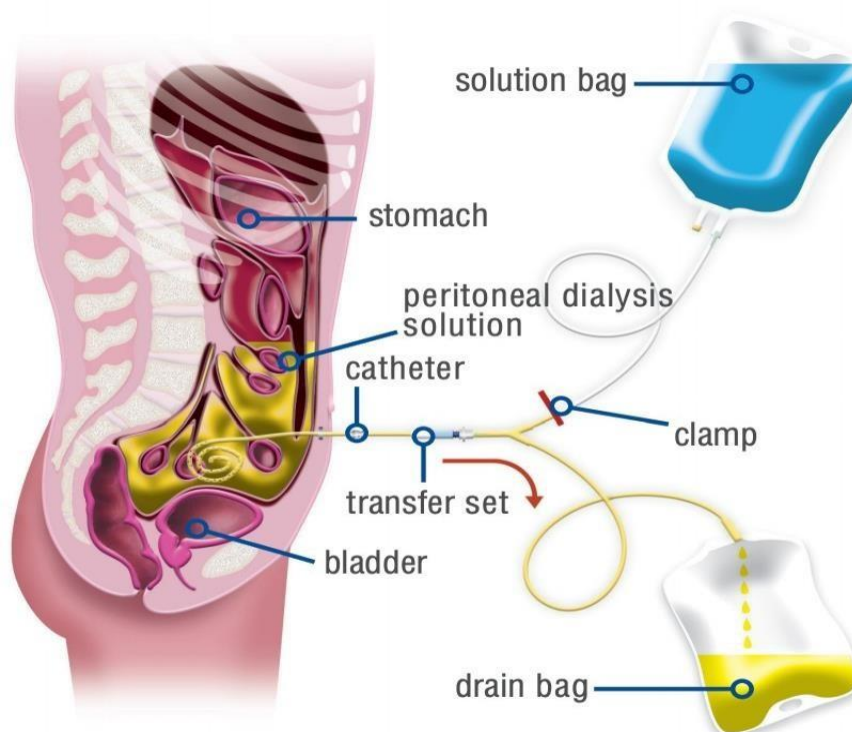


Figure10:peritonealdialysisprocedure

TYPES OF PERITONEAL DIALYSIS:

1. Intermittent Peritoneal Dialysis (IPD)
2. Continuous Ambulatory Peritoneal Dialysis (CAPD)
3. Continuous Cycling Peritoneal Dialysis (CCPD)

INTERMITTENT PERITONEAL DIALYSIS:

IPD is a type of dialysis where a special catheter is inserted into the patient's abdomen. This catheter has multiple holes which allow the dialysate (solution that absorbs waste products and excess fluids) to be infused into the abdominal cavity or peritoneal space.

The dialysate slowly absorbs the patient's waste products and excess fluids, and the process is repeated several times a day. IPD usually lasts for 24 to 36 hours, and it is usually repeated at short intervals of 1 to 3 days.

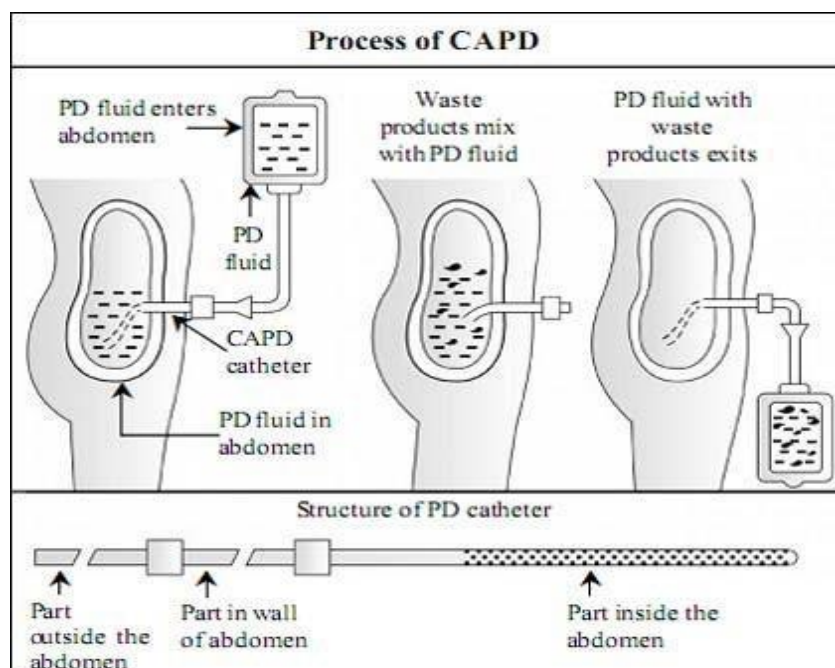


Figure11:processofcontinuousAmbulatoryperitoneal dialysis

CONTINUOUSAMBULATORYPERITONEALDIALYSIS:

CAPD means C – nonstop The process is continued(treatment without stopping for 24 hours aday,7daysaweek).A–itinerantThecasecanwalkaroundandperformroutineconditioning.P –

Peritoneal The peritoneal membrane in the tummy works as a sludge. D – Dialysis Thesystem of sanctification of blood. nonstop itinerant Peritoneal Dialysis(CAPD) is a form ofdialysis which can be carried out by a person at home without the use of a machine. As CAPDprovidesconvenienceandindependenceit'sapopulardialysis modalityinnumerous countries.

PROCESS OF CAPD: CAPD catheter The endless access for peritoneal dialysis(CAPDcatheter) is a soft thin flexible silicon rubber tube with multitudinous side holes. It's surgicallyfitted into the case's tummy through the abdominal wall, about an inch below and to the side ofthenexusor belly button.

The CAPD catheter isfittedabout 10 to 14 daysbefore CAPDthresholds. The PD catheter isthe“lifeline ”ofCAPDcases,just astheAVfistulaisto acaseon hemodialysis.

RENAL TRANSPLANTATION:

For those with end-stage renal disease, renal transplantation has been found to be a very effective treatment. Clinical results are now excellent, with 98% and 90–95%, respectively, patient and graft survival rates after one year. The majority of transplant recipients never need to go back to receiving dialysis. Although many patients with end-stage renal disease are frail and elderly and/or have a number of co-existing medical conditions that prevent them from undergoing surgery, kidney transplantation is the treatment of choice for patients with end-stage renal disease who are fit to receive a transplant.

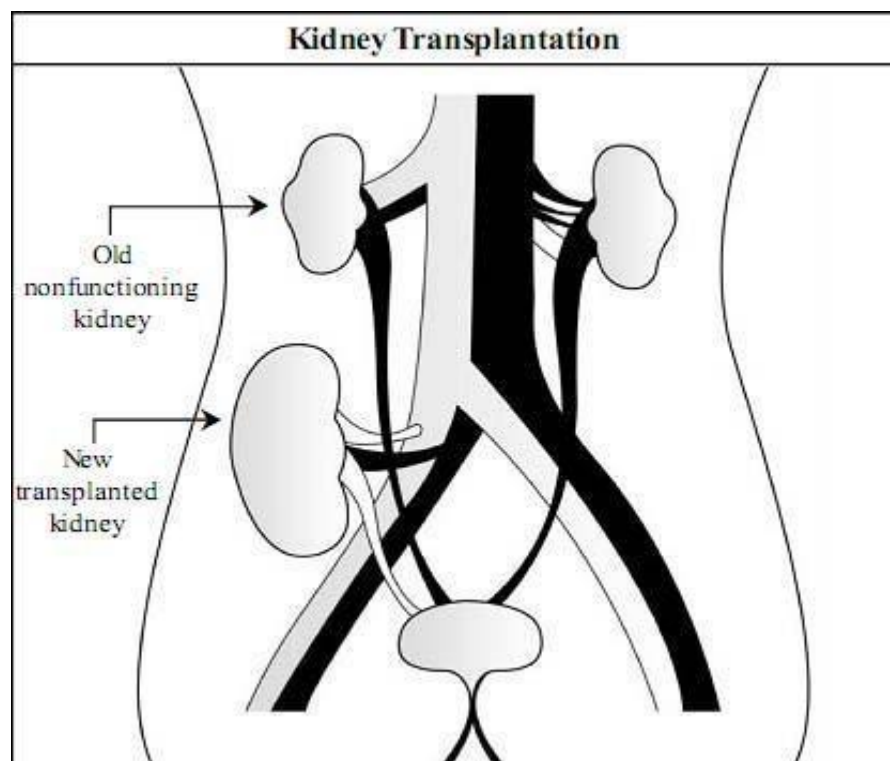


Figure 12: Renal transplantation

When the source of the kidney is a living donor, the transplanted kidney usually begins functioning immediately. However, when the source of the kidney is a deceased donor, the transplanted kidney may not start working right away. In a live kidney donor transplant surgery, both the recipient and the donor are operated on at the same time. The surgery lasts about three

to five hours and is performed under general anesthesia. The kidney is usually removed from the donor either by open surgery or by laparoscopy. After removal, the kidney is washed with a special cold solution and placed into the right lower (pelvic) part of the abdomen of the recipient.

After a deceased donor kidney is used, the transplanted kidney may take a few days or weeks to start working. The recipient with a delayed transplant may need dialysis until kidney function becomes adequate.

WHY DO WE NEED PRESCRIPTION PATTERNS?

Prescription patterns tell us a lot about the kind of drugs people use, how often they use them, and how well they follow regional, state or national guidelines about how to treat their conditions.

The goal of prescription patterns is to ensure that patients receive the most effective treatment for their condition, while minimizing the risk of adverse effects or drug interactions. Proper prescription patterns can also help to reduce the incidence of medication errors, improve patient outcomes, and optimize the use of healthcare resources.

A recent study has found that prescribing quality is an important dimension that needs to be constantly evaluated. This means that doctors need to be careful when prescribing drugs, since this can lead to problems such as increased side effects, drug interactions, and the development of drug resistance.

A lot of research has been conducted to study the way doctors prescribe medications across the country. Prescribing is one of the main causes of irrational drug use. Poor prescribing habits result in ineffective and unsafe treatments, aggravation or prolongation of disease, patients suffering and harm, and higher costs. The frequency of irrational prescriptions cannot be reduced without a critical root cause analysis.

A prescription pattern is essentially a set of guidelines or recommendations for the appropriate use of medications based on various factors such as the patient's medical history, symptoms, age, weight, and other relevant factors.

Having a standardized prescription pattern can help doctors and other healthcare professionals make more informed decisions about the appropriate treatment to prescribe for their patients. It

can also help prevent overuse, underuse, or misuse of medications, which can have negative consequences on patients' health.

In addition, prescription patterns can help ensure consistency in the prescribing practices of healthcare professionals, which can improve patient outcomes and reduce healthcare costs. By using a standardized approach to prescribing medications, healthcare professionals can also identify any potential drug interactions or contraindications that could affect patients' safety.

Overall, prescription patterns are an important tool for healthcare professionals to ensure that patients receive the best possible care and treatment for their medical conditions.

PRESCRIPTION INDICATIONS:

a. The average number of medicines specified per hassle was calculated to measure the degree of polypharmacy. It was calculated by dividing the total number of different medicine products specified by the number of hassles surveyed. Combinations of medicines specified for one health problem were counted as one.

B. Chance of medicines specified by general name was calculated to measure the tendency of defining by general name. It was calculated by dividing the number of medicines specified by general name by the total number of medicines specified, multiplied by 100.

C. Chance of hassles in which an antibiotic was specified was calculated to measure the overall use of generally overused forms of medicine remedy. It was calculated by dividing the number of patient hassles in which an antibiotic was specified by the total number of hassles surveyed, multiplied by 100.

D. Chance of hassles with an injection specified was calculated to measure the overall position use of generally overused forms of medicine remedy. It was calculated by dividing the number of patient hassles in which an injection was specified by the total number of hassles surveyed, multiplied by 100.

- 1) **Chandel Ritesh Kumar et al., (2016)** Chronic kidney disease is a global health threat, especially for developing countries, due to its increasing incidence, poor progression and high treatment costs. Treatment includes dialysis and kidney transplantation. Appropriate drug selection for patients with chronic kidney disease (CKD) is important to avoid adverse drug reactions and ensure optimal treatment outcomes. Prescribing drugs rationally is a difficult task in CKD patients. Therefore, the present study was planned to know the prescription pattern of drugs in chronic kidney disease on maintenance hemodialysis in Jaipur, Rajasthan. The study was conducted in the Department of Pharmacology in collaboration with the Department of Nephrology, S.M.S. Medical College & Hospital, Jaipur (Rajasthan) from April 2017 to March 2018. The socio-demographic profile and details of the medication administered were recorded in a pre-designed and pre-tested form. The results were expressed as percentages and parts. Pearson's correlation coefficient r was calculated to show the correlation between drug interaction and drug per prescription. In the present study, of 160 chronic kidney patients, most (75.63%) were men with a mean age of 39.5-13.29 years and 24.37% were women with a mean age of 40.41-13.53 years. Comorbidities included anemia (98.13%), hypertension (95.65%), infections (22.5%), and diabetes mellitus (6.85%). Average number of drugs per prescription were 7.84 $\pm$ 1.40.

- 2) **Sourav Chakraborty saugata ghosh et al., (2016)** To study the prescribing pattern of drugs for patients with chronic kidney disease (CKD) on maintenance hemodialysis. This prospective observational study was conducted in a teaching hospital hemodialysis unit with CKD patients on maintenance hemodialysis. Patients' clinical profile, drug use pattern, and medication-related problem data were collected in a structured case report form, and the data were analyzed descriptively. Data from 100 patients recruited over 6 months were analyzed. The mean age was 51 (42-57) years; 57% were male, mean [standard deviation (SD)] urea level was 160.11 (70.32) mg/dL, mean (SD) creatinine level was 8.73 (5.29) mg/dL. A large number (46%) suffered from diabetic nephropathy. The most common comorbidities were anemia (89%), followed by hypertension (85%). The mean (IQR) number of drugs per prescription was 10 (9-13), with the majority being

cardiovascular drugs (23.41%), followed by gastrointestinal drugs (15.76%) and vitamins (12.29%). The median (IQR) number of potential drug-drug interactions per prescription was 2 (2-

3). The incidence of adverse drug reactions (ADRs) was 46%, with hyponatraemia being the most common (32%), followed by hypoglycaemia (16%) and hypokalemia (10%). Adherence was low in the majority (64%) of patients. There is a high incidence of polypharmacy along with significant medication-related problems, such as B. High drug-drug interactions/prescribing, high incidence of ADRs and low adherence. Population

- 3) **Narayana Murthy et al., (2017)** CKD (Chronic Kidney Disease) is a general term for heterogeneous diseases affecting kidney structure and function. It is defined as either renal damage or a decreased glomerular filtration rate of less than 60 mL/min/1.73 m² for 3 months or more. The purpose of the present work is to examine the pattern of drug use in chronic kidney disease patients undergoing hemodialysis at the Department

of Nephrology, Rajarajeshwari Medical College and Hospital, Bangalore. The study included 52 patients, including 41 men, 11 women, with a mean age of 47.6 years. In our study, many patients had hypertension (HTN) 88.46% (46), with calcium channel blockers (CCB) 08.48% (38) being the most commonly prescribed antihypertensive drug. Approximately 1/3 of the patients with diabetes mellitus (DM) 36.53% (19) most of these patients were treated with oral antidiabetics (OHA) and less than half of the patients were treated with insulin 01.56% (07). Other drugs such as phosphate binders (calcium carbonate and acetate) were most commonly prescribed by 11.16% (50), aspirin by 08.70% (39) and statins by 10.04% (45) pt. A total of 448 drugs were prescribed. In 52 points, i.e. about 8.61 drugs/prescription, showing polypharmacy. Patients undergoing hemodialysis with CKD.

- 4) **Purna Atray et al., (2021)** The primary intent of the study is to analyze the prescribing pattern and to identify the various drug interactions (DDIs) associated with therapy in patients with chronic kidney disease (CKD). A total of 214 patients with chronic kidney disease and transplantation were eventually enrolled after strict adherence to selection criteria in this observational study conducted over a 6-month period in the nephrology

department of a multispecialty hospital. Relevant data was extracted from prescriptions. The calculated mean age was 51.51 ± 16.07 (mean standard deviation) years with male predominance (69.15%). Hypertension (33.17%) and diabetes (26.63%) are the most common comorbidities. The average number of drugs prescribed per prescription was 7.83. Based on the first anatomical level of ATC classification, drugs from hematopoietic agents were a highly recommended class of drugs (20.15%), followed by agents contributing to the cardiovascular system (19.08%), and drugs from the digestive tract and metabolism (17.94%). . This study demonstrates the variability of drug use in CKD patients.

- 5) **Ashraf Tadv et al., (2018)** Chronic kidney disease (CKD) is a global public health problem associated with various complications. CKD patients undergoing hemodialysis have associated comorbidities, and rationally prescribing drugs in these patients is a difficult task. Evaluation of drug prescribing patterns in CKD patients on maintenance hemodialysis. A hospital-based cross-sectional observational study was conducted at King Khalid General Hospital, Al Majmaah, over a period of one year. The records of the patients in the specified period were viewed and data on prescriptions were analyzed. A total of 41 patient prescriptions were analyzed. The most common concomitant comorbidity was hypertension in 82.9% of patients, followed by anemia in 73.1% of patients and secondary hyperparathyroidism in 63.4% of patients. 85.4% of the patients had more than one comorbidity. The total number of drugs prescribed was 504 and the average number of prescriptions per patient was 12.3. The percentage of drugs prescribed using generic names was 71.4 and 65.3% of the drugs prescribed were from the WHO Essential Medicines List. The total number of fixed dose combinations used was only 1.2%. The study profiled drugs prescribed for CKD patients on maintenance hemodialysis in a secondary care hospital in Saudi Arabia. In this study, a large number of drugs were used per prescription, increasing the possibility of drug interactions and adverse events.

