Volume 2, Issue 2, May - August 2021

Pharma Insight

Newsletter

A Triannual Newsletter from Department of Pharmacy Practice, KLE College of Pharmacy, Bengaluru

About College

KLE College of Pharmacy is the constituent unit of KLE Academy of Higher Education & Research (Deemed to be University), Belagavi, which is Re-Accredited by NAAC "A" grade by UGC, up to January 2021. We are running D.Pharm, B.Pharm, M.Pharm, Pharm.D and PhD in a spacious well-equipped building of its own with hostel, library and sports facilities. The pharmacy curriculum is approved by Pharmacy Council of India (PCI) and All India Council for Technical Education (AICTE) and the UG programme is accredited by the NBA (National Board of Accreditation) and AICTE, New Delhi.

Department of Pharmacy Practice

KLE Academy of Higher Education and Research (KAHER), Belagavi has started Doctor of Pharmacy course in its constituent college, KLE College of Pharmacy, Bengaluru in the year 2014. To impart education, the pharmacy practice department is having adequate infrastructure and facilities as per the requirement of statutory bodies for the students from Doctor of Pharmacy course. All the faculty members have rich experience to make the student excel in her/his studies and suit professional opportunities in the hospital, clinical research and pharmaceutical industries.

Our department is associated with Aster CMI Hospital, Hebbal, which is located just 11 kms. away from the college premises. Moreover, bus facility is available from Hostel to the college and hospital.

Further, the department is keen to have collaboration with other hospitals, clinical research organizations and pharmaceutical industries towards the research projects and pharmacy practice services.

KLE CoP, Bengaluru Rotaract Club Chartered Into Rotary Club, Bangalore Zone

The Rotaract club of an organization brings people (over 18 years) together to exchange the ideas with the leaders in the community to develop leadership and professional skills and have fun through service. In communities worldwide, Rotary Club and Rotaract members work side by side to take action through service. The purpose of Rotaractors who are affiliated to the clubs is to find the innovative solutions to the world's most pressing challenges in the community.

The Rotaract Club of KLE College of Pharmacy Bengaluru has chartered into the Rotary fold of Rotary Bangalore North West RI Dist. 3190 on Saturday, March 27, 2021 in an impressive function held in the college premises. In this function, Chief Guest PDG Rtn. Rajendra Rai, Guest of Honour DRCC Rtn. Jayachandra Aradhya, President Rtn. Sumathi Rao, Director Youth Service Rtn. Dr Sarsija Suresh, Secretary Rtn. Pratap Ujjini, Principal Rtn. Dr. Raman Dang, and Chief Advisor Rtn. Dr. Mamatha A were presided as key members among the participants of this function. The Rotary Club members unveiled a Logo of the club and the website. Rtn. Mr. J Kuber Singh, B. Pharmacy student was inducted as Charter President of the Rotaract Club of KLE College of Pharmacy Bengaluru, and he was handed over the Gong, Gravel and Presidential collar. As a part of this event, the KLE Rotaract club has started with a total of 80 volunteers as the rotaractors. Of these, 13 members were nominated as the Rotaract Cabinet members.

Rotaract KLE Bangalore is keen to assist for all the projects handled by District Rotary Bangalore. Few such initiatives included: Allotment of beds in hospital, Free education to community on pandemic, Free RTCPR camps, Awareness on the prevention of fungus in post-covid patients, and Diet and care post for Covid-19 patients. In addition, this amalgamation helps to strengthen KLE NSS team objectives such as: (1) Building a society which is better for living, (2) Developing leadership qualities within students and (3) making the students aware about their responsibilities towards the nation. In this direction, KLE Rotaract club has collaborated with the government and non-governmental organisations such as NSS, Civil Defence, Bruhat Bengaluru Mahanaragara Pallike and Police departments. In addition, Rotaract Club of KLE Pharma BLR took the responsibility to run the helpline with 30 volunteers through 3190 War room and it reached 600 plus people to provide its services. Rotaract KLE is launching a newsletter from June 1, 2021 known as "The Pledge" to document its activities and services.

Since the focus of Rotaract club members is on community service, the students from Doctor of Pharmacy course can play a significant role in addition to the students from B. Pharmacy course. The proposed key areas for pharmacy students include: prevention and control of communicable and non-communicable diseases, sanitation facilities for prevention of diseases, medication management, balanced diet, reduction of various pollutants to protect from diseases, family welfare, mother and child health, education and counselling about the importance of medication adherence on the prevention of long term complications, implementation of the government health schemes and policies and collaborative services with core health care professionals. In view of these expected services, KLE Rotaract Club has taken right step to contribute for better public and patient care with the help of Rotary Club, Bangalore.