- 6) Fathea Abobker Gole et al., (2014)** End-stage kidney disease (ESKD) is now a worldwide pandemic. A systematic review was conducted by searching the PubMed, EMBASE and Google Scholar databases to identify all relevant articles published in English from 2003 to 2012, End Stage, Terminal, Chronic, Renal, Kidney, Risk Factors, Arab, North Africa and Libya. In 2003, the reported incidence of ESKD and the prevalence of dialysis-treated ESKD in Libya were equal at 200 per million population (PMP). In 2007, the prevalence of dialysis-treated ESKD was 350 PMP, but the true incidence of ESKD was not available. The latest published WHO data from 2012 showed that the incidence of dialysis-treated ESKD had increased to 282 PPM and the prevalence of dialysis-treated ESKD had reached 624 PMP. The main causes of ESKD were diabetic kidney disease (26.5%), chronic glomerulonephritis (21.1%), hypertensive nephropathy (14.6%) and congenital/hereditary disorders (12.3%). The total number of dialysis centers was 40 with 61 nephrologists. The nephrologist/internist to patient ratio was 1:40 and the nurse to patient ratio was 1:3.7. Between 2004 and 2007, only 135 life-threatening kidney transplants were performed. ESKD is a major public health problem in Libya, with diabetic kidney disease and chronic glomerulonephritis being the main causes. The most common comorbidities were hypertension, obesity and the metabolic syndrome.
- 7) Purna Atray et al., (2021)** The primary intent of the study is to analyze the prescribing pattern and to identify the various drug interactions (DDIs) associated with therapy in patients with chronic kidney disease (CKD). A total of 214 patients with chronic kidney disease and transplantation were eventually enrolled after strict adherence to selection criteria in this observational study conducted over a 6-month period in the nephrology department of a multispecialty hospital. Relevant data was extracted from prescriptions. The calculated mean age was 51.51 ± 16.07 (mean standard deviation) years with male predominance (69.15%). Hypertension (33.17%) and diabetes (26.63%) are the most common comorbidities. The average number of drugs prescribed per prescription was 7.83. Based on the first anatomical level of ATC classification, drugs from hematopoietic agents were a highly recommended class of drugs (20.15%), followed by agents

contributing to the cardiovascular system (19.08%), and drugs from the digestive tract and metabolism (17.94%). . This study demonstrates the variability of drug use in CKD patients.

8) Avez ALI et al., (2021) The current study was conducted to review and evaluate the pattern of medication use in patients with chronic kidney disease (CKD). A 12-month prospective observational study involving 384 CKD patients was conducted at Shadan Teaching and General Hospital, Peerrancheru (Hyderabad). The inclusion and exclusion criteria. Of the 384 patients, 249 (65%) were male and 135 (35%) were female with a mean age of 58.28 (SD: 13.12). A total of 384 prescriptions with a total of 3634 drugs were examined, of which drugs affecting the cardiovascular system were prescribed most frequently (36.37%). The average number of drugs per prescription was found to be 9.08 when considering the total number of prescriptions. The percentage of drugs prescribed under generic names was 15.57%. The percentage of encounters with antibiotics was 25%, while the percentage of encounters with injections was 86%. The percentage of drugs prescribed from the Essential Drug List or Formulary was 26.36%. Assessing patterns of medication use in CKD patients against the WHO core indicators helps to underpin current hospital guidelines for optimal use of medication. The introduction of a clinical pharmacist together with a multidisciplinary team provides patients with intensive care and helps improve the clinical outcome...

9) Paik J.M.a,b,c,d et al., (2017) The medication burden of patients with end-stage renal disease (ESRD) on hemodialysis, a patient population with a high comorbidity burden and complex care requirements, is among the highest of any of the chronic diseases. The goal of this study was to describe the medication burden and prescribing patterns in a contemporary cohort of patients with ESRD on hemodialysis in the USA. We used the United States Renal Data System database from January 1, 2013, and December 31, 2017, to quantify the medication burden of patients with ESRD on hemodialysis aged ≥ 18 years. We calculated the average number of prescription medications per patient during each

respective year (January–December), number of medications within classes,

including potentially harmful medications, and trends in the number of medications and classes over the 5-year study period. Results: We included a total of 163,228 to 176,133 patients from 2013 to 2017. The overall medication burden decreased slightly, from a mean of 7.4 (SD 3.8) medications in 2013 to 6.8 (SD 3.6) medications in 2017. Prescribing of potentially harmful medications decreased over time (74.0% with at least one harmful medication class in 2013–68.5% in 2017). In particular, the prescribing of non-benzodiazepine hypnotics, benzodiazepines, and opioids decreased from 2013 to 2017 (12.2%–6.3%, 23.4%–19.3%, and 60.0%–53.4%, respectively). This trend was consistent across subgroups of age, sex, race, and low-income subsidy status. Patients with ESRD on hemodialysis continued to have a high overall medication burden, with a slight reduction over time accompanied by a decrease in prescribing of several classes of harmful medications. Continued emphasis on assessment of appropriateness of high medication burden in patients with ESRD is needed to avoid exposure to potentially harmful or futile medications in this patient population.

- 10) Rowa Al-Ramahi et al., (2012)** To determine the medication prescribing pattern in hospitalized patients with chronic kidney disease (CKD) in a Malaysian hospital, we prospectively studied a cohort of 600 patients in two phases with 300 patients in each phase. The first phase ran from early February to late May 2007 and the second phase from early March to late June 2008. Patients with CKD who had an estimated creatinine clearance of 50 mL/min and were older than 18 years were included. A data collection form was used to collect data from the patient's medical records and chart review. All systemic drugs prescribed during the hospital stay were included. Patients were prescribed 5795 drugs. In the first phase, patients were prescribed 2,814 prescriptions containing 176 different drugs. In the second phase, 2,981 out of 158 drugs were prescribed. The mean number of drugs in the first and second phases was 9.38 and 9.94, respectively (P-value = 0.066). The five most commonly used drugs were calcium carbonate, folic acid/vitamin B complex, metoprolol, lovastatin, and ferrous sulfate. The most commonly used drug classes were mineral supplements, vitamins, antianemics, antibacterials, and beta-blockers. This study provides an overview of

prescribing practice in a cohort of hospitalized CKD patients and identifies potential areas for improvement in prescribing

11) Janet Mary Oommen et al., (2012) Pattern of chronic kidney disease patients undergoing hemodialysis at both hospitals. The study was conducted in a tertiary care hospital and a private hospital over a period of nine months. Patients with chronic kidney disease who were on maintenance hemodialysis for at least one month were included. Information such as sociodemographic and clinical characteristics, previous medications, comorbidities and current medications were noted on self-created patient forms. Mean standard deviation and percentages and relevant statistical tests such as the Chi-square test were used. The majority of patients were middle socioeconomic class in private hospitals and lower middle class in tertiary hospitals. Most were unemployed (50.60%, 36%), married (90.36%, 88%) and had high school diplomas (62.65%, 45.33%). Approximately 78 (93.97%) patients had tertiary health insurance and 39 (52%) had private health insurance. Hypertension has been found to be the leading cause in tertiary and private hospitals. Calcium channel blockers (77.10%, 53.30%) were commonly prescribed in both hospitals. Erythropoietin (69.80%), calcium acetate (21.70%) and antidiabetics (insulin 10.84%) in tertiary hospitals, while newer and more expensive drugs such as darbepoetin, iron supplements and lanthanum carbonate were prescribed in private hospitals.

12) Anina Anil et al., (2021) The study was conducted prospectively by using a sample size of 135 patients with the aim of assessing the prescription pattern of drugs used in chronic kidney disease patients undergoing haemodialysis in nephrology department for a study period of 6 months. The obtained parameters were analysed and the results concluded that the most prescribed drug in the study population was antihypertensives (16%) which was followed by multivitamins (13%), haematinics (11%), diuretics (7.4%), erythropoietin stimulating agents (7.2%) and phosphate binders (6.7%). The study has helped to provide an overall estimate of the drugs being prescribed among the CKD patients in the concerned tertiary care hospital. Incorporating a standard assessment and

treatment may reduce the complications and adverse reactions seen in these patients and would help doctors, medical professionals and family members to better understand the physical and psychological problems of patients with CKD on haemodialysis. This would in turn improve their quality of life and reduce the mortality risk in this population.

13) Fahad M et al., (2018) This study was performed to analyze various demographic data such as age, gender, nationality, status of the patients, and the causes of end-stage renal disease (ESRD) of 349 patients who were undergoing hemodialysis (HD) during the period from January 2013 to December 2015 at the Dialysis Center of King Khalid Hospital in Tabuk City. One hundred and fifty-two patients (43.6%) were on HD in 2015. Age of the patients ranged from 9 to 93 years and the mean age was 51.3 ± 17.6 years. Majority of the patients, i.e., 140 (40.1%) were in the age group of 40–59 years, followed by the age group of 60–79 years by 27.8% (97 patients). Saudis constituted 84.2% (294) and non-Saudis accounted 15.8% (55) of the patients over the years studied. There were 198 males (56.7%) and 151 females (43.3%). The death rate in 2014 was 6.2%, whereas it increased in 2015 to 10.5%. The high escape rate (10.3%) of patients was in 2014. Diabetic nephropathy was the most common cause of ESRD, accounting for 30.4% of all cases, followed by unknown etiologies accounting for 25.2%. Nearly 22.6% of all ESRD cases had hypertension. Primary glomerular disease was seen in 8.9% and obstructiveuropathy in 3.7%. Other causes constituted 7.4% of the cases. The data of ESRD patients in Tabuk City are comparable with that of other regions of the Kingdom of Saudi Arabia. We conclude that analysis studies of HD centers help to understand the problems and the needs of the patients, find the solutions, and create a connection between the consumers and health-care providers.

14) Sridhar Srimath et al., (2017) Patients on hemodialysis are highly dependent with several comorbid conditions who often have unsatisfactory rehabilitation, poor prognosis and suffer additional burdens including invasive interventions and time commitment. Patients suffer from further losses in professional, social, sexual and psychological contexts, in addition to physiological and emotional shocks felt at the time of diagnosis

and during the course of treatment. Hence a study is conducted to assess the drug use patterns and QoL (SF-36) in HD patients (n=105). Hypertension (100%) was found to be the most common comorbid condition followed by anemia (85.71%), DM (60%), CAD (33.33%), hyperlipidemia (26.67%) and hypothyroidism (14.8%). Among drug use patterns anti-hypertensives (100%), anticoagulants (100%) and erythropoietin (100%) were most commonly prescribed. The present study revealed that the study sample undergoing hemodialysis had lower health related QOL scores for all the 8 domains for the first assessment compared to the second assessment. But there was no significant difference between the two assessments. After the follow up, in both males and females, all the domain scores were found to be significantly improved. In males, after follow up, bodily pain was more improved followed by vitality, general health, role physical, social functioning, role emotional and mental health. In females, after follow up, bodily pain was more improved followed by general health, vitality, social functioning, mental health and physical functioning.

- 15) S. Rakshana and Preetha Selva et al., (2018)** Chronic kidney disease patients need to take careful care when taking drugs, in order to prevent further renal damage. This study looked at the prescription patterns of drugs used by chronic kidney disease patients. Out of the 448 patients studied, 237 were male and 211 were female. 45.98% of the people in the study were between the ages of 46 and 60. The total number of drugs prescribed was 3132. Of these, 533 were vitamins, 470 were anti-ulcer drugs, 417 were diuretics, 309 were antibiotics, 260 were antiemetics, 228 were anti-hypertensives, 211 were antihistamines, 211 were antiplatelet drugs, and 202 were antidiabetics. 2518 (80.39%) of the drugs were taken by oral route and 493 (15.75%) were taken by injection. According to WHO drug prescribing indicators, an average of 7.2 drugs were prescribed per encounter. This study shows the current prescribing practice of nephrologists for hospitalized patients with chronic kidney disease. Due to polypharmacy, it is inevitable that clinicians will prescribe generic drugs from the National list of Essential Medicines or rationalized drug therapy.

16) Abdul Nafih¹, et al., (2017) Background Patients treated with hemodialysis and renal transplant require complex therapy regimens that manage comorbid conditions such as diabetes, hypertension, and so on; as a result, they may develop drug-related issues. Inappropriate medication use raises the risk of drug-related problems, which can manifest as excessively extended hospital stays, higher expenses, and overuse of medical services. Prescribing pattern among the patients treated with hemodialysis and renal transplantation are not well characterized previously. Objectives The objective of the study is to investigate drug prescription trends in hemodialysis patients and to study the prescribing patterns of medications in kidney transplantation patients. Materials and methods The prospective observational study was conducted over a period of 8 months, i.e. from October 2021 to June 2022 in end stage CKD patients treating with maintenance hemodialysis and renal transplant. Different classes of drugs prescribed and percentage of drugs per prescription was estimated in this study. Data were analyzed descriptively. Results 105 patients recruited have been analyzed of which 76 (72.38%) were male and 29 (27.6%) were female. Polypharmacy (use of ≥ 5 medications) was observed in 91.5% in hemodialysis patients and 100% in renal transplant patients. The most prescribed drugs in hemodialysis patients were Cardiovascular Drugs 72 (100%), and in renal transplant patients, immunosuppressants were highly prescribed 33 (100%). Conclusion This study concludes that the cardiovascular agents and immunosuppressants were the most common drugs prescribed among the hemodialysis and renal transplant patients respectively. Polypharmacy among overall patients was observed and it may initiate drug-related problems.

Hemodialysis is a treatment for patients suffering with end-stage renal disease (ESRD). Hemodialysis patients require several medications to manage their co-morbidities and complications of ESRD. Medication safety and efficacy in these patients depend on prescription patterns and medication adherence. Prescription pattern studies in haemodialysis can provide useful insights into the pharmacotherapy of these patients and help identify gaps and opportunities to improve medication safety and efficacy.

The need for the study of prescription pattern trends in hemodialysis patients is evident for the following reasons:

Hemodialysis patients have a burden of co-morbidities, and medication therapy is essential for the management of these comorbidities. However, medication-related problems, such as drug interactions, adverse drug reactions, and medication non-adherence, are common in these patients and may contribute to increased morbidity and mortality.

Hemodialysis patients often require multiple medications to manage their comorbidities. The complexity of medication therapy in these patients can lead to medication errors and suboptimal treatment outcomes.

There is a lack of prescribing guidelines specific to hemodialysis patients. Prescribing guidelines for the general population may not be appropriate for these patients, as they have altered pharmacokinetics and pharmacodynamics due to ESRD and hemodialysis.

There is a knowledge gap in the prescribing patterns and medication safety in hemodialysis patients. Prescription pattern studies in these patients can help identify gaps in knowledge and inform the development of guidelines and educational interventions to improve medication safety and efficacy.

Hemodialysis is a costly treatment, and medication-related problems can increase the economic burden on patients and the healthcare system. Prescription pattern studies can identify opportunities to improve the cost-effectiveness of medication therapy in hemodialysis patients.

AIM:

To determine the prescription pattern trends in hemodialysis patients.

OBJECTIVE:

- ❖ To collect the data from the dialysis ward and nephrology department of Vijaya Krishna multi-specialty hospital.
- ❖ To categorize the prescriptions based on gender and age.
- ❖ To study the prescription pattern in the treatment of haemodialysis with comorbid conditions.
- ❖ To list out the frequently prescribed drugs and the drug classes.

STUDY DESIGN:

This is a prospective observational study conducted for 6 months at Vijaya Krishna multi-specialty hospital, Suryapet. Patients who met the inclusion criteria are taken into consideration.

COLLECTION OF DATA:

Using suitably designed collection data, the following details are collected.

- ❖ Patient demographics.
- ❖ Laboratory investigation reports.
- ❖ Patient treatment charts.
- ❖ Diagnosis.
- ❖ Duration of frequency of hemodialysis.

INCLUSION CRITERIA

- ❖ Patients who are receiving hemodialysis treatment
- ❖ Patients who are at 30 years old
- ❖ Patients who have been on hemodialysis treatment for a minimum of 3 months
- ❖ Patients who have provided informed consent to participate in the study

EXCLUSION CRITERIA:

- ❖ Patients who have received kidney transplant
- ❖ Patients who are pregnant or lactating
- ❖ Patients with a history of allergy or adverse reaction to the medication being studied
- ❖ Patients with a history of substance abuse or dependence

METHODS AND COLLECTION OF DATA:

- ❖ Data is collected through:
 - ❖ Patient interview to determine their chief complaints, history of present illness, past medical history, and diet intake.
 - ❖ Medical records.
 - ❖ Patient prescription.

DURATION OF THE STUDY:

The study has been conducted for a period of 6 months.

PLACE OF THE STUDY:

The study was carried out in Vijaya Krishna multi-specialty hospital of the nephrology department in Suryapet.

Table1representsATotalof60prescriptionsthatwerecollectedrandomlyfromthepatientsandwereanalyzedforaprescriptionpatterninHaemodialysispatients.Among60studysubjects, 85 % are males, and 25% are females this study reveals that the majority of cases aremales.

Table1:Distributionbasedongender

GENDER	NO.OFPATIENT'S	%OFCASES
Male	45	85%
Female	15	25%
Total	60	100%

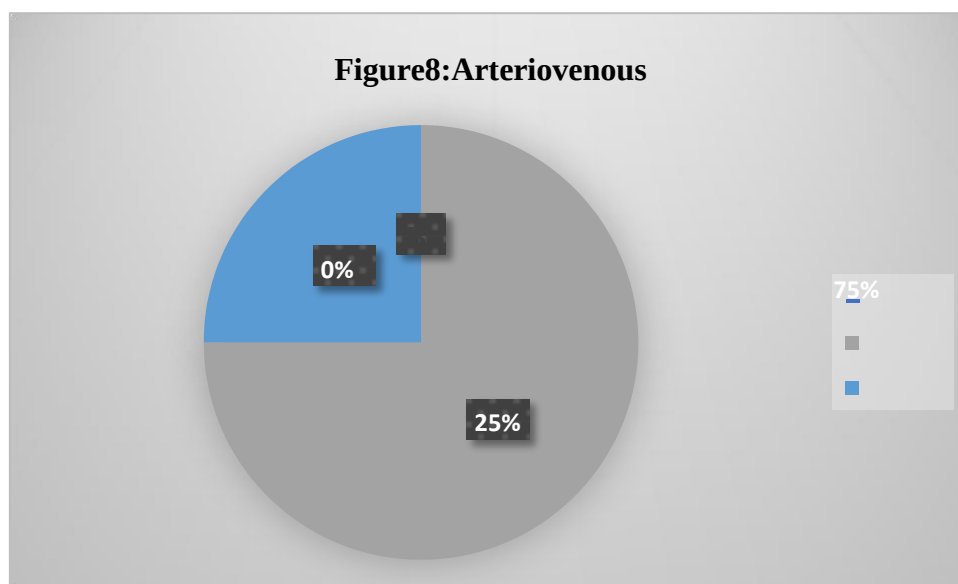


Figure1:DistributionBasedonGender

Table 2 represents the age and gender-wise distribution of patients involved in the study. During the study, the maximum number of patients were found in the age group 30-40 years, 16.6% are from 40-50 years, 26.7% are from 50-60 years, 30% are from 60-70 years, and 18.4% are from 70-80 years.

Table 2: Distribution based on age group

AGE(YEARS)	NO.OF PATIENTS MALE(%)	NO.OF PATIENTS FEMALE(%)	(%)NO.OF CASES
30-40	4(8.8%)	1(6.7%)	8.3%
40-50	7(15.5%)	3(20%)	16.6%
50-60	14(31.1%)	2(13.3%)	26.7%
60-70	12 (26.6%)	6(40%)	30%
70-above	8(18%)	3(20%)	18.4%
Total	45(100%)	15(100%)	100%

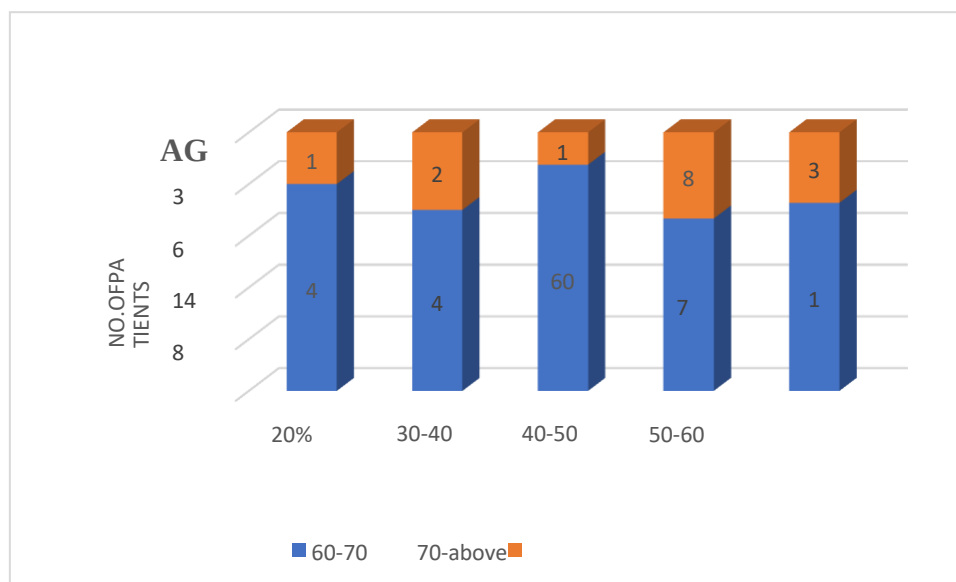


Figure 2: Distribution Based on age group

Table3RepresentBMIinthestudy.Amongthe60patients,totalNormalweight25(41.6%)wereoverweig
ht22(36.7%)wereObeseweight9(15%) wereunderweight4(6.7%).

Table3:Distribution basedonBMI(bodymassindex)

WEIGHT	NO.OFPATIENTS	NO.OFCASES(%)
Underweight	4	6.7%
Normal	25	41.6%
Overweight	22	36.7%
Obese	9	15%
Total	60	100%

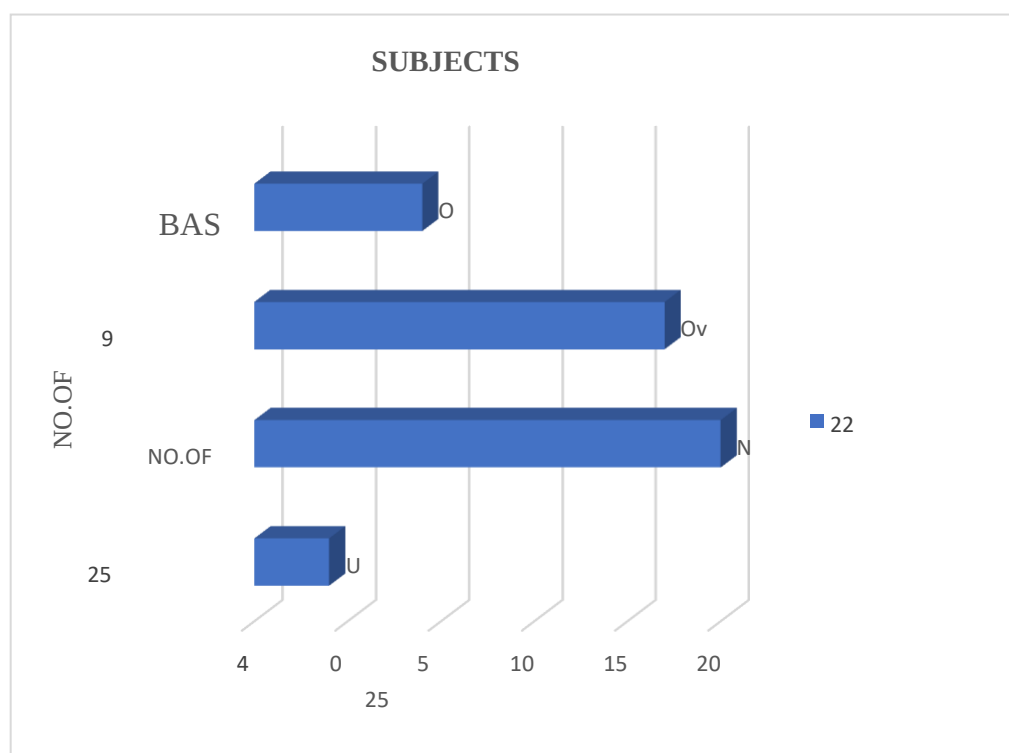


Figure3:DistributionBasedonbodymassindex

Table4representstheDominociliaryAmong60subjects 63.4%arefromaruralarea,and36.6%arefromurbanareas thisstudyrevealsthatthemajorityofcasesarefromurbanareas.

Table4:Distributionbasedondomiciliary

DOMICILIARY	NO.OFPATIENTS(%)	NO.OFCASES%
Rural	38	63.4 %
Urban	22	36.6%
Total	6	100%

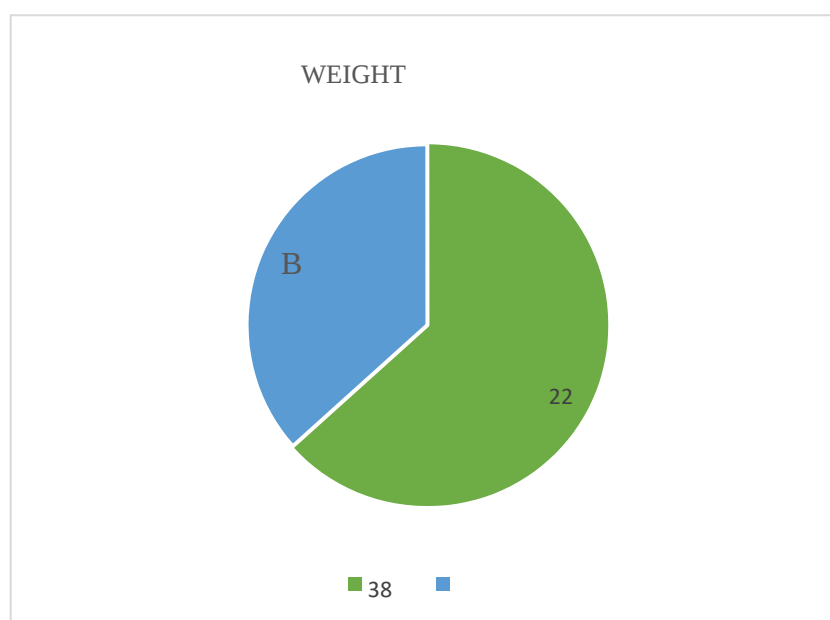


Figure4:DistributionBasedondomiciliary

Table5representsthealcoholandnon-alcoholicandgender-wisedistributionofpatientsinvolved in this study. Among 60 subjects 75% are alcoholic and 15 % are non-alcoholic, thisstudyreveals thatthemajorityofalcoholicpatientsareundergoinghemodialysis.

Table5:Distributionbasedonsocialstatus(alcoholic)

TYPE	NO.OFPATIENTS(%)	%OFCASES
Alcoholic	45	75 %
Non-alcoholic	15	15%
Total	60	100%

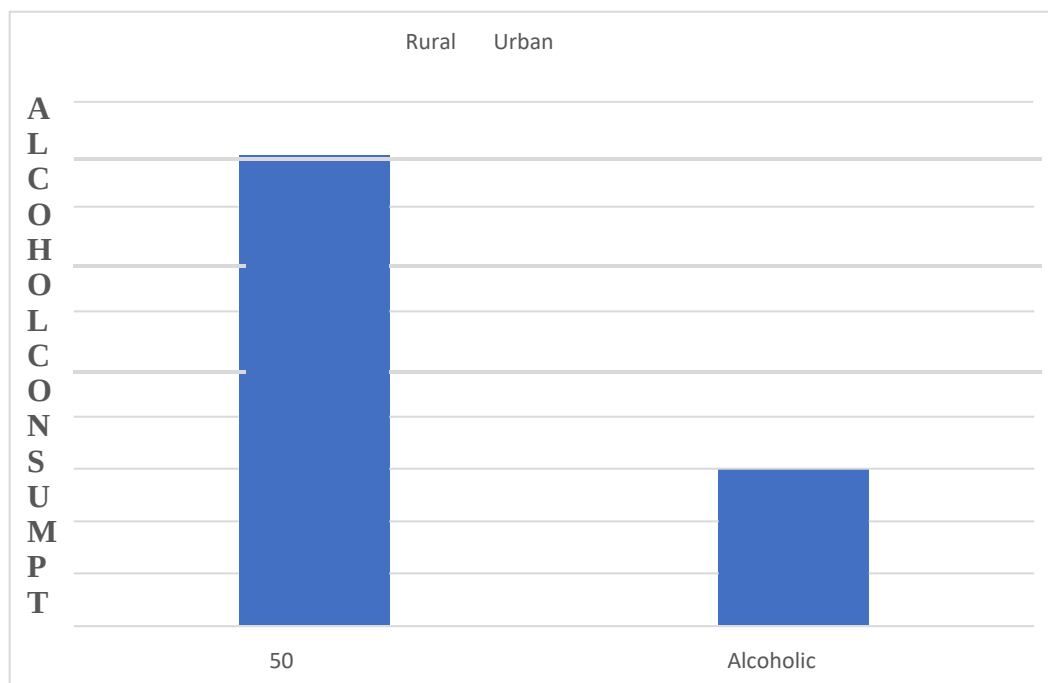
**Figure5:DistributionBasedonsocial status(Alcohol)**

Table 6 represents the smoker and non-smoker and gender-wise distribution of patients involved in this study. Among 60 subjects 75% are alcoholic and 15 % are non- smoker, this study reveals that the majority of alcoholic patients are undergoing hemodialysis.

Table6:Distributionbasedonsocialstatus(smokers)

TYPE	NO.OFPATIENTS	%OFCASES
Smoker	48	80%
Nonsmoker	12	20%
Total	60	100%

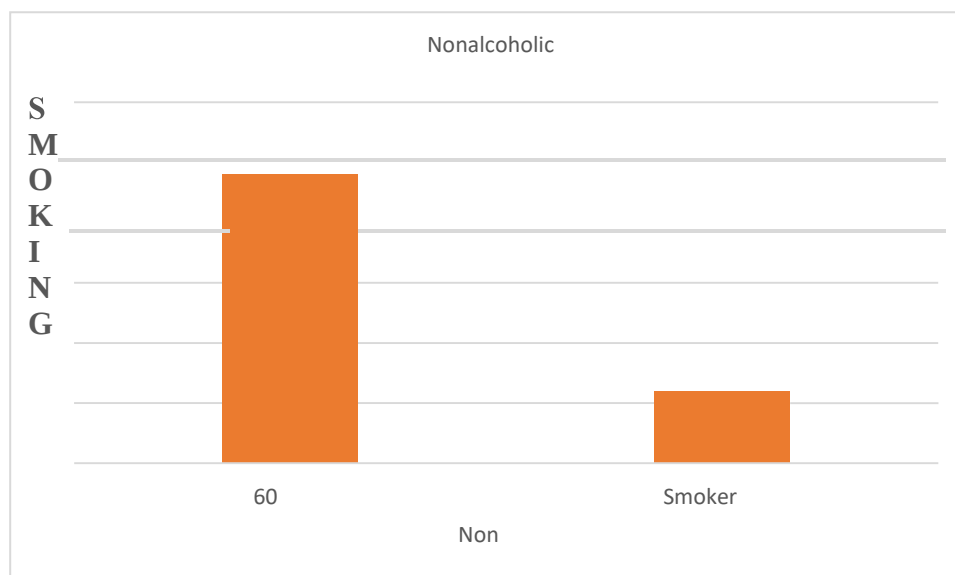


Figure6:DistributionBasedonsocialstatus(smoker)

Table7Representsthedurationofhaemodialysis,among60subjects,Thereareabout30%ofpatients haveundergonehemodialysis inthepastyear.58.4%wereundergoinghaemodialysisfor1-5 years,and about11.6% hadundergonehaemodialysisfor 5-10years.

Table7:Distributionbasedonthedurationofhaemodialysis

DURATION	NO.OFPATIENTS	%OFCASES
1year	18	30%
1-5years	35	58.4%
5-10years	7	11.6%
Total	60	100%

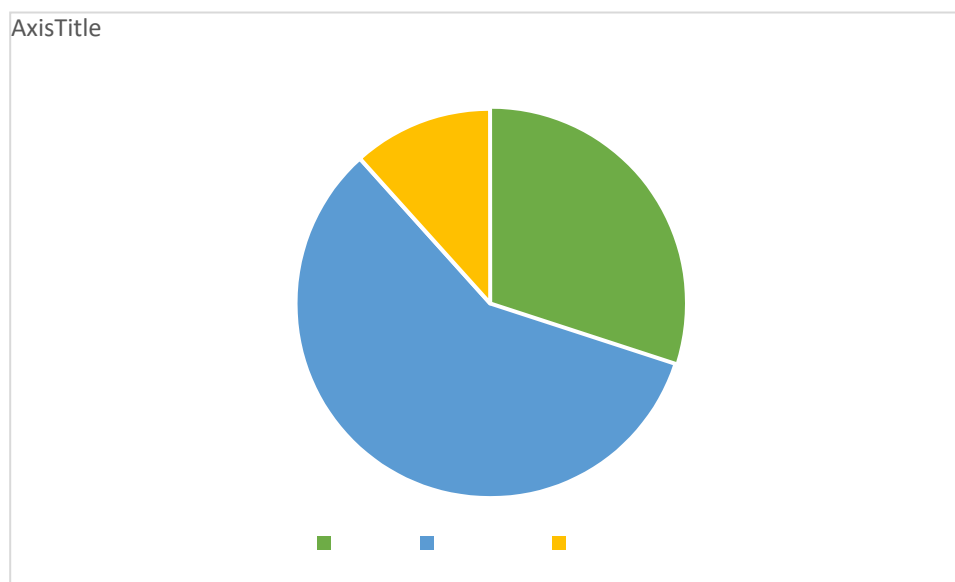


Figure7:Distributionbasedonthedurationofhemodialysis

Table8representsthefrequencyofHaemodialysis,Among60subjects41.7%havebeenundergoing hemodialysis 3 times a week, followed by (58.3%) of the patients undergoinghemodialysis2 timesaweek.

Table8:Distributionbasedonthefrequencyofhaemodialysis sessionsperweek.

FREQUENCY	NO.OFPATIENTS	%OFCASES
Weeklytwice	25	41.7%
Weeklythrice	35	58.3%
Total	60	100%

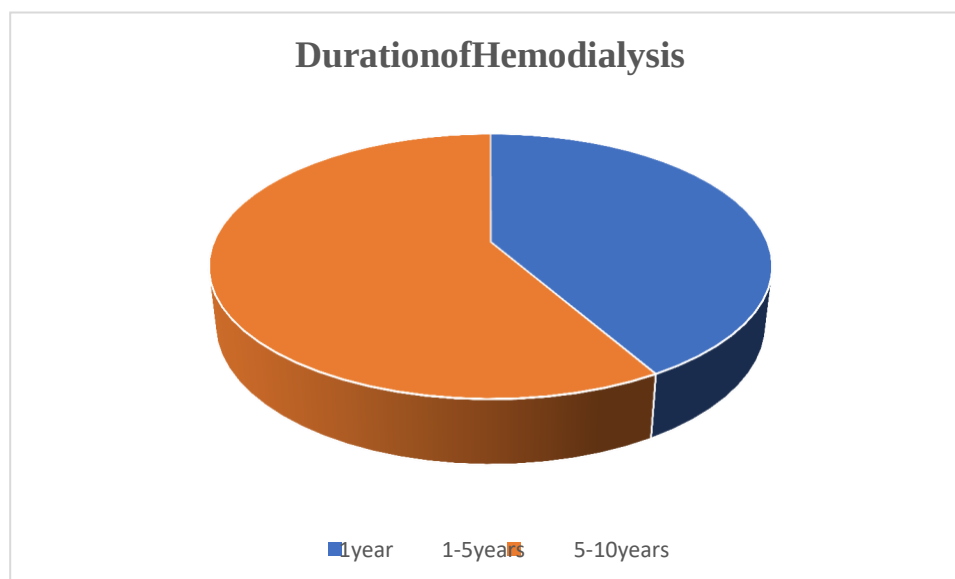


Figure8: Distribution Based on the frequency of hemodialysis

Table 9 represents that Among 60 subjects almost all the patients enrolled in this study have at least more than one comorbid condition. 18.4% with hypertension, 13.3% with DM, HTN+DM 33.3% is the most common comorbid conditions 16.7% are with CVD, 3.4% DM+hypothyroidism, 8.2% with anemia, and 6.7% with GIT that we observed.