Dr. Mahesh N.M.
Professor and Head, Department of Pharmacy Practice

Section Editor : Dr. Mahesh N.M.

DEPARTMENT SERVICES

Adverse Drug Reactions Reported by Interns*

Generic Name	Dosage form	Adverse Drug Reaction
Paclitaxel	Injection	Interstitial Pneumonitis
Ferric carboxymaltose	Injection	Rashes on both hands
Paclitaxel	Injection	Breathlessness, Fever spikes
Iohexol	Injection	Rashes, blisters
5-Fluorouracil	Injection	Impaired hearing, Glaucoma
Diclofenac	Injection	Itching, rashes
Ferric carboxymaltose	Injection	Giddiness, breathing difficulty, cough
Piperacillin + Tazobactum	Injection	Itching
***January to April , 2021**		

Case Presentations, Journal Club and New Drug/Medical Device Presentations*

Type of Presentation	Hospital	Online
Case presentation	40	08
Journal Club presentation	40	08
New Drug presentation	53	10
***January to April, 2021**		

Department Publications

Sl.No.	Type	Published	Accepted	Communicated
1	Research Articles	2	0	0
***January to April, 2021**				

Job Profile of A Clinical Pharmacist

Clinical pharmacy is the area of practice in which pharmacist provides patient care that optimises medication therapy and promotes health, wellness and disease prevention. The main goal of every clinical pharmacist (CP) is to make sure that the medication prescribed by the physician to the patient is safe and effective for his or her medical condition. CP usually carries out the following duties in the hospital.

Analyse Patient's Medical and Medication History: CP needs to document past medication and medical history. Based on this information, the interaction of medications currently prescribed by the physician with the past medications can be assessed before recommending the medications to physician, which is safe, effective and non-interacting.

Create Clinical Criteria: CP needs to collect the information about the signs and symptoms of the present and past illnesses. Following the prescription of medication by the physicians, clinical pharmacists can fix the clinical criteria for each prescribed medication based on its primary and secondary indications through extensive academic drug research/database.

Analysis of Laboratory Data: CP need to document the abnormal laboratory results due to particular disease / disorder. Following the administration of prescribed medications, clinical pharmacist needs to keep a track of the laboratory data changes due to prescribed drug if any, which may be indicative of organ damage. Through academic drug research, a drug that does not modify the laboratory data can be recommended to treating physician.

Reporting Adverse Drug Events: CP can keep a track of possible side effects following the initiation of drug treatment on daily basis. If any adverse drug reactions are reported, it can be documented after consulting the treating physician.

Ms. Priya S
Pharm D. IV Year

NEW DRUGS/DRUG FORMULATIONS APPROVED IN INDIA

GENERIC NAME	DOSAGE FORM	ROUTE & STRENGTH	INDICATIONS	APPROVAL DATE
Avanafil	Tab	PO: 50mg /100 mg/200 mg	Erectile dysfunction	Feb 26, 2021
Omidenepag isopropyl	Eye Drops	LA: 0.002% w/v	Glaucoma, Ocular hypertension	Mar 12, 2021
PO: Per Oral; LA: Local application; Tab: Tablet				

- www.cdsco.gov.in

Mr. Sidharth BC
Pharm D. IV Year

Dapagliflozin: New Indications

Dapagliflozin is the second agent in a new class of oral antihyperglycemic drugs: Sodium-Glucose Co-transporter 2 (SGLT2) inhibitors. SGLT2 is responsible for the majority of the renal glucose reuptake; inhibition of the co-transporter allows for increased renal glucose excretion that consequently leads to reduced plasma glucose levels. Dapagliflozin also reduces sodium reabsorption and increases the delivery of sodium to the distal tubule. This may influence several physiological functions including, but not restricted to, lowering both pre- and after load of the heart and down regulation of sympathetic activity, and decreased intraglomerular pressure which is believed to be mediated by increased tubuloglomerular feedback.

The Food and Drug Administration has approved Dapagliflozin to reduce the risk of hospitalization for heart failure in adult patients with type-2 diabetes and established cardiovascular (CV) disease or multiple CV risk factor based on the Dapagliflozin Effect on Cardiovascular Events–Thrombolysis in Myocardial Infarction 58 trial.

The FDA approval of Dapagliflozin to reduce the risk of CV death and hospitalization for heart failure in adults with heart failure (New York Heart Association class II-IV) with reduced ejection fraction (HFrEF) with and without type 2 diabetes was based on the Phase III Dapagliflozin and Prevention of Adverse-Outcomes in Heart Failure trial, which showed Dapagliflozin, achieving a statistically significant and clinically meaningful reduction of CV death or hospitalization for heart failure when compared to placebo. On February 24, 2021, the National Institute for Health and Care Excellence has published guidelines to use dapagliflozin as an option for treating symptomatic chronic HFrEF in adults when added to optimized standard care.