Table9: Distribution based on co-morbidities

CO-MORBIDITIES	NO.OF (MALE)%	NO.OF (FEMALE)%	TOTAL % OF CASES
Hypertension	8(17.7%)	3(20%)	18.4%
Diabetes mellitus	7(15.6%)	1(6.7%)	13.3%
HTN+DM	16(35.5%)	4(26.7%)	33.3%
Cardiovascular disease	9(20%)	1(6.7%)	16.7%
DM+hypothyroidism	1(2.3%)	2(13.3%)	5%
GIT	2(4.5%)	1(6.6%)	5%
Anaemia	2(4.5%)	3(20%)	8.4%
Total	45(100%)	15(100%)	100%

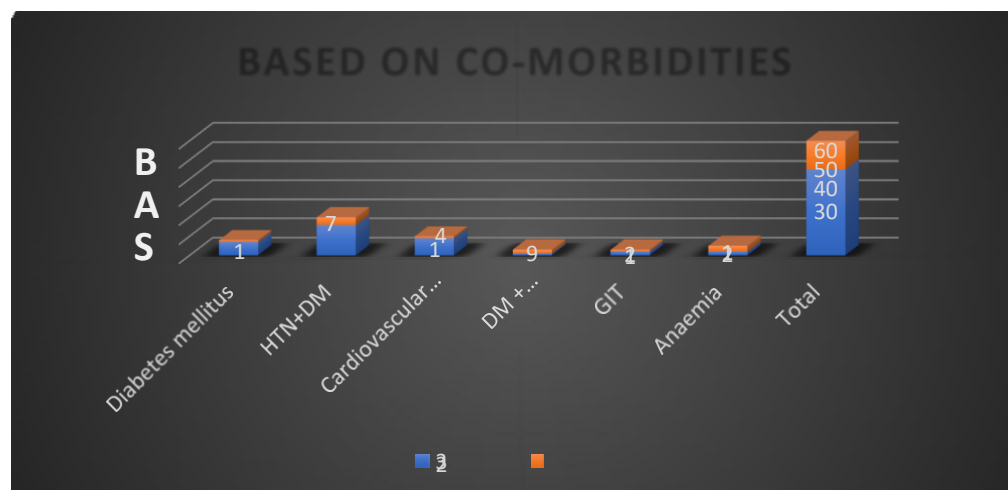


Figure9:DistributionBasedonco-morbidities

Table 10 Represents The drug classes involved in this study. Among 60 prescriptions, a total of 272 drugs were found in 8 different class. Among them that most commonly prescribed drugs were found to be Antihypertensive 95(35.0%) followed by Antidiabetic 45(16.5%) followed by Multivitamins 55(20.3%) followed by Antiplatelets 20(7.3%) followed by hematinic 28(10.3%) followed by proton pump inhibitors 15(5.6%), followed by statins 10(3.6%) followed by Anti-thyroid drugs 4(1.4%).

Table10:Distributionbasedonthe classification of drugs

DRUG CLASS	No.OF DRUGS	% OF DRUGS
Antihypertensives	95	35.0%
Antidiabetic	45	16.5%
Multivitamins	55	20.3%
Antiplatelets	20	7.3%
Hematinics	28	10.3%
Proton pump inhibitors	15	5.6%
Statins	10	3.6%
Antithyroid	4	1.4%
Total	272	100%

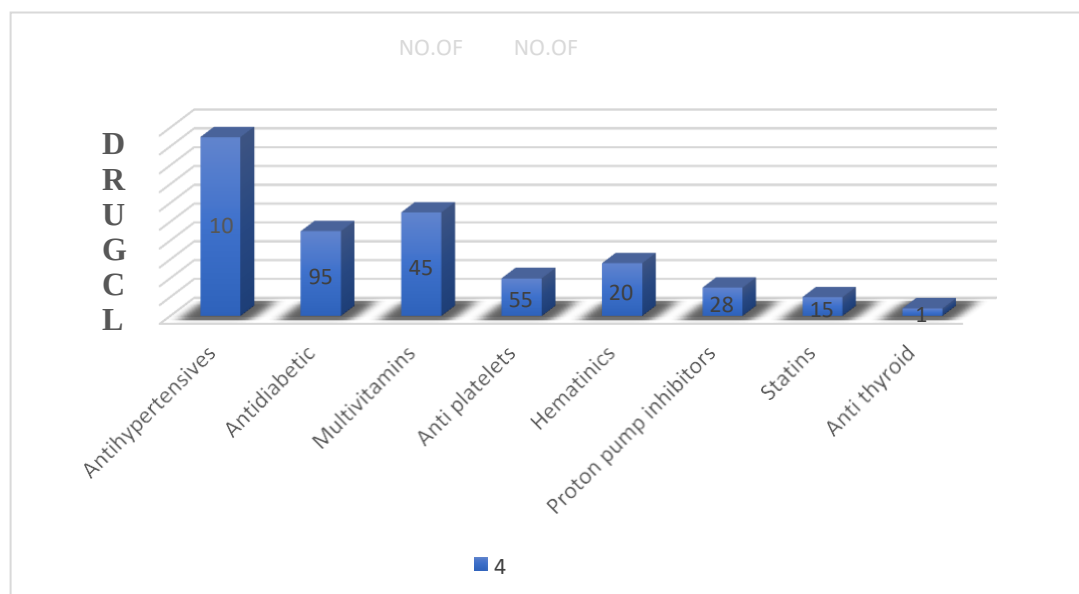


Figure10:DistributionBasedondrugclassifications

Table 11 represent the list of class that comes under Antihypertensives 75 drugs were prescribed in 60 prescriptions, out of which calcium channel blockers 32 (33.6%) along with Beta-blockers, 20 (21.0%) with Angiotensin 2 receptors 18 (19.0) and calcium-channel blockers + Beta-blocker's 19 (20.1%). The class of Calcium Channel Blockers was found to be the most frequently prescribed drug among Antihypertensives.

Table11:Distributionbasedonantihypertensivedrugs

CLASS OF DRUGS	NO OF DRUGS	% OF DRUGS
Calcium-channel blockers	32	33.6%
Beta blockers	20	21.0%
Angiotensin 2 receptors	18	19.0%
Calcium-channel blockers + beta blockers	19	20.1%
Diuretics	6	6.3%
Total	95	100%

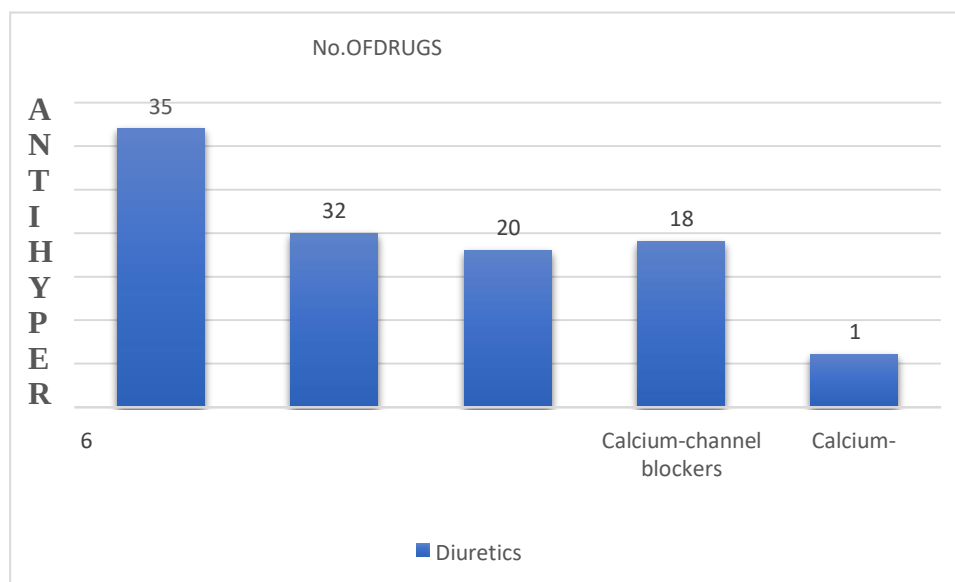


Figure11:Distributionbasedonantihypertensives

Table 12 Figure 20 Represents the list of class that comes under the Diabetic drugs. 45 Diabetic drugs were prescribed in 60 prescriptions, of which Biguanides + sulfonylureas 36 (80%) were prescribed Human insulin 9 (20%). The Drug biguanides + sulfonylurea was found to be the more frequently used drugs in Human Insulin.

Table 12: Distribution based on anti-diabetic drugs

CLASS OF DRUG	NO. OF DRUGS	% OF DRUGS
Biguanide + Sulfonylurea	36	80%
Human insulin	9	20%
TOTAL	45	100%

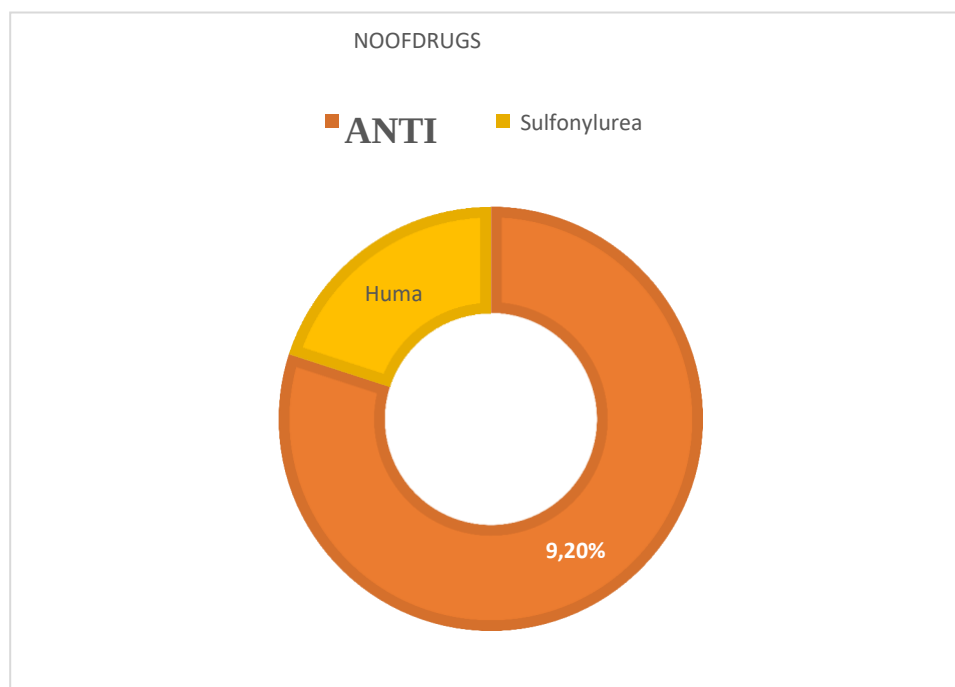


Figure12:DistributionBasedonAnti-Diabetics

Table 13 represents the list of drugs that belongs to the class of Anti-platelets.

20anti-platelets drugs were dispensed in 60 prescriptions, out of which 10(50%) wereprescribedwith Aspirin,10(50%)with Clopidogrel.

Table13:Distributionbasedonanti-plateletdrugs

CLASSOFDRUG	NO.OFDRUGS	%OFDRUGS
Aspirin	10	50%
Clopidrogrel	10	50%
TOTAL	20	100%

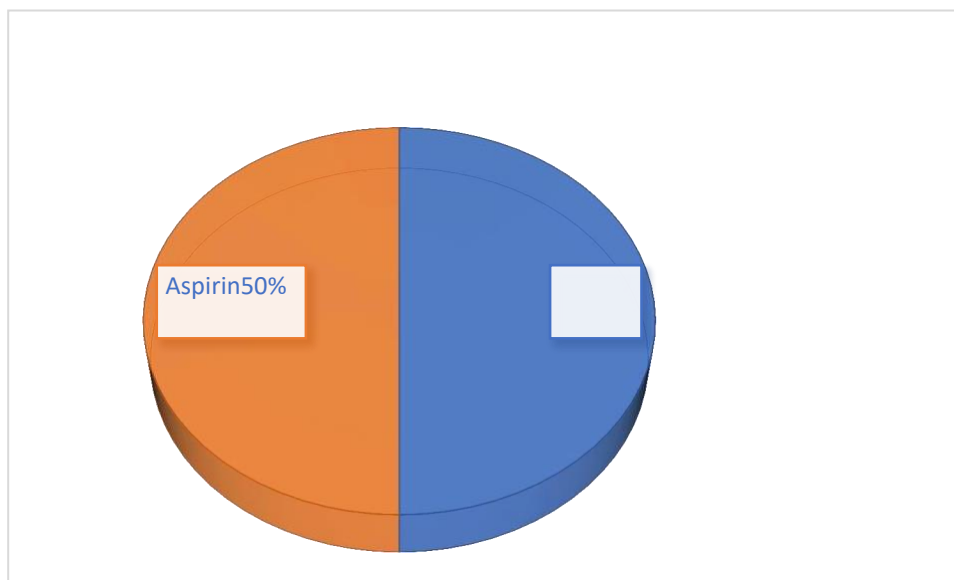


Figure13:DistributionBasedonAntiplatelets

Table14representssthe list of drugsthatwereunderthecategoryofHaematinics.Among60patients 18 (64.3%) were prescribed folic acid followed by 6(21.4%) given parental ironfollowed 4(14.3%) dispensed with oral iron. The drug folic acid was found to be the mostcommonlyprescribed drug among haematinics.

Table14:Distributionbasedonhaematinics

CLASSOFDRUG	NO.OFDRUGS	%OFDRUGS
Folicacid	18	64.3 %
Parentaliron	6	21.4%
Oraliron	4	14.3%
TOTAL	28	100%

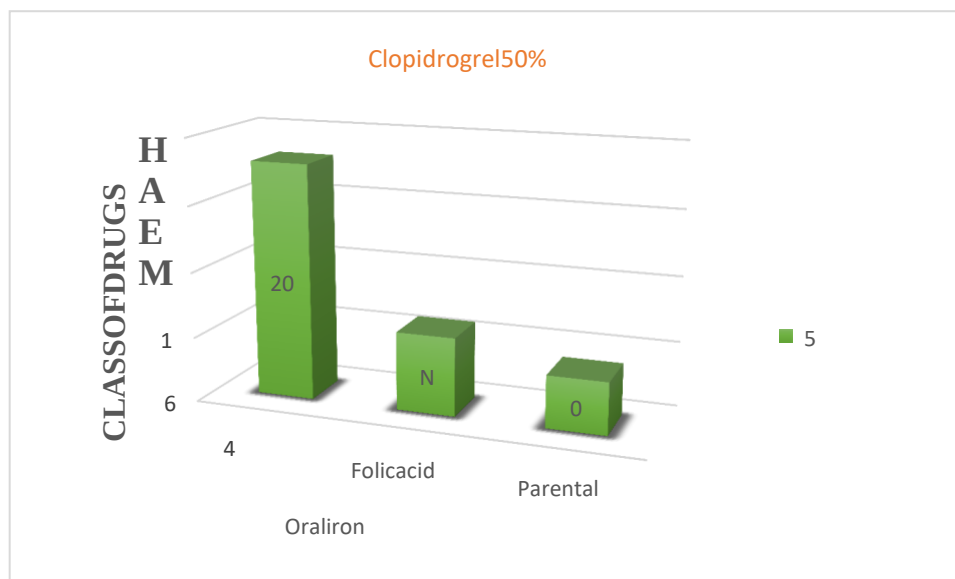


Figure14:DistributionBasedonHaematinics

Table 15 represents the list of drugs that belongs to the class of multivitamins. Among 60 patients 25 (45.4%) were dispensed with Neurobionforte followed 17 (30.9%) were dispensed with Revitfe followed 13 (23.7%) were given with Nephropowder. the drug Neurobionforte was found to be the most commonly prescribed drug among Multivitamins.

Table15:Distributionbasedonmultivitamins

CLASS OF DRUGS	NO. OF DRUGS	% OF DRUGS
Neurobionforte	25	45.4%
Revitfe	17	30.9%
Nephropowder	13	23.7%
TOTAL	55	100%

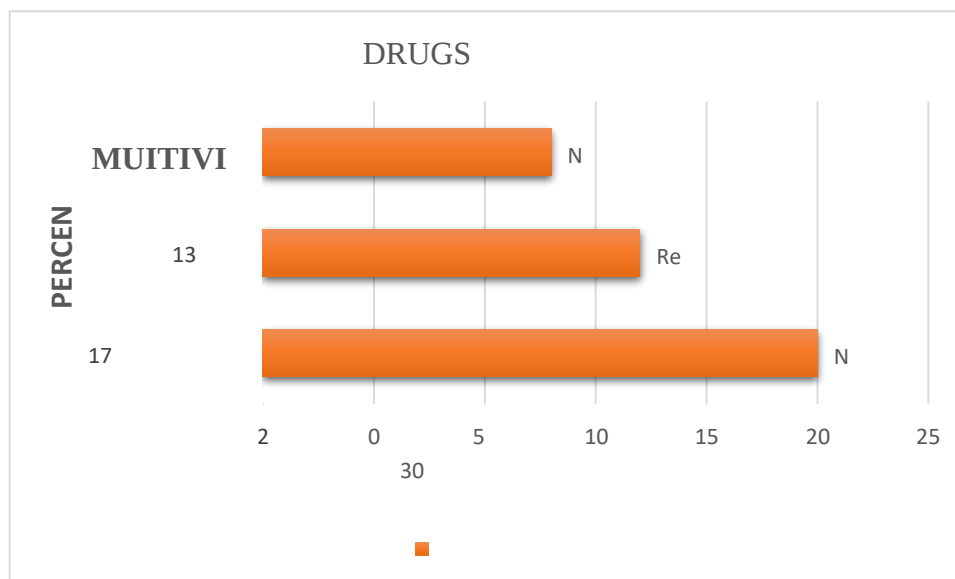


Figure15:DistributionBasedonMultivitamins

Table 16 represents the list of drugs that come under the class Statins. Among 60 patients, 10 (100%) were prescribed Atorvastatin. The drug Atorvastatin was found to be the most commonly prescribed drug among statins.

Table16:Distributionbasedonstatins

CLASS OF DRUG	NO. OF DRUGS	% OF DRUGS
Atorvastatin	10	100%
Others	0	0 %
TOTAL	10	100%

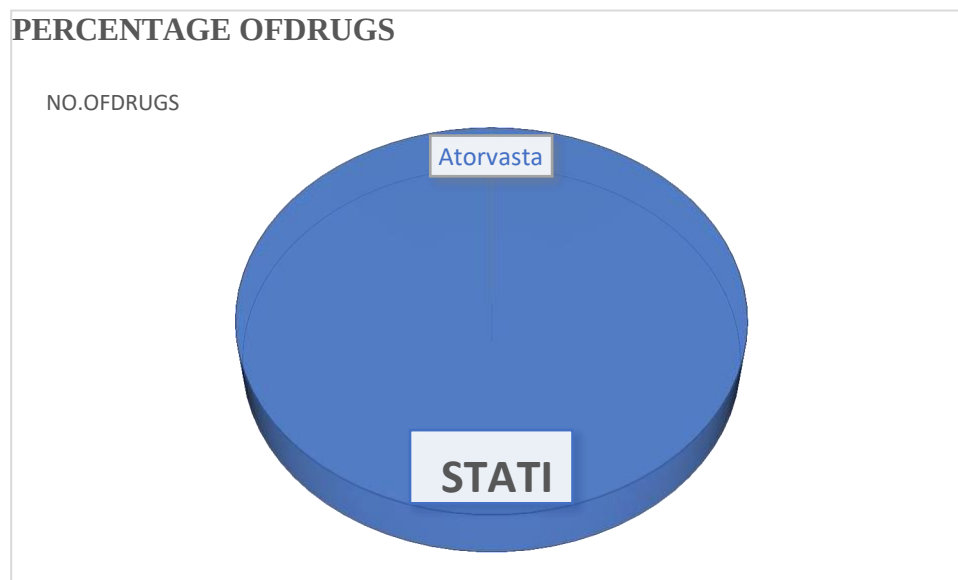


Figure16:DistributionBasedon statins

Table 17 represents the list of drugs that comes under the class proton-pump inhibitors. 15 Proton-pump Inhibitor drugs were prescribed in 60 prescriptions, out of which 9 (60%) were prescribed with pantoprazole, and 6 (40%) were prescribed with Omeprazole.