The approval of Dapagliflozin for adults with chronic kidney disease who are at risk of disease progression was based on the multicenter; double-blind expansion Dapagliflozin and Prevention of Adverse Outcomes in CKD Phase III study. The trial demonstrated that Dapagliflozin, on top of standard-of-care treatment with an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker, reduced the relative risk of worsening of the renal function, onset of end stage kidney disease, or risk of CV or renal death by 39%, the primary composite endpoint, compared to placebo in patients with CKD Stages 2-4 and elevated urinary albumin excretion.

- Jhund PS et al. Circulation. 2021;141 (15):1227–1234.
- Adler AI et al. The Lancet Diab. Endocrino. 2021;9(5):261-63.
- https://www.astrazeneca-us.com/content/az-us/media/press-releases/2021/farxiga-approved-in-the-us-for-the-treatment-of-chronic-kidney-disease-in-patients-at-risk-of-progression-with-and-without-type-2-diabetes-04302021.html.

Mr. Fenil RA,
Pharm D. IV Year

NEW DRUGS APPROVED BY FDA

Brand Name	Generic Name	Route and Dose	Indications	Approval Date
VERQUVO	Vericiguate	PO: 2.5 mg OD	Congestive Heart Failure	Jan 19, 2021
CABENUVA	Cabotegravir +Rilpivirine	IM: 600 mg +900 mg	Human Immunodeficiency Virus infection	Jan 21, 2021
LUPKYNIS	Voclosporin	PO: 23.7 mg BID	Lupus nephritis	Jan 22, 2021
TEPMETKO	Tepotinib	PO: 450mg OD	Non-small cell lung cancer	Feb 02, 2021
UKONIQ	Umbralisib	PO: 800 mg QID	Marginal zone lymphoma, Follicular lymphoma	Feb 05, 2021
EVKEEZA	Evinacumab-dgnb	IV: 15mg/kg over 60 min once monthly	Homozygous familial hypercholesterolemia	Feb 11, 2021
COSELA	Trilacicilib	IV:250mg/meter^2 4hr before chemotherapy	Chemotherapy-induced myelosuppression in patients with small cell lung cancer	Feb 12, 2021
AMONDYS 45	Casimersen	IV Inf.: 30mg/kg once weekly over 35-60 min	Duchenne muscular dystrophy	Feb 25, 2021
NULIBRY	Fosdenopterin	IV: 0.9 mg/kg QID	Molybdenum cofactor deficiency type A	Feb 26, 2021
PEPAXTO	Melphalan flufenamide	IV inf.: 40mg over 30 min	Relapsed or refractory multiple myeloma	Feb 26, 2021
AZSTARYS	Serdexmethylphenidate + dexmethylphenidate	PO: 39.2 mg OD	Attention deficit hyperactivity	Mar 03, 2021
FOTIVDA	Tivozanib	PO:1340 mcg OD	Patients with renal cell carcinoma	Mar 10, 2021
PONVORY	Ponesimod	PO: 20mg OD	Patients with relapsing forms of multiple sclerosis	Mar 18, 2021
ZEGALOGUE	Dasiglucagon	SC: 0.6mg OD	Severe hypoglycaemia	Mar 22, 2021
QELBREE	Viloxazine	PO: 100 or 200 mg QID	Attention deficit hyperactivity disorder	Apr 02, 2021
NEXTSTELLIS	Drospirenone+ Estetrol	PO: 14.2mg QID	To prevent pregnancy	Apr 13, 2021
JEMPERIL	Dostarlimab-gxly	IV: 500mg OD	Endometrial cancer	Apr 22, 2021
ZYNLONTA	Loncastuximabtesirine-lpyl	IV:0.15mg/kg OD	Certain types of relapsed or refractory large B-cell lymphoma	Apr 23, 2021

IM: Intramuscular; SC: Subcutaneous; IV: Intravenous; PO: Oral; IV Inf.: Intravenous Infusion; OD: Once daily; BID: Twice a day; TID: Three times a day; min: Minutes

- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021

Mr. Midhun JM
Pharm D. IV Year

NEW MEDICAL DEVICES APPROVED BY FDA

Device Name	Category	Approval Date
Imagio® Breast Imaging System	Breast imaging system that uses both Optoacoustic and ultrasound images to examine breast lesions	Jan 11, 2021
Diamond Temp™ Ablation Catheter	Catheters used to treat a paroxysmal atrial fibrillation, by ablating a small area of the heart tissue	Jan 28, 2021
Restylane Defyne	Gel implant (dermal filler) injected into the chin region to improve the chin profile appearance in patients over the age of 21	Jan 29, 2021
Shockwave Intravascular Lithotripsy System with the Shockwave C2 Coronary Intravascular Lithotripsy Catheter	Catheter containing integrated lithotripsy emitters, which can break up hard materials (calcification) that restricts blood flow to the heart.	Feb 02, 2021
Patient Specific Talus Spacer	Implant for patients with avascular necrosis of the ankle joint to regain motion and reduce pain without an amputation or fusion.	Feb 17, 2021
TheraSphere™	Radiation treatment for unresectable hepatocellular carcinoma.	Mar 17, 2021
ClearVisc Ophthalmic Viscosurgical Device	Ophthalmic device containing a transparent thick liquid used to protect eye tissue during eye surgery, including cataract surgery.	Mar 23, 2021
Harmony Transcatheter Pulmonary valve system	Catheter System is used to treat a leaky native or surgically repaired right ventricular outflow tract.	Mar 26, 2021
Simplify® Cervical Artificial Disc	Implant that replaces one or two adjacent damaged or diseased discs between the vertebrae, or bones, of the neck (cervical spine areas C3 to C7).	Apr 01, 2021

- https://www.fda.gov/medical-devices/recently-approved-devices/2021-device-approvals

Ms. Winny J
Pharm D. IV Year

INVITED ARTICLES

Role of Nurses with Pharmacists in Drug Related Programs

Nurses are licensed professionals in the healthcare industry. Traditionally, they are authorized to administer the medications to the sick, in and out of healthcare. This is a known fact. Nurses have too many tasks to carry out while caring for the patient, medication administration being one among the many. Hence, the support rendered by the pharmacist would certainly make a difference. As we travel along the roads of advancement, we see that developed countries do not leave this particular responsibility to the nurse alone.

This is where the team of pharmacists and clinical pharmacologists come into the picture of drug administration. Though they are not directly involved in this act, their involvement is very well understood as vital by advanced countries since many years now. However, in India it is being practiced only since recent times. This mainly aims at avoiding errors in medication administration.

How does their service combine with nursing services?

The pharmacist has to work along with the nurse, not as an option but as an essentiality. Their services probably applied in different stages as mentioned below:

Stage1: Doctor's prescription is audited by pharmacist to avoid wrong medication or dosage as prescribed for the patient.

Stage 2: During the online drug indent by the nurse, the pharmacist to avoid errors conducts audits.

Stage3: The drug is loaded and counter checked by the pharmacist to make sure the right drug is delivered to the patient

How does one make this possible?

The healthcare industry should make standard operating procedures and policies, which make the involvement of the pharmacist with the nursing team mandatory. A clinical pharmacist's involvement in conducting various sessions as part of continuous nursing education would make this process easy and bring awareness among the nurses. Nowadays, most hospitals understand the importance of these two departments working together for error free patient care.

The future needs to pave a platform for the healthcare industry to establish error free patient care largely. Thus making the quality of patient care great. In turn, this allows them to receive positive and outstanding feedback as the ultimate outcome.

Dr. Rohini Paul
CNO Multiple Units, Bangalore
& Head Nursing Education, India
Aster DM Healthcare

Clinical Pharmacist Driven Oral Chemotherapy Clinic

The utilization of oral chemotherapy agents in cancer patients is rapidly rising for various types of cancer. Convenient route of administration, tolerability and fewer hospital visits are some of the advantages. However, several risks have emerged with the increase in its use. It presents with unique issues regarding patient safety like non-compliance, adverse effects, and high cost. A study conducted in Toronto, Canada showed that the formation of a multidisciplinary oral chemotherapy clinic helps to improve patient care outcomes.

To ensure safe prescribing, dispensing, administration and monitoring at our facility, oral chemotherapy clinic was implemented. It includes a team of medical oncologists, clinical pharmacist, and social worker. Frontline counseling is crucial to ensure proper education to the patient and his/her caretaker. This is an excellent opportunity for a clinical pharmacist to play a critical role in a patient's successful drug therapy.

The clinical pharmacist provides consultation by handing over the printed information on the drugs, educates on the medication administration, counsels about the possible drug side effects, ensures medication adherence, and manages the drug toxicity. We provide a pre-printed chemotherapy prescription authorized by oncologist in adherence to the American Society of Clinical Oncology/Oncology Nursing Society (ASCO/ONS) prescribing guidelines. In addition, a detailed drug history is taken to prevent the drug interactions, drug-related problems, and potentially inappropriate medications. We also provide oral chemotherapy reminder leaflet to improve and document medication adherence.

The clinical pharmacist plays a vital role in deciding the brand of various chemotherapy agents, displaying business acumen skills. On subsequent reviews, refill prescriptions were issued and dosage modifications were made based on the tolerance, blood parameters like hematology, renal and hepatic doses. By reviewing all the orders, pharmacists make significant interventions that further contributes to patient safety. The clinical pharmacist takes an initiative to do telephonic and video consultations to follow up and address medication related concerns.

Oncology pharmacists who are practicing with the recommendation of advanced drug therapy approaches are an integral part of the cancer care team. Their value in oncology drug therapy has been well documented in several clinical studies. The pharmacist intervention leads to positive financial outcome associated with chemotherapy. This indicates that Onco-pharmacist play a great value in the drug therapy of each cancer patient as one among Cancer care team like in our hospital facility.

• https://www.mdedge.com/fedprac/avaho/article/207812/mixed-topics/focus-implementation-and-impact-pharmacy-driven-oral

Dr K. Tasmiya
Clinical Pharmacist
Aster CMI Hospitals

ALUMNI EXPERIENCE

My name is Shristi Nayak (2014-2020 Batch). Six years which I spent in KLE College of Pharmacy, Bangalore were the most blissful years of my life. 'Time flies' like an arrow. The days I spent at KLE were exactly like this proverb. Memories of joy, intrigue, apprehension are still freshly etched in my mind. I feel privileged and proud to be a part of KLE since I had an opportunity to be moulded by the eminent teachers who taught me lessons that extended well beyond the four walls of a classroom.

Being one of students from the first batch of Doctor of Pharmacy course from KLE College Pharmacy, Bangalore, I had a challenging time at initial stages. But KLE is an institute with outstanding faculty right from Principal, HODs, teaching staff and non-teaching staff including office staff. They were always there to clear concepts of various subjects and help where ever approached. This college is what everyone expects to be. KLE has the pleasant environment which attracts the students to be in college premises every day.

Apart from the studies, I have also enjoyed the co-curricular activities. This college believes in imparting moral, ethical knowledge among the students. KLE made me do hard work for the way to success. This college has motivated and encouraged me to face the risks in the life and learn new things. I would strongly encourage anyone aspiring to join pharmacy profession to be a part of this institution. I am always thankful to KLE for making me a professional person, which I am today.

Dr. Shristi Nayak
Safety Science Analyst, COVANCE Ltd., Bangalore

I am Nandyala Sunil of Doctor of Pharmacy Programme, 2014-2020 batch of KLE College of Pharmacy, Bangalore. I am so delighted to have an opportunity to share my experience about the college with the readers of this newsletter.

I feel contented to have had such an encouraging and enabling environment at college. Thanks to our warm and ready-to-help professors. I have gained the skills that would help me not only on the technical front but also on my personal front. Our university/college library hosts a good number of multi-authored books that transcended our knowledge and creativity. Our college has also helped me to balance my interest towards the studies, arts, and sports.

It takes a myriad of dedication to enable offering internship programs to the students on board, which our university did effortlessly. I interned at KC General Hospital, Malleshwaram. Our college has offered tremendous support in guiding our project "Effect of antibiotic stewardship in peri-operative setting in a secondary care teaching hospital" during the fifth year of Pharm D. course.

I am glad to have chosen to study at KLE College of Pharmacy, Bangalore for it not only provided me with a degree and a career but also helped me shape my personality for a brighter future.

Dr. Nandyala. Sunil
Safety Associate Trainee, IQVIA, Bangalore

INTERNS DESK

Digoxin in Heart Failure with a Reduced Ejection Fraction: A Risk Factor or a Risk Marker?

Digoxin is a purified cardiac glycoside extracted from the foxglove plant. Since 1785, it is in clinical use. There are two factors associated with its restricted use. First one is about its uncertain clinical efficacy in modern heart failure patients and second factor is its increased risks with long-term use especially its proarrhythmic properties. This article focuses on the role of digoxin in patients who are suffering from heart failure with reduced ejection fraction.

Digoxin has been reported to exert favorable hemodynamic effects by increasing the ejection fraction, cardiac index and by reducing the pulmonary capillary wedge pressure. Intravenous digoxin administration has been demonstrated to reduce cardiac norepinephrine spillover in patients with severe heart failure and elevated left ventricular filling pressures. In patients with chronic heart failure, oral digoxin therapy led to a significant drop in plasma nor-epinephrine levels. Interestingly, digitalis glycosides appear to exert a differential physiologic effect on the patients with heart failure when compared to normal subjects. Intravenous digoxin bolus produced a drop in forearm vascular resistance and a sustained decrease in the efferent sympathetic nerve activity in heart failure patients but not in normal subjects. This sympathoinhibitory response to digoxin is unrelated to its positive inotropic action. Digoxin may also improve the carotid sinus baroreflex sensitivity by preventing acute resetting of baroreceptors. Digoxin also enhances the cardiac vagal tone, which is reflected in an increase in heart rate variability. Digoxin reduces the heart rate by an average of 4–7 bpm during sinus rhythm. In addition, it has been reported to decrease the plasma renin activity. However, digoxin discontinuation has been linked to a rise in plasma brain natriuretic peptide levels.