Table17:Distributionbasedonprotonpumpinhibitors

CLASS OF DRUG	NO. OF DRUGS	% OF DRUG
Pantoprazole	9	60%
Omeprazole	6	40%
Others	0	0%
TOTAL	15	100%

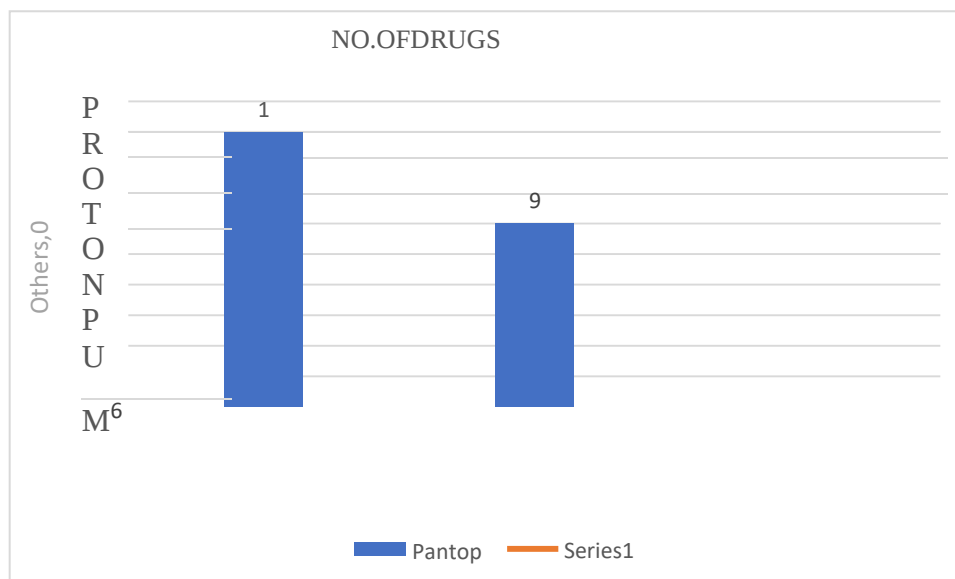


Figure17:DistributionBasedonprotonpumpinhibitors

Table 18 represents the list of drugs that comes under the class anti thyroid drugs. Among 60Patients, 4(100%) were prescribed levothyroxine. The drug levothyroxine was found to Be themostcommonly prescribed drugamong anti-thyroids.

Table18:Distributionbasedonantithyroiddrugs

CLASSOFDRUG	NO.OFDRUGS	%OFDRUG
Levothyroxine	4	100%
TOTAL	4	100%

CONCLUSION

In this study, we found that the males aged 60 -70 years and the females aged 45 -55 years were more exposed towards haemodialysis. Hypertension and Diabetic mellitus were observed as the major co-morbid conditions which is a major risk factor for hemodialysis.

This study identified and concluded that the most commonly prescribed medications in this study are calcium channel blockers followed by Beta blockers, Anti-Diabetic drugs, Antiplatelets, multivitamins, statins and heamatinics. Patients in the dialysis unit are exposed to multiple drugs at a time, as the patients were associated with multiple medical conditions thereby, a high risk of adverse drug outcomes can be reported by the Hemodialysis patients. The clinical pharmacist is responsible to create awareness about rational use of medications. The study mainly assessed the standard treatment pattern which further helps in reducing the resultant complications among the haemodialysed subjects. Patient Education can also be an important factor in order to achieve personalized therapeutic goal of individual patient, which can improve their quality of life.

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PATIENT PROFORMADATACOLLEC TIONFORM

Patientdemographicsdetails

Name: Gender:

IP/OP: Unit:

Age: Weight:

BMI:

- Underweight:
- Normalweight:
- Obeseweight:
- Overweight:

Domiciliarystatus:

Rural: Urban:

Occupation:

Socialstatus: Smoker/Non-smoker: Alcoholic/Non-Alcoholic:

Durationofhaemodialysis:

FrequencyofHaemodialysis: weekly2times Weekly3times

Co-morbidities:

No. of drugs

prescribed>Listofdrugsp

rescribed:

S.NO	Drugs	Indication	Dose	ROA	Frequency
1					
2					

3					
---	--	--	--	--	--

4					
5					
6					
7					
8					
9					
10					

TITLE

FORMULATION AND EVALUATION OF ORAL DISINTEGRATING TABLETS OF TORSEMIDE

ABSTRACT

Swallowing difficulties are common across the age spectrum, but are more prevalent among the elderly and young children. Self-destructing pills that can only be opened by speaking their own code would solve the problem of swallowing altogether, allowing for a jolt to get things moving. The goal of this inquiry was to formulate and plan a Superdisintegrant-enabled, orally disintegrating tablet (ODT) containing Torsemide. The Superdisintegrants croscarmellose sodium, crospovidone, and sodium starch glycolate were used in the preparation of the orally disintegrating tablets by a synchronized burden. Hardness, friability, thickness, and disintegration consistency were measured of the assembled tablets. In 23 seconds, the majority of the superdisintegrant disintegrated, which appears to be 98.82% silent conveyance at this time or less, as per the conceivable outcomes of modern packaging. When used in the form of an ODT, the superdisintegrant croscarmellose sodium provides rapid disintegration.

Key Words: Torsemide, Croscarmellose Sodium, Crospovidone, Sodium starch glycolate and Oral Disintegrating Tablets.

INTRODUCTION

The ODTs' assessment structure, which has seen recent mechanical kinds of improvement, satisfies the fundamental of understanding requirements without interrupting its sameness. Patients who have difficulty swallowing conventional tablets or holders will find that ODTs provide their basic needs. 2 The fact that you don't have to dilute them with water or chew them up beforehand is just another perk of ODTs. Some ODTs, sometimes referred to as clear verbal breaking down pills, are designed to isolate within minutes. Other ODTs contain a handful of bosses that can increase the speed of crippling inside the verbal opening (Superdisintegrant), and these are commonly known as verbal stalling tablets, the disintegration of which can take up to a second. 3 Patients with getting through queasiness, who are traveling, or who have following to

no agree to water are similarly astounding contenders for ODTs¹, who have for the most part been the objective of these unused verbal dissolving/deteriorating appraisal structures. Compared to traditional appraisal methods, the primary benefit of ODT choosing is that it incorporates the best features of both liquid and regular tablet designs. It's easier to take than a pill, thanks to the liquid form's simplified swallowing aid. Oral disintegrating tablets (ODTs) offer the potential advantage of essentially more cautious dosing than the primary alternative, verbal liquids. "A solid evaluation structure containing strong substances or dynamic settling that separate rapidly generally inside so to speak seconds when set upon a tongue," as described by the US Food and Drug Administration (FDA).

This evaluation framework firmly establishes the potential augmentation of dry and liquid coordinate. A few noteworthy ODT developments permit high-volume medicine stacking; they're tasty; they provide an excellent mouth feeling; and they flush out superfluous enhancement within the mouth following spoken interaction. The potential of ODT to improve the bioavailability of poorly dissolvable medications by reversing their toxic profile and hepatic maintenance medicines has been investigated. Fast isolating pills, quick dissolving tablets, expedient dissolving tablets, porous tablets, and rapid melts are all names for the same thing: tablets that dissolve quickly and completely in the mouth. The United States Pharmacopeia (USP) recognized these dosage forms as ODTs despite the fact that they contain a massive number of over words. Recently, the term "orodispersible tablet" has been standardized by the European Pharmacopeia to refer to tablets that disintegrate instantly and within three minutes of being placed in the mouth.⁴

According to the FDA, ODT is "A solid evaluation structure containing supportive substance or lively settling which falls to pieces rapidly for the main piece inside perhaps seconds when put upon the tongue." By and large, ODT isolation times might range from seconds to minutes. Orally isolated pills have five advantages:^{6,7,8}

Bioavailability of medications is increased when they travel from the mouth and throat through the esophagus and into the stomach in the form of spit.

Increased bioavailability with fewer side effects and improved clinical efficacy management can be achieved with pregastric support.

- Comfortable communication with those who refuse to take a pill, such as the young, the old, the mentally ill, the injured, and the recalcitrant.
- • Agreement of membership in a definite group after being separated from liquids.
- • The evaluation structure may be swallowed dry, making it an advantage for patients who are traveling and may not have access to clean water very away.
- • The unusual mouth feel of ODTs is helpful in retraining the prefrontal cortex to view the solution as "appealing reality," especially in young patients.
- Advantages of liquid medications can be communicated in the same way as solids.
- • Rapid decomposition of medication and support, potentially allowing for an immediate commencement of action

IMPORTANT CRITERIA FOR EXCIPIENTS USED IN THE FORMULATION OF ODTs:^{9,10}

- It needs the option to go into isolation immediately.
 - The ODTs should be unaffected by their individual characteristics.
- It must have no connection to the word "quiet" or any other excipients.
- It must not compromise the item's logical and palatable qualities.
 - When deciding on creating a (or a snare mixture), it's important to think about the thing's durability and reliability down to the smallest detail.
 - The excipients used will have molding properties within a range of 30-35°C.
 - Polyethylene glycol, cocoa margarine, and hydrogenated vegetable oils are just a few examples of polymeric mixtures that induce FOR in the folios. Assembling the ODTs: 11, 12, 13, 14

The inarguable headway gained in understanding how to coordinate ODTs is comprised of:

These include: outlining, freeze drying/lyophilization, sublimation, shower drying, mass release, and direct weight.

Drying out, or lyophilization:

Subliming water from an object and then freezing it is a crucial step in ODT preparation. Freeze-dried items isolate faster than other open solids because of the preparation method. The proximity of dazzling and distinct improvement to building professionals and occasionally to trustworthy other than via freeze-drying prepare may account for the accelerated deterioration standard for the subtle components. Relative water insolubility, small particle size, and excellent liquid quality in suspensions are the optimum pharmacological characteristics for this cycle. Considering the solidify point unhappiness and the improvement of cleaned solid on setting, which seem to crumble on sublimation, are the fundamental challenges associated to water-dissolvable medications. In addition to covering up unpleasant flavors and preventing the breakdown of progress, the increasing availability of cryoprotectants like mannitol and crystal forming materials has increased crystallinity. By using a freeze-drying technique, stable compounds can be controlled at room temperature, which should facilitate the preparation of dangerously high-temperature scenarios. The participation is limited by factors other than the basic cost of alteration and supervision. In many of the most recent assessments, structures have been damaged in multiple ways, including the absence of limit necessary for a normal level of discomfort.

Molding:

To outline a compound, one can either immerse, dissolve, or scramble the medication with the dissolvable, and then irrelevantly the saturated mix into tablets (weight forming with lower strain than standard tablet weight), or disperse the dissolvable from a calm methodology or suspension at encompassing weight (no vacuum lyophilization). The tablets specified by weight framework are dehydrated. The formed tablets achieve an amazingly penetrable game plan, which transforms the crippling and crumbling velocity of the object because the weight obligation related is lower than ordinary tablets. However, precise screening of the powder mixture is essential for increasing the rate of its breakdown. Since its mechanical quality provides practically disintegration and breaking amidst handling, it is commonly employed with dissolvable decorations (saccharides) that cause mouth to feel and crippling of tablets.

Spraying to Dry:

Because the managing dissolvable is lost in the course of the sprinkle drying association, the resulting powders are unusually delicate and fine. Allen and Wang used the shower drying handle to neatly stack ODT. Manitol was used as the construction virtuoso, sodium starch glycolate as the superdisintegrant, citrus extract and sodium bicarbonate were used to revive the separating and disintegrating processes, and hydrolyzed and non-hydrolyzed gelatin was used as the supporting association.

A general cleaning:

The development includes cooling the flaming blend with a mixture of polyethylene glycol and methanol that dissolves in water, and the subsequent arrival of fragile mass via extruder or needle to request an office from the thing into indeed locations using warming sharp edge to outline tablets.¹⁸

Granulation in parts:

PEG6-Sterate, a hydrophilic waxy coating, was used by Abdelbary et al. to create ODT. The waxy surface of superpolystate may melt between 33 and 37 degrees Celsius, and its hydrophilic to lipophilic congruity may be 9. It's absurd that it travels as a folio and increases tablets' actual resistance, but it does have an effect on tablets' weakening since it separates in the mouth, solubilizes quickly, and leaves no room for a twist of fate. The value of ODT was established for super polystate by a tranquil granulation approach in which the granules were encased in a fluid of some kind. Paracetamol was used as the demonstration medication, and mannitol and crosscarmellose sodium were used as excipients that dissolve in water and as a weakening agent, respectively.

Phase transition process:

The disintegration of ODT was studied by Kuno et al., who used erythritol (m.p. 122°C), xylitol (m.p. 93-95°C), trehalose (97°C), and mannitol (166°C) to examine the Organize transition of sugar alcohols. A powder containing two sugar alcohols with high and low dissolving centers was compressed at a temperature between their consolidating networks, yielding tablets that could be easily transported. The tablets aren't of sufficient hardness, in terms of molecular similarity, before warming involvement. Warming cycles softened the tablets because an increase in cover

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particle size, or the holding surface area within the tablets, was authorized by the Organizational transition to sugar alcohol with a lower consolidation point.

Effective sublimation of ODT relies on the proximity of particularly penetrable improvement inside the tablet format. Standard tablets typically contain water-dissolvable embellishments, but they quickly deteriorate due to excessive porosity and a lack of care. Sublimation from an encased tablet can be used to treat the porosity of volatile compounds like camphor. Subliming surface shed from packed tablets created using a combination of mannitol and camphor was used by Koizumi et al. to create ODT. After pills were made available, camphor was sublimated in a vacuum at 800 degrees Celsius for 30 minutes.

TECHNOLOGIES THAT CAN BE TRUSTED^{15,16,17}

The Zydis surprising:

You can use Zydis without water, and it takes less than three seconds to isolate on your tongue, making it a potentially useful set of dried areas of strength for linguistic building. The medicine is actually encased in a structure that dissolves in water and then, after being exposed to air, solidifies and breaks apart. In order to facilitate rapid disintegration and huge genuine backbone to endure managing with, the structure integrates water-soluble saccharides and polymer (gelatin, dextran, alginates). During the transmission phase, water is used to transport porous particles for rapid isolation. The problem of sedimentation in dispersed fix is dealt with by using a variety of gums. Glycine is used to stimulate the reduction of the zydis unit during the cycle and long-term storage. Since the zydis appraisal structure is so little, each unit is packaged in a peelable upset pack that allows for easy removal without damaging the contents. A potential drug replacement for Zyprexa would ideally be water-insoluble, extremely stable, and have a small particle size (50 microns or less). Drugs that can be taken in water

Enhancing Orasolv:

CIMA's fastest dissolution decision ever. Coordinate burden at cow weight drive prepares tablets to accommodate linguistic separation and debilitating time. Orasolv movement is a form of mildly fizzy tablet that dissolves quickly in the mouth. Thanks to the development of bubbly scientists, the medicines can now be tasted and administered through spittle. The silence causes a

deafening numbness in the mouth. Orasolv's moo-like mechanicalness is where it falls short most critically. The provided tablets are easily broken, so extra care must be taken when packaging them.

Progress with Durasolv:

This is not a guaranteed upgrade by the CIMA lab; it only makes Odt's timeline second best. This advancement results in quiet, fillers, oil, and tablets structured in the usual formats. Durasolv's finer components have better mechanical quality than their forerunners' for the express reason that they are compacted to a greater degree. The demand for Durasolv is so high that the standard upset pack of vials will eventually be completely full. It's a great innovation for anything that needs elaborate firework displays.

Astonishing development in the tab:

Yamanouchi has given his approval. Wow means "without water" in Wowese. Wow tabs are compressed tablets with granules manufactured from saccharides of moo and height moldability that dissolve intra buccally. It is used to ask for a tablet with a rapid dissolving rate and an appropriate level of hardness. The ability to mold the material is the key to crushing it. Moo's form seems to have reduced compressibility for tabletting and a quick rate, which is consistent with its moldability. However, this configuration is swapped out in the case of a significant increase in moldability. In this, hot decorations are combined with saccharides that can be easily shaped into moo and then compressed into a tablet. Due to its inherent toughness, the wow tab definition is not surprising to weather forecasters. The tab system is brilliant, because it makes sense for both standard holders and the angry mob.

Developments in cotton:

Fuisz obtains it. Cotton cake innovation calls for an alluring going instrument to create floss like transparent improvement. This sugar, which has the consistency of glass, can be combined with the prescribed prescription to make a tablet. An effect has an abnormally high dissecting height. When placed on the tongue, it spreads out and separates quickly.

Ora quick technology:

K V Fix Affiliation, a backer of the Oraquick ODT definition, guarantees that its flavor masking progression, i.e., microsphere improvement (Micromask), offers superior mouth feel to taste concealing alternatives. In addition to allowing for faster, more innovative sensible production, the taste-masking tool doesn't require the use of any solvents. A tablet with reliable mechanical quality and no off-putting flavor mask is the result of careful weighing. Fast rot is confirmed in seconds with exceptional flavor masking using Oraquick. KV repair has items, with various sorts of medications including analgesics, hack and cold, psychotics, and underground dreadful tiny creature infective, but the advancement employing Oraquick improvement has nothing.

Development of Nanocrystals:

Soul the Prussian Head generally agrees with this. In addition to lyophilization, the nanocrystal movement also includes the colloidal dispersion of medicine material and water-soluble decorations filled into problem pockets. For both safe and potentially harmful medications, this method eliminates the need for group collaboration throughout steps like visualization, granulation, mixing, and tableting. This pattern holds true at low dosages of medication since social gatherings are inconsequential.