The patients who were randomized to the replacement of digoxin with placebo or continuation of digoxin in the clinical trial showed clinically significant differences in the treatment outcome. Patients who discontinued digoxin experienced worsening of their maximal exercise capacity accompanied by an increased incidence of treatment failures. On the contrary, patients allocated to the active treatment group maintained a lower body weight and heart rate and a higher ejection fraction.

Nevertheless, in our view, cardiac glycosides should not be discarded from the heart failure drug therapy armamentarium. Digoxin probably still plays a role in patients with severe heart failure with the evidence of congestion in patients who are unable to tolerate high doses of disease-modifying agents due to borderline blood pressure/renal function. However the serum digoxin concentration, creatinine and potassium levels should be closely monitored to minimize the risk of toxicity.

- Yancy CW et al. Circulation 2013;128:e240–e327.

Ms. Merlin SJ
Pharm D. Intern

Nano-Based Drug Delivery System for Hacking Colon Cancer Cells

Use of the nanoparticles for early diagnosis and monitoring of the efficacy of drug therapy in colorectal cancer is well known. Recently, nanomedicine covers the use of the combination therapy of cytotoxic agent, which are entrapped within the targeted nanocarriers. This helps in the site-specific drug delivery, increased efficacy and a sustained release including alteration of elimination cycle of the drugs selected for treating colorectal cancer.

The initiation of research started with a combination strategy of the drugs in which the first-line chemotherapeutic drug 5-fluorouracil and natural P-gp inhibitor (to overcome drug resistance) was encapsulated in a nanodroplet for the management of colorectal cancer. Considering the formulation aspects, nanoparticles are mainly composed of lipids and these lipids are having a specific mode of action on the cancer cells.

The efficacy of nanoparticles in the treatment of colorectal cancer cells are as follows. (1) Degradation: Nanoparticles prevent the enzyme and metabolic degradation of the drugs which makes environment unsuitable for the cancer cells. (2) Size: Nanoparticles can interact upon the intracellular and the cell membrane and hence have an immense property to deal with the drug resistance. (3) Targeting: Nanomedicine facilitates active and/passive targeting by taking the asset of the leaky microvasculature of the tumor cells, therewith improving the bioavailability of the drugs, reducing adverse effects and increasing the therapeutic drug concentration in the cancer cell. Passive targeting by making use of the enhanced permeation, and retention effect. (4) Drug Loading: Enormous drug loading efficacy, improved chemotherapeutic effect. (5) Tumor marker: Nanoparticles can target the carcinoembryonic antigen which is the tumor marker for colorectal cancer. (6) Administration: Nanomedicine can be effectively administered by inhalation, rectal, oral and systemic routes; these ways of administration are well adapted for the treatment of gastrointestinal diseases which includes colorectal cancer which helps in improving the patients comfort and compliance.

Future Perspective:

The upcoming future of definite-targeted Nano formulation includes the most efficient combination for colorectal cancer is just around the corner and a trend should be followed to initiate marketing of the Nanomedicine for the management of the colorectal cancer and other ailments.

- Kotelevets L et al. Int J. Pharmaceutics 2016; 514(1):24-40.
- Cisterna BA etal. Nanomedicine 2016;11(18):2443-56.

Ms. Savitha VN
Pharm D. Intern

STUDENTS DESK

Grant for the Import / Manufacturing of Medical Devices

The Ministry of Health and Family Welfare, Government of India has notified the regulation for the following medical devices as per the notification: S.O. 775(E) dated February 8, 2019. This will be effective from 01-04-2021. Accordingly the importers / manufacturers are required to take the license for either to import/manufacture below mentioned medical devices from the Central Licensing Authority/State Licensing Authority. The list of such devices as per Central Drug Standard Control Organization are as follows.

- All implantable medical devices
- CT scan equipments
- MRI equipments
- Defibrillators
- PET equipments
- Dialysis machines
- X-ray machines
- Bone marrow cell separators

In this regard, it may be pertinent to mention that 97 of Devices rules 2017 provides the details about applicability of the said rules in respect of various actions or operations undertaken under Drugs and Cosmetics rules for the substances and devices referred to in Rule 2 of the MDR2017 priories 2 commencement of MDR 2017.

In case, an existing importer/manufacturer of the above medical devices has submitted the application to Central Licensing Authority/State Licensing Authority as the case may be for the grant of import /manufacturing license in a report of the set medical devices provisions of MDR 2017, the said application shall be deemed to be valid and importer or manufacturer can continue to import/ manufacture the set devices up to six months from issue of the order or till the time.

This order was approved by Drug Controller General of India (DCGI) under the file F. No. 29 /Misc /03/2021-DC (28), CDSCO, and Government of India.

- https://cdsco.gov.in/opencms/opencms/en/Latest-Public-Notices/

Ms. Alekhya TS,
Pharm D. I year

Remdesivir: Preventing its Hoarding and Black Marketing

Remdesivir was the first drug approved by the FDA for treating the SARS-CoV-2 virus. The broad-spectrum antiviral is a nucleotide analogue prodrug. The U.S. Food and Drug Administration (FDA) approved Remdesivir based on the three randomized, controlled clinical trials (NCT04280705, NCT04292899, NCT04292730) that included 2043 participants from 17 countries who were hospitalized with mild-to-severe COVID 19. The FDA granted approval and reissued the revised Emergency Use Authorization to Gilead Sciences Inc.

In India, the cases of COVID 19 were found increasing rapidly. This had led shortage of Remdesivir injections. It has been brought to the notice of Ministry of Health and Family Welfare, Government of India that the states of Madhya Pradesh, Gujrat and Maharashtra were reporting shortage of Remdesivir injections. This may perhaps lead to its hoarding and black marketing.

Thus, Drug Controller General of India (DCGI) requested the Ministry of Health and Family Welfare to initiate remedial action to ensure the supply of Remdesivir injection to public and private hospitals where there was shortage of the injection. Also, requested to instruct enforcement staff to keep continuous monitoring on the situation and to keep strict vigil so that any incidence of black marketing and over-charging of the drugs can be prevented.

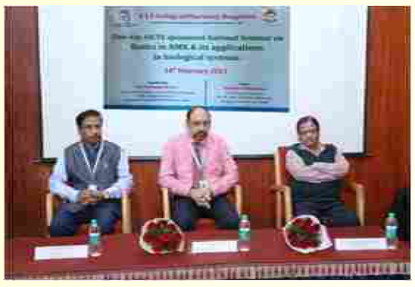
This notice was issued on April 7, 2021 by DCGI under the File No. ED/Misc-273/2020-3 in Enforcement Division of Central Drugs Standard Control Organization.

- https://cdsco.gov.in/opencms/opencms/en/Latest-Public-Notices/

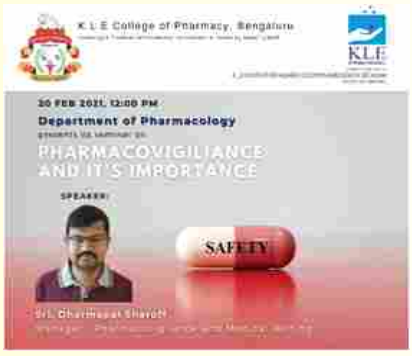
Ms. Hritika P,
Pharm D. I year

DEPARTMENTS ACTIVITY

KLE NSS team joined its hand on January 26, 2021as a part of Republic day. It has carried out **village camps, polio eradication drive and nomination for the national award** submission. NSS activities were appreciated. Dr. Mamatha A., NSS Program officer has coordinated the events.

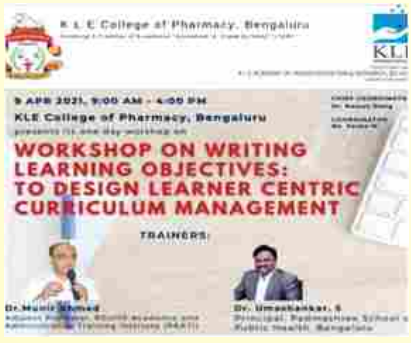


AICTE sponsored one day National seminar on **Basics in NMR and its Applications in Biological Systems** was conducted at KLE College of Pharmacy, Bengaluru Campus on February 10, 2021. It was organized by the Department of Pharmaceutical Chemistry. Professor (Dr.) Suryaprakash N, IISc, Bengaluru was the speaker on the above mentioned topic.



One day seminar on **Pharmacovigilance and its Importance** was conducted at KLE College of Pharmacy, Bengaluru Campus on February 10, 2021. It was organized by the Department of Pharmacology. Manager at Pharmacovigilance and Medical writing, Mr. Dharmapal Sharoff was the speaker on the above mentioned topic.

A Guest talk on **Power Your Qualification with Qualities** was conducted at KLE College of Pharmacy, Bengaluru Campus on April 08, 2021. It was organized by the Department of Pharmacognosy. Mr. Ajit Kaikini, Director Buoyancee Growth and Corporate Training, Bangalore was the speaker on the above mentioned topic.



A workshop on the **Writing Learning Objectives: To Design Learner Centric Curriculum Management** was conducted at KLE College of Pharmacy, Bengaluru Campus on April 09, 2021. Dr. Munir Ahmed and Dr. Umashankar were the speakers on the above mentioned topic.