A feedstock containing a sugar transporter can be mistreated with streak warm management, leading to a development known as shear form advancement: in sight of arranging of floss. In this cycle, sugar is continually exposed to diffusive control and a temperature incline, which elevates the temperature of the mass to create an internal, stream state, allowing some of it to move with yielding of mass. The spinning head that tosses the floss is the source of the gushy mass. The resulting floss is a bit foggy, so it's chopped and recrystallized using planned processes to standardize its stream qualities and make it suitable for mixing. It is then combined with additional tablet excipients and a functional settling to form a tablet. The supplementary blend is compressed into a tablet. Fluff can be used to incorporate the flaming settling and other excipients prior to finishing the recrystallization process. When combined with got or uncoated microspheres, the shear structure floss is used to make EZ nibbling or streak group tablets.

Breakthrough in the pharmaceutical industry: SPI Pharma has licensed this cutting-edge innovation. ODT is promoted by occupying the coprocessed excipients, and it isolates in 30–40

seconds. In this development, the drug, flavoring, and oil are all blended dry and then compressed into tablets by weight. The tablets purchased are of sufficient quality to fill all packets and holders.

This forward momentum in Frosta is authorized by Akina. It arranges the potential of smaller plastic granules and co-processing at moderate strain to areas of high value for high-porosity materials. Produced from: 1. a non-aggressive and plastic outer surface

Booster for Water Interruptions and Safe

The weak plastic surface is combined with water entrance enhancer and then pulverized with lock, and the association is formed. The pills were tested and found to have a bafflingly high hardness and a rapid isolation time ranging from 15 to 30 seconds.

Groups That Coordinate ODTs 18, 19

Regular doctors are in the greatest position to keep up with the latest developments and educate their patients about what's in store as a result of taking the basic package. The vast majority of ODT recipients have only a superficial understanding of the cutting-edge assessment framework. The onset of pill isolation in the mouth would be unnoticed by patients. They might hope for a more immediate beginning to events. A lack of confusion or perplexity can be avoided with some explanation from a reserved expert. As is the case with all forms of evaluation, certain groups of patients will benefit more than others from these developments. Patients who are always on unsettling minimal creature cholinergic remedies may not be the greatest candidates for these treatments. There is no need for water anyway.

EVALUATION OF ODTs^{20,21,22,23}

Evaluation cutoff points of tablets mentioned within the Pharmacopeias should be taken into account, and a variety of unexpected tests are surveyed here.

Because of the specific cycles and decorations used within the saving, hardness is a fundamental characteristic that ODT is aiming for. To facilitate early isolation within the mouth, the ODT's hardness restriction is typically kept at a lower range. Standard hardness testers can be used to measure the tablet's hardness.

Friability: A formulator may find it difficult to keep an ODT's percent friability within allowable ranges, given that any approach to the social occasion of an ODT runs the danger of increasing the values for percent friability. Therefore, it is crucial that this tipping point was identified and that the outcomes are acceptable (between 0.1% and 0.9%).

Time to wet and water-handling capability:

The contact point is linked to the wetting season of the assessment structure. The ODT's wetting season is a further key breaking point that must be taken into account in order to gain insight into its brittle qualities. A shorter wetting time suggests the pill can be isolated more quickly.

The major procedure²⁹ can be used to conduct a survey of the wet season of the tablets. A petridish holds five sheets of 10cm wide indirect tissue paper. Petridish includes a water-soluble collection procedure that only takes ten milliliters. The tablet is placed on the outer layer of tissue paper with care. Wetting time is the amount of time it takes for water to penetrate the tablet's outermost layer.

The tablet's size just before being placed within the petridish is a significant factor in the water digestion allocation survey (Wb). Take the tablet out of the petridish when it has been wetted (Wa). There is no fixed formula for determining R, the amount of water consumed.

$$100 * (W_a - W_b) / W_b = R$$

Assessment of sponge-like absorbency:

Evaluations of ODT moisture uptake should be written to guide the choice of criteria. Ten pills from each location were stored in a desiccator with calcium chloride at 370 degrees Fahrenheit for 24 hours. The tablets were then measured and put on display at room temperature until they reached a relative persistence of 75%. The dessicator achieved the necessary humidity by using a three-day soak in a solution of dusted sodium chloride. To evaluate the moisture uptake from other excipients, one tablet was preserved as a control (without super disintegrants). The rate of weight gain in tablets was measured and recorded.

Disabling test: the first minute provides the best opportunity for isolating ODTs, and the separation duration that stability can endure ranges from 5 to 30 seconds. However, the

evaluation of astonishingly low weakening durations is not achieved by the typical procedure for performing disintegration tests on such estimating structures. The death knell for ODT testing is a lively replication of mouth separation.

When ODT doesn't employ taste masking, it's difficult to tell how the ODT's deterioration methods differ from the conventional tablet's development strategy. According to the USP monograph, it is possible for drugs to have a crumbling state. Evaluation of ODT should use the same media as evaluation of their normal pill supplements, such as 0.1N HCl, pH 4.5, and pH 6.8 compositions. In most cases, 50 revolutions per minute (rpm) is used when dissolving the primer of ODT tablets, and this has been confirmed by experience with a USP 2 paddle device. Under the circumstances specified in the USP monograph, the separation of ODTs is, as may be expected, quite rapid. As a result, a relative profile could be energised by using lower paddle rates. Massive tablets exceeding or equaling one gram in weight and containing appropriately thick particles may cause a vessel's inclination that is otherwise resistant to greater paddle speeds to change. Due to these two factors, a mixing speed of 25-75 rpm is deemed appropriate. While the USP 1 (canister) device may have certain useful applications for ODT, it is rarely used due to the superior express certifiable qualities of tablets. It is possible that tablet fragments or disintegrating tablet masses could enter the holder at the shaft, where there is next to no appropriate mixing. This would lead to unpredictable rot profile results.

LITERATURE REVIEW ON TOPIC

Chandrashekhar Patil et al., (2023) A multi-home created adversary of diabetic impulsed dissolving tablet segregated with a monetarily open metformin tablet was the motivation for this unending examination. Curcuma longa, Cinnamomum zeylanicum, Zingiber officinale, and Trigonella foenum-graecum are just few of the natural medicines with anti-diabetic qualities found in the multi-homemade foe of diabetic tablet. Curcuma longa, Cinnamomum zeylanicum, Zingiber officinale, and Trigonella foenum-graecum are all included in this plant-based blend. To achieve this specificity, MCC is used as a diluent and sodium saccharin is used as a gaining ground master within the tablet definition. Superdisintegrants like croscopolldone, sodium starch glycolate (SSG), and a combination of the two were used to aid in the formation of a tablet's

disintegration rate and strength. Evaluations of the tablets' composition, hardness, friability, wetting time, in-vitro diffusing time, and in-vitro consistent delivery were conducted. The poly-typical opponent of the diabetic tablet was evaluated at each cutoff, and all of the endpoints were considered to be very good. The polyherbal anti-diabetic pill was carefully monitored to ensure it met the required standards for thickness, hardness, weight variation, friability, and in-vitro consistent conveyance.²⁴

Dr. A. Abdul Hasan Sathali et al., (2022) Creative hypertension may be a foreseen infection of hypertension. If not treated properly, it can lead to strokes, myocardial infarctions, cardiovascular collapse, and chronic renal disappointment. Efforts have been undertaken to expedite the onset of action, medicinal response, quiet certification, and basic passage of torsemide, a drug used in the treatment of hypertension. Coordinate weight method was used to formulate fast-dissolving tablets (FDTs) of torsemide with varying concentrations of super-disintegrants. Fourier transform infrared spectroscopy (FT-IR), differential scanning calorimetry (DSC), and other techniques were used to evaluate the setup tablets before and after they were used. Calorimetry, Micromeritics, Hardness, Weight, Friability, Time to Separate, Time to Wet, Water Retention, and In-Vitro Decomposition are all taken into account. The FTIR analysis supported the view that the excipients and medication are well-balanced. All definitions, as assessed by micromeritics, had an appealing to unbelievable stream limit. Tablet hardness and friability gave the impression that the layout plans had remarkable mechanical quality. Super-disintegrant Croscopolone was used to make batch F27, but it failed miserably in terms of tablet isolating, wetting time, water digestion degree, and in-vitro dissolution.²⁵

Neve T.D. et al., (2022) Torsemide (Peak), a circled diuretic, is a course IV prescription within the Biopharmaceutical Coordinate System (BCS), and the purpose of the energy survey was to improve its water solubility and disintegration qualities via a solid scrambling technique. The hydrophilic transporter polyvinylpyrrolidone K-90 (PVP-K30) was used to create dissolvable scattering and scouring procedures that were then used to build solid Pinnacle scatterings at grouped levels. Assessments for tranquil substance, surrender rate, dissolvability, and Fourier transform infrared spectroscopy (FT-IR) were used to determine the passed solid scatterings. Torsemide tablets with and without a currency opening were tested for their crumbling qualities. It seems like there was a four-overlay improvement in dissolvability as compared to the parent

calmafterthesolidscatteringswereformed,andthiseffectwasmostpronouncedforamedicine:transporter ratio of 1:2. One possible barrier to disintegrationidentified byFT-IRanalysis was the absence of made transactions between the drug and the transporter. Solids scrambling tablets appeared to have a stunning breaking down profile in reflected stomach fluidpH 1.2 at 37°C 0.5 than the trade Highest point tablets, in terms of both ruthless separation time(9.01 min) and crumbling capability in 30 min (43.62%). Since both Top solid scatterings andtrade tablets are fast vehicles, Weibull and Krosmeier models were used to select the medicationreleasecentrality.Thefindings ofthisstudysuggestthatsoliddiffusingtechniquescanbeusedtoimprovePinnacle debilitating's solubility andspeedin water.26

Meer R. Zafar et al., (2020) ADHF, or persistently compensated heart failure, is also known as volume over-inconvenience. Those with ADHF are more likely to prioritize office confirmations for volume over inconvenience. Overuse inconvenience can be attributed to factors such as drug resistance, extraordinary salt demand, comorbidities, and spoiling advancement. Although diuretics have been the cornerstone of treatment for cardiovascular collapse (HF) during the past few decades, the field has made significant strides in that time. Even though diuretics can stimulate the renin-angiotensin-aldosterone system (RAAS) and cause potentially harmful side effects as diuretic resistance, neurohormonal underwriting, and kidney failure, they are nevertheless necessary. In recent years, there has been a surge of curiosity about cutting-edge frameworks for balancing volume over annoyance in ADHF. Treatment of volume overload in patients with ADHF is recommended by both the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) guidelines. Therefore, ultrafiltration (UF) is a promising new alternative to dialysis for the management of volume overload in patients with ADHF. This review article is an example of publicly available clinical data on the use of diuretics and UF in patients with ADHF, and it highlights the difficulties associated with both approaches27.

P Abhinandana et al., (2019) Torsemide (Pinnacle), a member of the pyridine sulfonyl urea group of diuretics, and spironolactone (SPI), a potassium-saving diuretic, are used combined to treat congestive heart failure. A diuretic is a medication that increases urination frequency and urgency. For the concomitant evaluation of Torsemide and Spironolactone, as required by the By and large Leading group on Harmonization regulations (Q2B), an undeniable, right, right, and

sensitive maintained adjust arrange otherworldly execution liquid chromatographic procedure was brought. Using 10 mM potassium dihydrogen orthophosphate and acetonitrile as a commencing organizing inside the level of 20:80 v/v, and confirming perceivability at 235 nm, the piece was done on an Agilent 1220 LC structure with EZ Chrome Alite programming equipped with an Agilent C18 district (4.6250 mm, 5 m) and UV identifier. RSD 2% was regarded acceptable when the number of particle plates was >2000. The outcomes were well-coordinated between 10 and 22 micrograms milliliter⁻¹ for Apex and 100 and 220 micrograms milliliter⁻¹ for SPI. In reality, the method was put to use in order to correct the coordinates. The decision made was validated by the statistics as being timely, appropriate, and considerate.²⁸

Jaydeep Singh Baghel et al., (2019) Researching the use of mixed dissolvability made sure to sort out and develop a fast dissolving solid scrambling is a distinctive feature of the ongoing assessment study. Physiologically plausible water dissolvable additional chemicals (solubilizers) were combined with the poorly dissolvable medicine torsemide (display prescription) in an effort to speed up its dissolution and diffusion. Methodologies and Surfaces: To improve the dissolvability of the drug torsemide, which is poorly soluble in water, a combination of solubilizers was used. This combination included sodium caprylate, sodium citrate, sodium acidic disastroous affirmation, and beta cyclodextrin as mixed dissolvable structures. Solubility, infrared, ultraviolet, and differential scanning calorimetry all contributed to a complete picture of torsemide. Long-term room-temperature and low-temperature quality assessments of torsemide scrambled in solid form were carried out. Everything was completely accurate and microbiologically stable when combined. In conclusion, the torsemide's inadequate water dissolvability has been addressed by employing the mixed dissolvability concept in energizing fix stacking.²⁹

LITERATURE REVIEW ON DRUG

V. K. Chopra et al., (2023) Heart attacks are linked to more frequent hospitalizations, slower rates of growth in years lived, and a greater likelihood of betting on average performance. When other methods of decongestion for cardiovascular failure have failed, torsemide is one of the last

resort recalled circle diuretics in India. All of this torsemide use, from dose titration, is founded on pragmatic considerations. Due to the lack of robust confirmation thinking around which treatment options can be produced for people with cardiovascular breakdown, circle diuretic treatment is limited to a select few instances. A leading group of expert cardiologists and nephrologists from India collaborated to create this comprehensive evaluation record for the usage of torsemide in patients with cardiovascular breakdown, regardless of renal shortfall. This comprehensive analysis of torsemide will anticipate an excellent correlation with circle diuretic therapy in conventional patients with cardiovascular breakdown.³⁰

Ahmed Kamal Siddiqi et al., (2023) Torsemide may be more beneficial than furosemide, although only about 10% of patients with cardiovascular breakdown (HF) are actually taking it. Previous studies comparing furosemide and torsemide in HF patients have yielded seemingly contradictory findings, particularly with regards to hospitalizations and mortality. To far, there have been many studies comparing the effects of furosemide and torsemide on mortality and hospitalization rates for heart failure patients; our goal was to compile these studies into a comprehensive meta-analysis. We conducted a comprehensive search of PubMed/Medline, the Cochrane Library, and Scopus from inception to June 2023 for studies comparing furosemide with torsemide in adults (>18 years old) with irreversible or foreseeable HF. All-cause mortality data was extracted, combined with HF-related and general hospitalization data, and then deleted. Taking into account the self-defining effects show, box and plots were developed. Our study of an 8-month follow-up at a single facility included data from 17 separate studies (n = 11,996 patients). Furosemide and torsemide groups in HF patients showed no difference in all-cause mortality in our pooled analysis (OR = 0.98, 95% CI: 0.75-1.29, P = 0.89). However, compared with furosemide alone, torsemide was associated with a significantly lower incidence of both HF-related and all-cause hospitalizations (OR = 0.73, 95% CI: 0.54-0.99, P = 0.04). When used alone or in combination with furosemide, torsemide significantly lowers hospitalizations for HF and other causes, without improving death. In patients with HF who are not reaching a state of adequate control, we support switching with furosemide to torsemide.³¹

Sujana Reddy et al., (2022) The bewitching, risky put-off type IV extraflimsiness mucocutaneous skin provides known as toxic epidermal necrolysis (TEN) and its close cousin, Stevens-Johnson syndrome (SJS), can occasionally be filled by medication. Sulfonamide

antimicrobials and incontestable anticonvulsants are the two most eminently unacceptable couples. Using hematoxylin and eosin recolor skin biopsies, we describe the case of a 41-year-old Dull female who first presented with SJS and then developed TEN. Her skin was splitting and deteriorating on almost 80% of her body's surface area. Torsemide was used to treat her massive, diffuse anasarca caused by alcoholic cirrhosis, and it was discovered that this led to TEN. A team of specialists from fields as diverse as dermatology, gynecology, rheumatology, nephrology, and psychiatry worked together during her month-long stay to diagnose and treat her relative calm. Intravenous steroid, cyclosporine, plasma exchange, and intravenous immunoglobulin were among these several medical interventions that were exchanged. Considering that over 30% of TEN takers pass, and this devotee was suffering from cirrhosis in its last stages, her assumption was particularly impoverished. Even if her TEN gradually improved over time, the hush was fraught with difficulty. This instance emphasizes the significance of remembering to be careful with sulfonamide medications when treating individuals who have a history of extreme sensitivity to sulfamedicines.³²

Melcy Mary Philip et al., (2019) The tablet form of Dytor contains a fixed-dose combination of the diuretics torsemide and spironolactone for the treatment of edema. It's possible that TEN is a legitimate, potentially life-threatening skin condition. A case report of a 47-year-old woman taking Dytor In addition (5/50 mg) therapy once daily for generalized edema is presented here. The patient presented with dermatology short-term division chief complaints of various disintegrations, including verbal distress, lip connection with scaling, redness and stinging sensation inside the two eyes, and various clear for the most part erythematous rashes all over the body for the previous two days. According to her evaluation and lab results, she had abnormally high levels of SGOT (140 IU/L), SGPT (228 IU/L), Snow covered mountain (162 IU/L), and blood urea (47 mg/dl). Dytor was abandoned because its development would have resulted in hazardous epidermal necrolysis. Dexamethasone implant, IgG implant, Cefotaxime mix, Cloxacillin e case, Cetirizine pill, Hydroxypropyl methylcellulose eye drop, and genuine mouth paint were added to the pharmaceutical suspension. A crisis workplace survived the stillness for 25 days. There was a distinct advance of silence. According to the WHO-UMC causality scale, this case falls within the plausible range.³³

Poornima Singh et al., (2019) A significant amount of effort should be put into technique development and streamlining to make an RP-HPLC procedure more practical, as this will also improve the overall performance of the system. An advanced methodology shouldn't be awkward to adopt. The goal of any plan of action should be to speedily complete preclinical diagram, determining show, and trade testing. Torsemide was confirmed in demonstration work using the RP-HPLC technique. Taking into account the R.S.D.(percent), linearity (relationship coefficient), and precision (character) as much as possible. Every step of the process was crystal clear and exactly what was supposed to happen. The manufactured framework effectively shattered the tablet definition. Maximum effort yielded outcomes that complied with ICH and USP standards. Central applications of the ICH methodology for supporting drug appraisal are included in the scope of this audit.³⁴

3. AIM AND OBJECTIVE

Aim:

The spot of the continuous survey is to Organize Torsemide verbal isolating tablets by utilizing superdisintegrants.

OBJECTIVE

Verbal affiliation is the chief outstanding course isolated with other appraisal structures since of simplicity of ingestion, torment avoidance, adaptability and over completely settled consistence at any rate one essential deterrent of solid estimation structure is the annoyance in swallowing (dysphasia) or gnawing in patients particularly pediatric and geriatric patients.