EDITORIAL DESK

Fast Dissolving Tablet: A Review

The Center for Drug Evaluation and Research, USFDA defines "A fast dissolving tablet (FDT) as a solid dosage form that can disintegrates into smaller granules which slowly dissolve in the mouth". FDT disintegration time varies from few seconds to minutes depending on the formulation and the size of the tablet. FDT is synonymously known as Fast disintegrating tablet/Mouth dissolving tablets/Fast melting tablets/Rapid melting tablets/Oral dissolving tablets and/Oral disintegrating tablets.

Potential Patients for FDT:

- Geriatric and pediatric patients, patients who have difficulties in swallowing conventional oral solid dosage forms (Ex: tablets, capsules), mentally ill patients, patients with disability, patients with nausea, vomiting, motion sickness, or allergic attacks.

Benefits of FDT:

- Can be administered without water, anywhere, anytime.
- An increased bioavailability of insoluble and hydrophobic drugs.
- Formulation stability for longer duration of time, since the drug remains in solid dosage form till it is consumed.
- FDT passes all the advantages of solid dosage forms like good stability, easy manufacturing, uniformity and accurate dosing and easy handling.
- Provides rapid drug therapy intervention.
- There is no risk of physical obstruction due to dosage form.
- It leaves minimal or no residue in the mouth after administration and also provide a pleasant mouth feel.
- Allows high capacity of drug loading.
- FDTs helps in avoiding hepatic metabolism by allowing pre-gastric drug absorption thus reducing the dose of potential drug.
- Adaptable to existing processing and packaging machinery.
- Cost-effective.

Limitations:

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.
- Drugs with relatively larger doses over 500 mg can not be formulated as FDT.
- It is not recommended in patients who are on anticholinergic medications as well as in patients with Sjogren's syndrome.

Commercial Products:

S.No.	Trade Name	Active Drug	Manufacturer
1.	Feldenfastmelt	Piroxicam	Pfizer Inc., USA
2.	Claritinredi Tab	Loratidine	Scheringplough Corp., USA
3.	Maxalt MLT	Rizatriptan	Merck and Co., USA
4.	Zyprexia	Olanzapine	Elililly, USA
5.	Pepcid RPD	Famotidine	Merck and Co., USA
6.	Zofran ODT	Ondansetron	Glaxo Wellcome, UK
7.	Zoming-ZMT	Zolmitriptan	Astra Zeneca, USA
8.	Zeplar TM	Selegilline	Amarin Corp., UK
9.	Tempra Quiclets	Acetaminophen	Bristolmyers Squibb, USA
10	Febrectol	Paracetamol	Prographarm, France
11	Nimulid MDT	Nimesulide	Panacea Biotech, India
12	Torrox MT	Rofecoxib	Torrentpharmaceuticals, India
13	Olanexinstab	Olanzapine	Ranbaxy lab Ltd, India
14	Romilast	Montelukast	Ranbaxy lab Ltd, India

Instructions:

Do's

- Perform hand hygiene and put on gloves.
- Fast dissolving tablets should be inserted/put in the mouth. During insertion in the mouth it should get dissolve or disintegrate in the mouth within 15 seconds to 3minutes without the help or need of any drinking agent like water.
- Make sure the patient doesn't have any food… or fluid for 5 minutes before or after taking the medicine.
- Tell the patient not to chew the tablet, as it will dissolve.
- Peel back the foil backing on one blister pack and gently remove the tablet.
- Tell the patient or parents to make it handy if they are taking for acute symptoms.

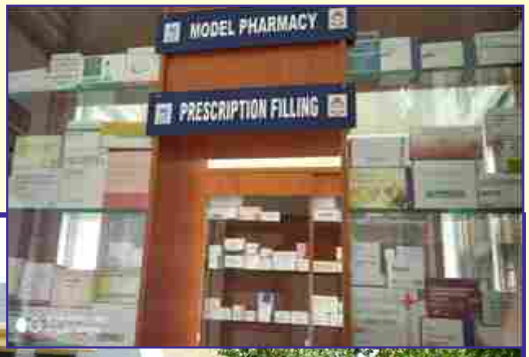
Don'ts

- Don't push the tablets out of the pack through the foil.
- Don't break or split the tablets.
- Don't open the foil packaging or remove the tablets until just before you administer it.

- Kaur T, Gill B, Kumar S et al., Int. J. Current Pharm Research 2011; 1:1-7
- Agrawal VA, Rajurkar RM, Int. Research J. Pharmacophore 2011;2(1):1-8

Ms. Arvinder K
Assistant Professor, Department of Pharmacy Practice

Model Community Pharmacy



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Feedback Link: **https://forms.gle/sy6fkH2oAs1tx6F66**

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