The quiet worth and consistence are fundamental in coordinate of the watchful medication improvement system; one such medicine improvement structure is verbal isolating tablets (O DTs) which has acquired assertion and inescapability inside the high level times.

The astounding variable for the business result of verbal disintegrating tablets is, in view of its fundamental impact on sorting out consistence of all age groups together. These assessments structures are coordinated so they weaken or isolate in patients fast upon contact with spit, inside the space of seconds without offer assistance of water provoking speedier start of advancement.

The essential objective of this is to think about how to redesign the dissolvability of Torsemide utilizing superdisintegrants.

4. PLAN OF WORK

1. Composing study
2. Assurance of medication
3. Keen method development
 - a. Change turn (Standard chart)
4. Arranging of verbal weakening tablets Torsemide.
5. Depiction of micrometric properties.
 - Spot of frest
 - Mass thickness
 - Tapped thickness
 - Carr's record
 - Hausner's certificate
6. Depiction of tablet for the going with limits
 - Weight assortment
 - Thickness
 - Hardness
 - Friability
 - Deteriorating time
 - Content consistency
7. In vitro disintegrating contemplates
8. Drug-Excipient composed endeavors
 - FT-IR

DRUG PROFILE:³⁴⁻³⁵

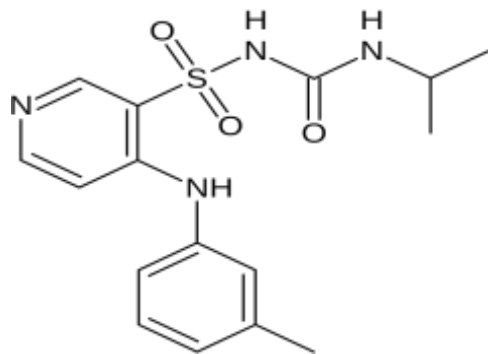
Drug: Torsemide

Synonym : 1-isopropyl-3-((4-m-toluidino-3-pyridyl)sulfonyl)urea, Demadex, luprac, torasemida.

Drug request: antihypertensive, diuretics, Sodium potassium chloride symporter inhibitors

Brand name (single medication): diuver, examide, luprac.

Structure:



Compound name/portrayal/iupac name: n-[(isopropylamino)carbonyl]-4-[(3-Methylphenyl)amino]pyridine-3-sulfonamide

Atomic condition

:C₁₆H₂₀N₄O₃S Atomic weight :

348.421

gm/mole. **PHYSICO-CHEMICAL PROPERTIES**

ERTIES

Description (physical state) serious areas of strength for: . Dis

solvability: water dissolvability

Segment plan and part: imbue ment (10mg/ml), tablet (5mg, 10 mg, 20mg, 100mg).

Consolidating point: 164-

164°C **Pka (strongest acidic) :**

5.92 **Pka (strongest urgent):** 4.2

Log p: 2.3

PHARMACOKINETIC PROPERTIES

Bioavailability: 80-90%

Half-life: 3.5hrs

Ingestion: human gastrointestinal support

Volume of stream : 12 to 15 l

Protein restricting : > almost 100%

%Metabolism : hepatic

(80%) **Metabolites:** m1, m2, m3, m4, m5 metabolites.

es.

Discharge : torsemide is cleared from the course by both hepatic osmosis (around 80% of rigid space) and delivery into the pee (by and large 20% of complete an open door in patients with normal renal capacity).

Contradicting impacts/side effects: wooziness, cerebral pain, burden, deficiency, spewing, hyperglycemia, past crazy pee, hyperuricemia, hypokalemia, unnecessary thirst, hypovolemia, shortcoming, esophageal channel, and dyspepsia

PHARMACODYNAMIC PROPERTIES

Part of activity : torasemide blocks the $\text{Na}^+/\text{K}^+/\text{2Cl}^-$ - transporter framework (through impedance of the chloride restricting site) in the lumen of the thick climbing part of the circle of henle, accomplishing a diminishing in reabsorption of sodium and chloride. This outcome is an

improvement in the speed of transport of changed liquid and electrolytes to the distal protests of hydrogen and potassium particles surge, while plasma volume fixing increases aldosterone creation. The drawn out development and high aldosterone levels advances sodium reabsorption at the distal tubules, and by developing the vehicle of sodium to the distal renal tubule, torasemide in a roundabout way expands potassium discharge through the sodium-potassium trade system. Torasemide's assets in different pieces of the nephron have not been shown. As such torasemide develops the urinary arrival of sodium, chloride, and water, yet it doesn't all around change glomerular filtration rate, renal plasma stream, or horrendous base agreement. Torasemide's belongings as an antihypertensive are an immediate consequence of its diuretic works out. By diminishing extracellular and plasma liquid volume, beat is diminished for a brief time frame outline, and cardiovascular result besides reduces.

Accommodating adequacy/signs: for the treatment of edema related with congestive cardiovascular breakdown, renal sickness, or hepatic illness. Additionally for the treatment of hypertension alone or in mix with other antihypertensive prepared experts.

Contraindications: torsemide tablet is contraindicated in patients with known preposterous sensitivity to torsemide or to sulfonylureas.

Torsemide tablet is contraindicated in patients who are anuric.

Composed endeavors

Drug composed endeavors : amikacin close by torsemide, this can develop the impacts of amikacin. This can make hurt the kidneys or hearing difficulty.

Gentamicin close by torsemide, this can create the impacts of gentamicin. This can make hurt the kidneys or hearing difficulty.

Levomethadyl acidic destructive deduction close by torsemide can manufacture the bet of a conflicting heart musicality

Liquor correspondences: torsemide and ethanol might have added substance impacts in chopping down your pulse. You could encounter migraine, tipsiness, dazedness, swooning, and besides changes in heartbeat or heartbeat

6. EXCIPIENTS PROFILE

CROSS CARMELLOSE SODIUM

Nonproprietary Name:

BP: Croscarmellose Sodium, JP: Croscarmellose Sodium, PhEur: Croscarmellose Sodium
USP-NF: Croscarmellose Sodium

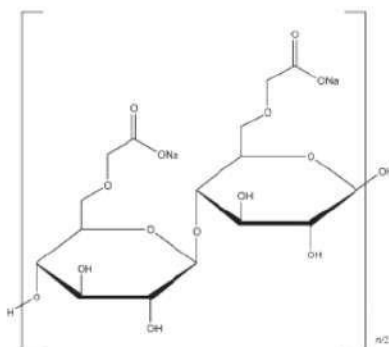
Synonyms:

Ac-Di-Sol; carmellosum naticum conexum; crosslinked carboxymethylcellulose sodium; Explocel; modified cellulose gum; Nymcel ZSX; Pharmacel XL; Primellose; Solutab; Vivasol.

Chemical Name and CAS Registry Number:

Cellulose, carboxymethyl ether, sodium salt, crosslinked [74811-65-7]

Structural Formula:



Functional Category: Tablet and capsule disintegrant.

Applications in Pharmaceutical Formulation or Technology:

Croscarmellose sodium is used in oral pharmaceutical formulations as a disintegrant for capsules, tablets and granules. In tablet formulations, croscarmellose sodium may be used in both direct-compression and wet-granulation processes. When used in wet granulations, the croscarmellose sodium should be added in both the wet and dry stages of the process (intra and extra-granularly) so that the wicking and swelling ability of the disintegrant is best utilized. Croscarmellose sodium at concentrations up to 5% w/w may be used as a tablet disintegrant, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/w in tablets prepared by a wet-granulation process.

Use Concentration (%)

Disintegrant in capsules 10–25

Disintegrant in tablets 0.5–5

7. METHODOLOGY

Buffer preparation:

Preparation of 0.2 M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.128 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 ml of distilled water and mixed.

Preparation of 0.2 M sodium hydroxide solution: Accurately weighed 8 gm of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed.

Preparation of pH 6.8 phosphate buffer: Accurately measured 250 mL of 0.2 M potassium dihydrogen orthophosphate and 112.5 mL of 0.2 M NaOH was taken into the 1000 mL volumetric flask. Volume was made up to 1000 mL with distilled water.

Analytical method development for Torsemide:

a) Determination of absorption maxima

A spectrum of the working standards was obtained by scanning from 200-400 nm against the reagent blank to fix absorption maxima. The λ_{max} was found to be 285 nm. Hence all further investigations were carried out at the same wavelength.

b) Construction of standard graph

100 mg of Torsemide was dissolved in 100 mL of pH 6.8 phosphate buffer to give a concentration in 1mg/mL (1000 μ g/mL) 1 ml was taken and diluted to 100 ml with pH 6.8 phosphate buffer to give a concentration of 0.01 mg/ml (10 μ g/ml). From this stock solution aliquots of 1.0 ml, 2.0ml, 3.0 ml, 4.0 ml, 5 ml, were pipette out in 10 ml volumetric flask and volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 10, 20, 30, 40 and 50 μ g/ml respectively. The absorbance of each concentration was measured at respective (λ_{max}) i.e., 285 nm.

Formulation development:

Drug and different concentrations of super disintegrants (Sodium starch glycolate, Cross carmellose Sodium, Cross povidone) and required ingredients were accurately weighed and

passed through a 40-mesh screen to get uniform size particles and mixed in a glass motor for 15 min.

- The obtained blend was lubricated with magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 min.
- The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table 7.1: Formulation table showing various compositions

INGREDIENTS	FORMULATIONS								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Torseamide	5	5	5	5	5	5	5	5	5
Croscarmellose Sodium	10	20	30	-	-	-	-	-	-
Crospovidone	-	-	-	10	20	30	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	10	20	30
Talc	5	5	5	5	5	5	5	5	5
Mg.Stearate	5	5	5	5	5	5	5	5	5
Mannitol	10	10	10	10	10	10	10	10	10
Lactose	65	55	45	65	55	45	65	55	45
Total weight	100	100	100	100	100	100	100	100	100

Evaluation of tablets:

Pre compression parameters:

Measurement of Micromeritic properties of powders

1. Angle of repose : The angle of repose of API powder is determined by the funnel method. The accurately weighed powder blend is taken in the funnel. The height of the funnel is adjusted in a way that the tip of the funnel just touched the apex of the powder blend. The powder blend is allowed to flow through the funnel freely on to the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$$\tan \Theta = h/r \dots\dots\dots(1)$$

Where , h and r are the height and radius of the powder cone.

Table 7.2 : Flow Properties and Corresponding Angle Of Repose

Flow Property	Angle of Repose (°)
Excellent	25-30
Good	31-35
Fair- aid not needed	36-40
Passable-may hang up	41-45
Poor-must agitate, Vibrate	46-55
Very Poor	56-65
Very, very Poor	>66

2. Bulk density

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in 100 ml graduated cylinder and the powder is leveled and the unsettled volume, V_0 is noted. The bulk density is calculated in g/cm^3 by the formula.

$$\text{Bulk density} = M/V_0 \dots\dots\dots(2)$$

V_0 = apparent unstirred volume

M= Powder mass

3. Tapped density

The powder sample under test is screened through sieve No. 18 and the weight of the sample equivalent to 25 gm filled in 100ml graduated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume V_0 is noted. Tappings are proceeded further for an additional tapping 750 times and tapped volume, V_b is noted. The difference between two tapping volume is < 2%, V_b is considered as a tapped volume V_f . The tapped density is calculated in g/cm³ by the formula.

$$\text{Tapped density} = M/V_f \dots\dots\dots (3)$$

M = weight of sample powder taken

V_f = Tapped volume

4. Compressibility index

The compressibility index of the powder blend is determined by Carr's index to know the flow character of a powder. This formula for Carr's index is as below:

$$\text{Carr's Index (\%)} = [(TD-BD)/TD] \times 100 \dots\dots\dots (4)$$

5. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hausner's ratio. It is calculated by the following equation.

$$H = \rho_T / \rho_B \dots\dots\dots (5)$$

where ρ_T = tapped density, ρ_B = bulk density

Table 7.3 : Scale of Flowability

Compressibility index (%)	Flow character	Hausner Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression parameters:

a) Thickness

The thickness of the tablets was determined by using Digital micrometer. 10 individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation 3 batches were calculated. It passes the test for weight variation test if not more than 2 of the individual tablet weights deviate from the average weight by more than the allowed percentage deviation and none deviate by more than twice the % shown. It was calculated on an electronic weighing balance.

c) Friability

The friability values of the tablets were determined using a Roche-friabilator. Accurately weighed six tablets were placed in The Roche friabilator and rotated at 25 RPM for 4 min. Percentage friability was calculated using the following equation.

$$\text{Friability} = ([w_0 - w]/w_0) \times 100$$

Where w_0 = weight of tablet at time zero before revolution.

w = weight of the tablet after 100 revolutions

d) Drug content

The content of drug carried out by 5 randomly selected tablets of each formulation. The 5 tablets were grinded to get powder; this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 285 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 min. and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) Dissolution test of Torsemide : Drug release from Torsemide tablets was determined by using dissolution test USP 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 medium as the dissolution medium of quantity 900 ml. The whole study is being carried out at room temperature of 37° C and at a speed of 75 RPM.

5 ml aliquots of dissolution media were withdrawn each time intervals (5, 10, 15, 20, 30, min) and appropriate dilution by UV spectrophotometer. The concentration was calculated using standard calibration curve.

Drug-Excipients compatibility studies: Drug excipients compatibility studies were carried out by mixing the drug with various excipients in different proportions (in 1; 1 ratio were to have maximum likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly. Fourier Transform Infrared Spectroscopy (FTIR) studies were performed on drug, optimized formulation using Bruker FTIR. The samples were analyzed between wave numbers 4000 cm^{-1} and 550 cm^{-1} .

8. RESULTS AND DISCUSSION:

Preparation of calibration curve of Torsemide:

The regression coefficient was found to be 0.999 which indicates a linearity with an equation of $y=0.018x-0.000$. Hence Beer-Lmbert's law was obeyed.

Table 8.1 : Calibration curve data of Torsemide in pH 6.8 phosphate buffer

Concentration ($\mu\text{g/mL}$)	Absorbance
0	0
10	0.188
20	0.363
30	0.547
40	0.734
50	0.923

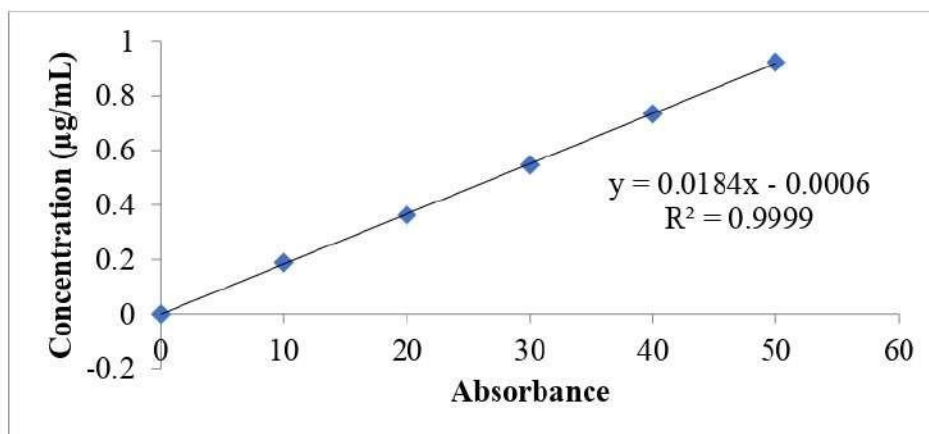


FIG 8.1: Calibration curve data of Torsemide in pH 6.8 phosphate buffer

EVALUATION OF PRE-COMPRESION PARAMETERS OF POWDER BLEND

Table 8.2: Evaluation of pre-compression parameters of powder blend

Formulation code	Angle of repose	Bulk density(gm/mL)	Tapped density (gm/mL)	Carr's index(%)	Hausner's ratio
F1	23.14 $\pm$ 0.3	0.51 $\pm$ 0.01	0.51 $\pm$ 0.01	5.16 $\pm$ 2.0	1.01 $\pm$ 0.02
F2	23.47 $\pm$ 0.4	0.55 $\pm$ 0.01	0.54 $\pm$ 0.02	6.48 $\pm$ 2.0	1.04 $\pm$ 0.03
F3	23.73 $\pm$ 0.5	0.59 $\pm$ 0.02	0.67 $\pm$ 0.03	9.74 $\pm$ 2.0	1.17 $\pm$ 0.03
F4	23.27 $\pm$ 0.4	0.53 $\pm$ 0.03	0.52 $\pm$ 0.04	8.22 $\pm$ 2.2	1.02 $\pm$ 0.03
F5	22.56 $\pm$ 0.2	0.45 $\pm$ 0.02	0.55 $\pm$ 0.01	12.54 $\pm$ 4.9	0.65 $\pm$ 0.23
F6	23.84 $\pm$ 0.4	0.57 $\pm$ 0.01	0.58 $\pm$ 0.01	14.86 $\pm$ 2.2	1.18 $\pm$ 0.03
F7	23.31 $\pm$ 0.3	0.44 $\pm$ 0.02	0.53 $\pm$ 0.03	14.33 $\pm$ 2.0	1.13 $\pm$ 0.23
F8	22.63 $\pm$ 0.4	0.46 $\pm$ 0.03	0.56 $\pm$ 0.02	13.62 $\pm$ 2.0	1.16 $\pm$ 0.02
F9	22.94 $\pm$ 0.2	0.58 $\pm$ 0.01	0.69 $\pm$ 0.01	11.89 $\pm$ 2.2	1.19 $\pm$ 0.02

- For each formulation blend of drug and excipients were prepared and evaluated for various pre compression parameters described earlier in methodology chapter.
- The bulk density of all formulations was found in the range of 0.44 $\pm$ 0.02 - 0.59 $\pm$ 0.02 and tapped density was in the range of 0.51 $\pm$ 0.01 - 0.69 $\pm$ 0.01
- The Carr's index and Hausner's ratio was calculated from tapped density and bulk density.

EVALUATIONS OF POST COMPRESSION PARAMETERS OF TORSEMIDE ODTs

Table 8.3: Evaluation of post compression parameters of Torsemide Fast dissolving tablets

Formulation codes	Average weight(mg)	Hardness (kg/cm²)	Friability (%loss)	Thickness (mm)	Drug content (%)	<i>In vitro</i> disintegration Time(sec)
F1	97.25	2.21	0.41	1.61	99.16	32
F2	98.68	2.44	0.34	1.64	97.41	25
F3	99.41	2.37	0.57	1.77	96.70	23
F4	100.02	2.22	0.32	1.52	99.25	42
F5	96.69	2.35	0.45	1.65	97.58	36
F6	97.47	2.48	0.58	1.88	98.85	30
F7	99.59	2.33	0.43	1.63	99.36	68
F8	98.23	2.46	0.46	1.76	98.61	53
F9	99.72	2.39	0.59	1.89	98.92	41

Weight variation and Thickness: All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown above. The average tablet weights of all the formulations were noted down.

Hardness and friability: All the ODT formulations were evaluated for their hardness using Monsanto hardness tester and the results are shown above. The average hardness for all formulations was found to be between (2.21- 2.48) kg/cm² which was found to be acceptable. Friability was determined to evaluate the ability of the tablets to with stand the abrasion during packing, handling and transporting. All the ODT formulations were evaluated for their percentage friability using Roche friabilator and the results are shown above. The average percentage friability for all the formulations was between 0.32 - 0.59 which was found to be within the limit.

Drug content: All formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown above. The assay values for all formulations were found to be in the range of (96.70 - 99.36). According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the ODT formulation complies with the standards given in IP.

***In vitro* disintegration time:** *In vitro* disintegration studies showed from 23-68 sec.

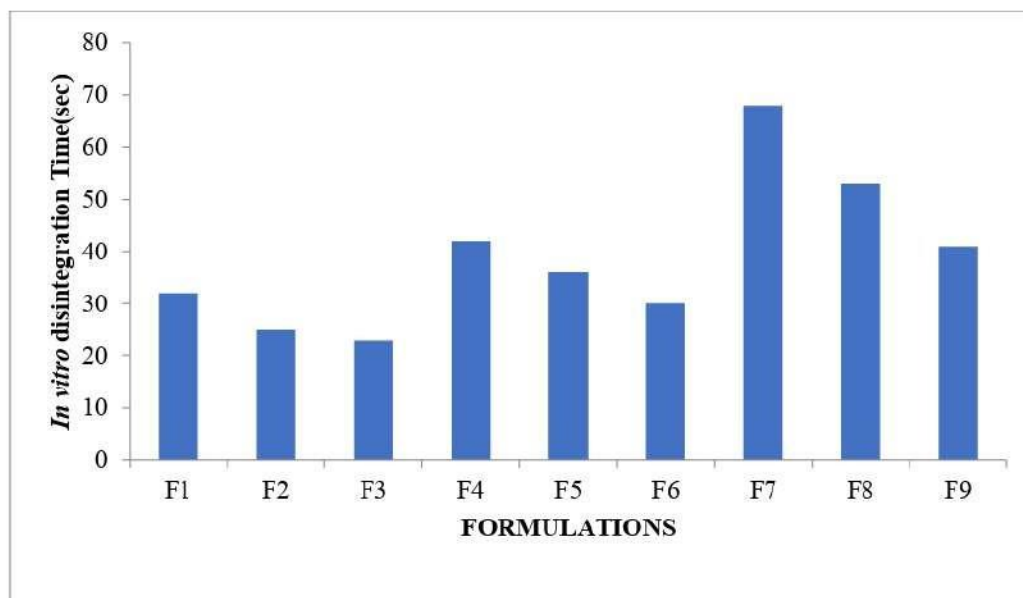


Figure 8.2: *In vitro* disintegration time

IN VITRO DRUG RELEASE SYDUIES OF TORSEMIDE

Table 8.4: *In vitro* Dissolution data of Torsemide

Time (mins)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	13.25	11.08	28.18	21.32	28.47	33.55	27.19	39.95	29.47
10	26.88	34.62	45.38	44.34	45.92	36.71	34.62	46.35	46.76
15	39.49	47.71	52.67	67.04	52.75	49.68	51.37	54.09	49.52
20	52.22	62.35	79.85	78.91	62.29	52.18	68.88	61.76	56.68
30	75.19	75.48	86.57	85.31	89.17	75.32	75.49	68.19	77.32
45	88.37	98.82	93.22	92.78	96.36	98.48	82.67	85.22	83.61

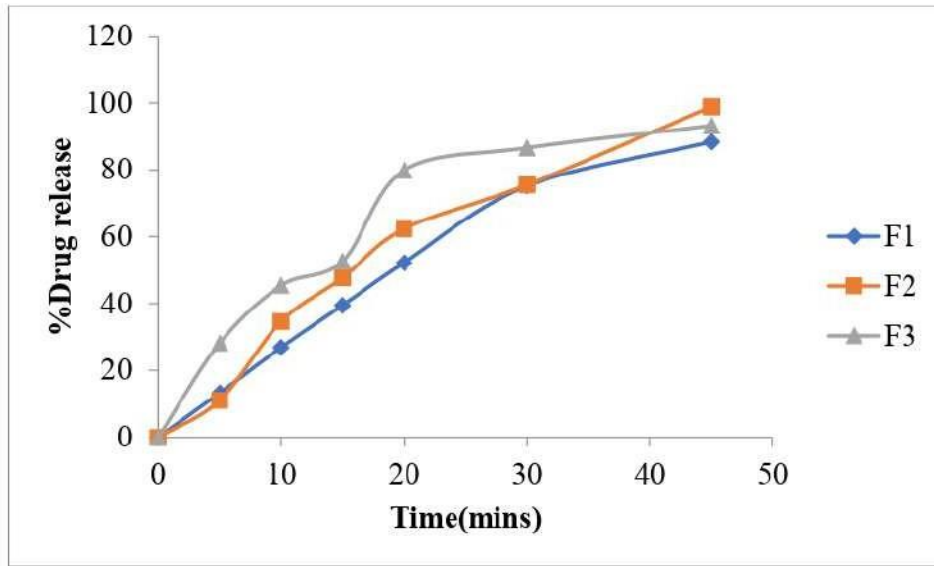


Fig 8.3: Dissolution profile of formulations F1, F2, F3

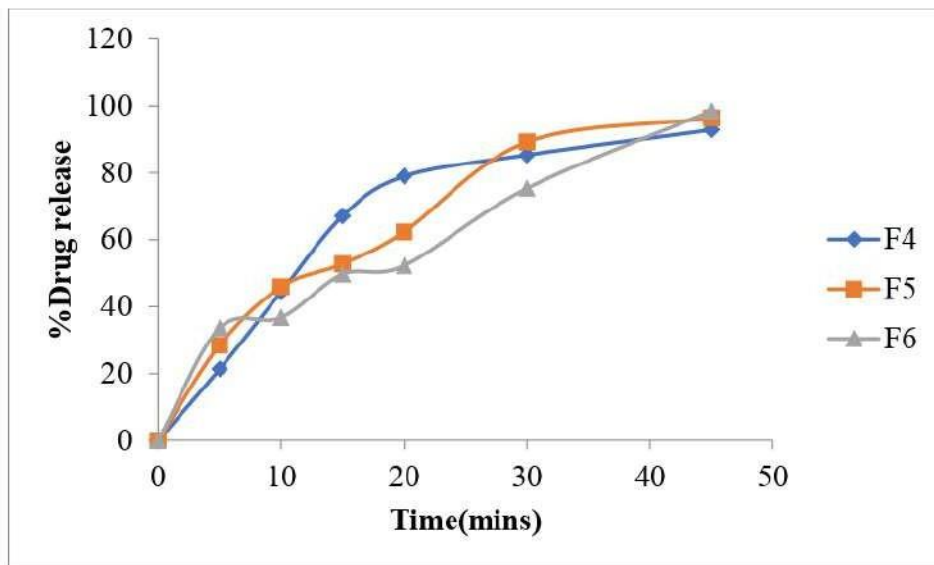


Fig 8.4: Dissolution profile of formulations F4, F5, F6

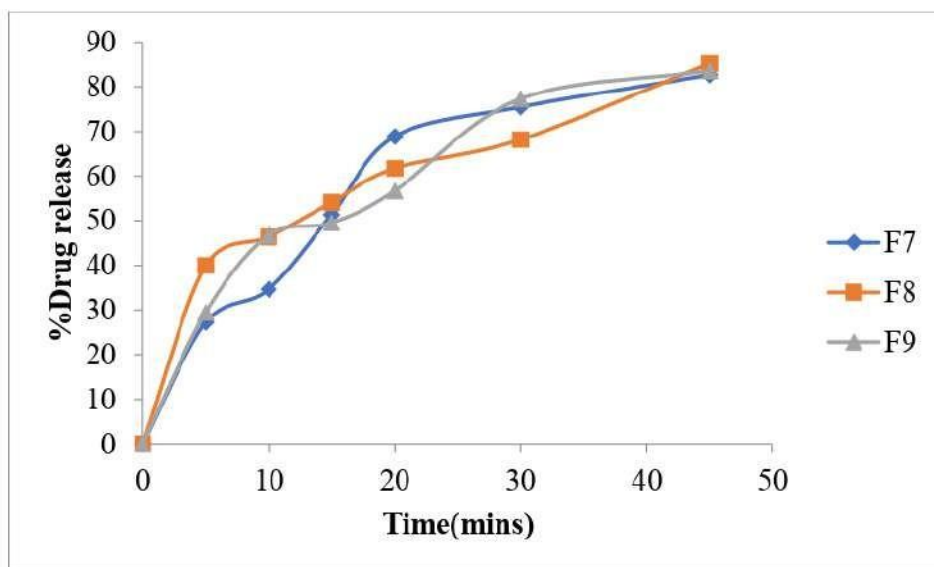


Fig 8.5: Dissolution profile of formulations F7, F8, F9

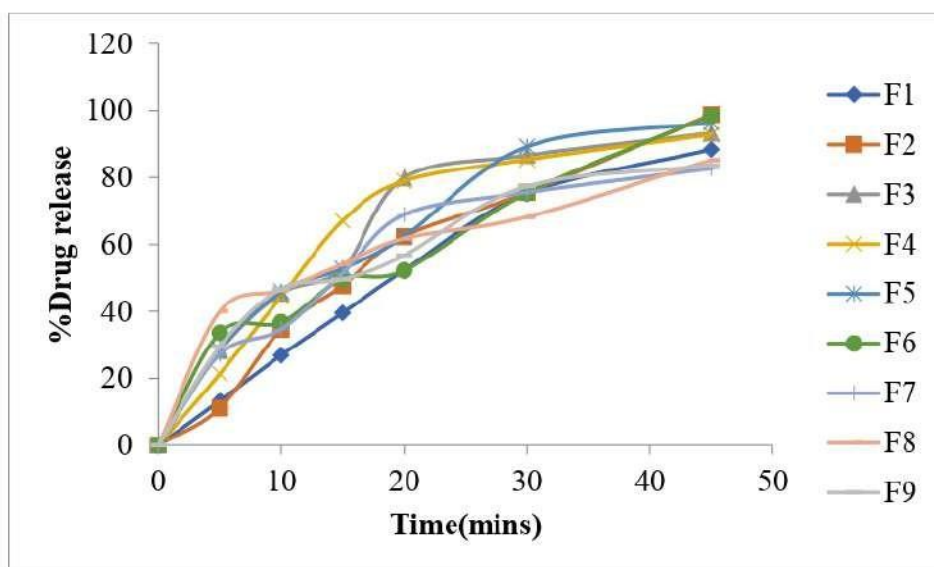


Fig 8.6: Dissolution profile of all formulations F1-F9

From the Table it was evident that the formulations prepared with Croscarmellose Sodium powder were showed good drug release i.e., 98.82 % (F2 Formulation) in higher concentration of blend i.e. 20 mg. Formulations prepared with Crospovidone showed good drug release i.e., 98.48 % (F6 Formulation) in 30 mg concentration when increase in the concentration of Crospovidone drug release unable to retarded. Formulations prepared with Sodium starch glycolate showed maximum drug release i.e., 85.22 % (F8 Formulation) at 45 min in 20 mg of blend.

Among all formulations F2 formulation considered as optimised formulation which showed maximum drug release at 45 min. i.e. 98.82 %. Croscarmellose Sodium was showed good release when compared to Sodium starch glycolate.

Finally concluded that F2 formulation (Contains Croscarmellose Sodium) was optimised better formulation.

FTIR RESULTS:

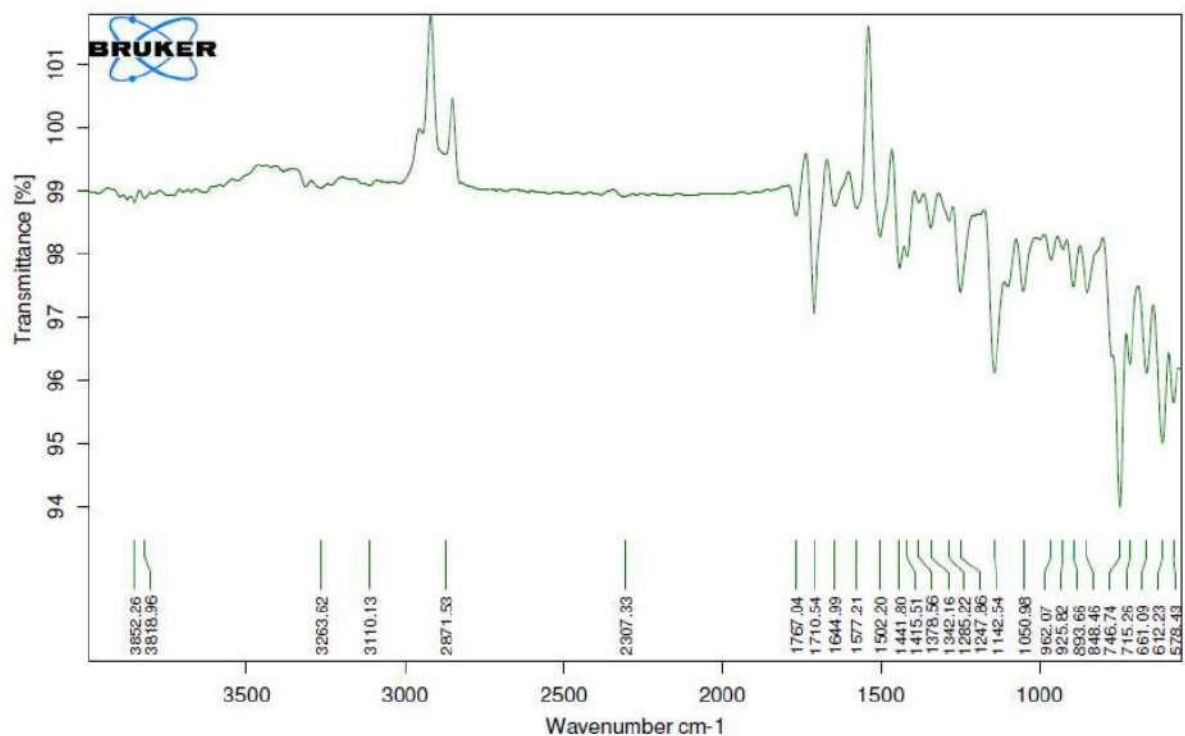


Fig 8.7: FTIR of Torsemide Pure Drug

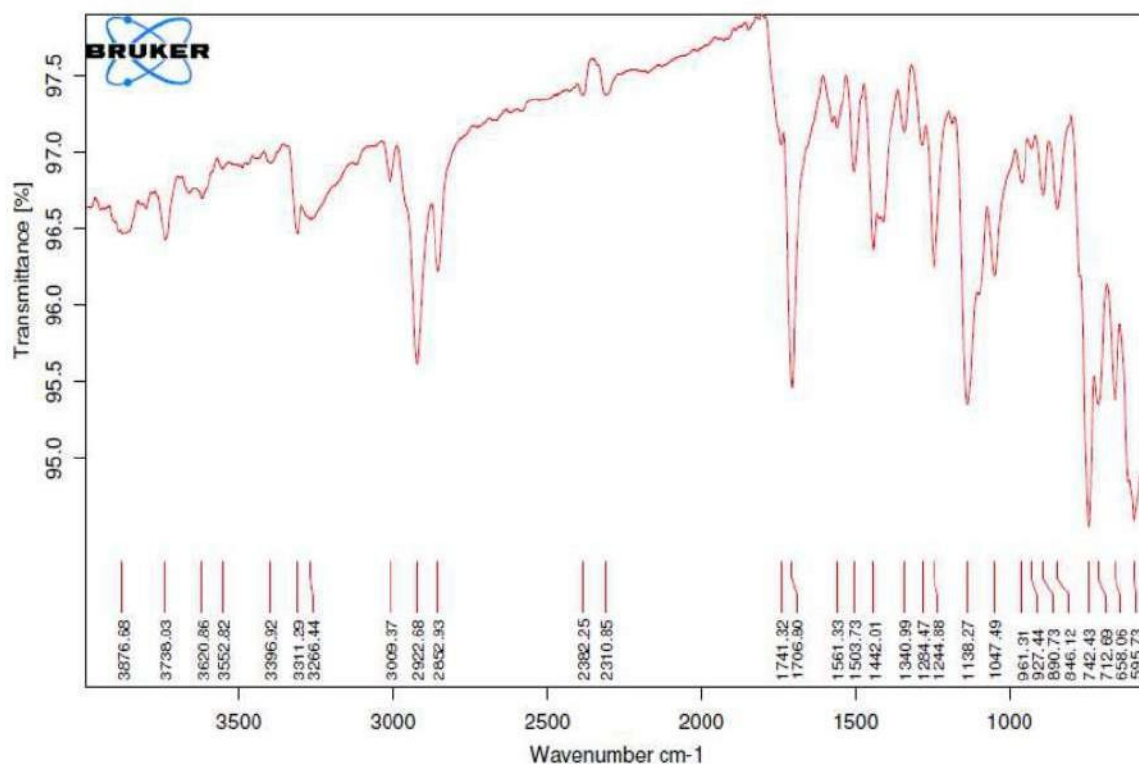


Fig 8.8: FTIR of Torsemide optimized formulation

Torsemide was mixed with proportions of excipients showed no colour change providing no drug-Excipient interactions

9. CONCLUSION

The Oral disintegrating tablets of Torsemide were formulated by using super disintegrants like Sodium Starch Glycolate, Cross Caramellose Sodium and Crospovidone. FTIR study reveals that there is no drug-excipients interaction between Torsemide and excipients. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. The use of Superdisintegrant Croscarmellose Sodium at the concentration of 20 mg given better release of drug when compared to other superdisintegrants. The Optimised Formulation (F2) was showed Highest Drug Release (98.82%) in 45 minutes. The proposed ideal and reproducible characteristics of disintegration time and drug release profile.

By employing commonly available pharmaceutical Sodium starchglycolate, Cross Caramellose Sodium and Crospovidone and Lactose a fast disintegrating tablet of Torsemide can be developed which can be commercialized. The developed formulation of Torsemide ODT showed good efficacy, rapid onset of action, better patient compliance.

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