St. Peter's
Institute of Pharmaceutical Sciences
NBA Accredited (B.Pharmacy) I Included in UGC 2(f)
Approved by PCI I Affiliated to Kakatiya University

#s2-4-1211, Vidyanagar, Hanamkonda, Telangana - 506001 India
Website: www.stpeters.co.in,
Email : spipswgl@gmail.com

NEWS LETTER OF CLINICAL PHARMACY

VOLUME- 6, ISSUE-1 JUNE –DECEMBER ,2023.

Chairman: Shri.T.Jayapal Reddy

Principal: Dr.Rajeshri Dhurke

Head of the Department: Dr.D.Praveen

Editor: Manusri Nardela

Vision

St.Peter's is committed to generate, disseminate and preserve knowledge and work with pioneers of this knowledge, and to be the most sought after institute globally in the field of pharmaceutical sciences by creating world class pharmacy professionals and researchers.

Mission

To achieve academic excellence with integrity and creating opportunities for leadership and responsibilities through groundbreaking performance in the field of Pharmaceutical Sciences by educating students with pharmaceutical needs of the society and to advance the knowledge through research and to serve the profession and community.

FDA APPROVED DRUG LIST – JUNE -DECEMBER,2023.

SNO	NAME OF DRUG	ACTIVE INGREDIENT	INDICATION

1.	Beyfortus	nirsevimab-alip	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease Press Release
2.	Vanflyta	quizartinib	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria
3.	Xdemvy	lotilaner	To treat Demodex blepharitis
4.	Izervay	avacincaptad pegol	To treat geographic atrophy secondary to age-related macular degeneration
5.	Zurzuvae	zuranolone	To treat postpartum depression
6.	Talvey	talquetamab-tgvs	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior therapies
7.	Elrexfio	elranatamab-bcmm	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
8.	Sohonos	palovarotene	To reduce the volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva
9.	Veopoz	pozelimab-bbfg	To treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
10.	Aphexda	motixafortide	To use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma

LIST OF DRUGS APPROVED BY CDSCO IN JUNE – DECEMBER,

2023

SNO	NAME OF DRUG	INDICATION	DATE OF ISSUE
1.	Treprostinil Bulk Drug and Treprostinil Solution for infusion 1mg/ml & 10mg/ml	For the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of disease in patients classified as New York Heart Association (NYHA) functional class III	27-07-2023
2	Icaridin API and Icaridin 20% w/v Spray	Indicated for mosquito and insect repellent	19-09-2023
3	Inclisiran solution for injection in prefilled syringe 284 mg/1.5 ml	Inclisiran is indicated in adults with primary hypercholesterolemia (heterozygous familial and non- familial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goal with the maximum tolrated dose of a statin, or - alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated	22-09-2023

URINARY TRACT INFECTIONS TRETMENT GUIDELINES

A urinary tract infection (UTI) is an infection in any part of the urinary system. The urinary system includes the kidneys, ureters, bladder and urethra. Most infections involve the lower urinary tract — the bladder and the urethra.

Table 1: Suggested regimens for antimicrobial therapy in uncomplicated cystitis

Antimicrobial	Daily dose	Duration of therapy	Comments
First-line women			
Fosfomycin trometamol	3 g SD	1 day	Recommended only in women with uncomplicated cystitis
Nitrofurantoin macrocrystal	50-100 mg four times a day	5 days	
Nitrofurantoin monohydrate/ macrocrystals	100 mg b.i.d	5 days	
Nitrofurantoin macrocrystal prolonged release	100 mg b.i.d	5 days	
Pivmecillinam	400 mg t.i.d	3-5 days	
Alternatives			
Cephalosporins (e.g. cefadroxil)	500 mg b.i.d	3 days	Or comparable
If the local resistance pattern for E. coli is < 20%			
Trimethoprim	200 mg b.i.d	5 days	Not in the first trimenon of pregnancy

Trimethoprimsulphamethoxazole	160/800 mg b.i.d	3 days	Not in the last trimenon of pregnancy
Treatment in men			
Trimethoprimsulphamethoxazole	160/800 mg b.i.d	7 days	Restricted to men, fluoroquinolones can also be prescribed in accordance with local susceptibility testing.

SD = single dose; b.i.d = twice daily; t.i.d = three times daily.

Table 2: Suggested regimens for empirical oral antimicrobial therapy in uncomplicated pyelonephritis

Antimicrobial	Daily dose	Duration of therapy	Comments
Ciprofloxacin	500-750 mg b.i.d	7 days	Fluoroquinolone resistance should be less than 10%.
Levofloxacin	750 mg q.d	5 days	
Trimethoprim sulphamethoxazol	160/800 mg b.i.d	14 days	If such agents are used empirically, an initial intravenous dose of a longacting parenteral antimicrobial (e.g. ceftriaxone) should be administered.
Cefpodoxime	200 mg b.i.d	10 days	
Ceftibuten	400 mg q.d	10 days	

b.i.d = twice daily; q.d = every day.

Table 3: Suggested regimens for empirical parenteral antimicrobial therapy in uncomplicated pyelonephritis

Antimicrobials	Daily dose	Comments
First-line treatment		
Ciprofloxacin	400 mg b.i.d	
Levofloxacin	750 mg q.d	
Cefotaxime	2 g t.i.d	Not studied as monotherapy in acute uncomplicated pyelonephritis.
Ceftriaxone	1-2 g q.d	Lower dose studied, but higher dose recommended.
Second-line treatment		
Cefepime	1-2 g b.i.d	Lower dose studied, but higher dose recommended.
Piperacillin/ tazobactam	2.5-4.5 g t.i.d	
Gentamicin	5 mg/kg q.d	Not studied as monotherapy in acute uncomplicated pyelonephritis.
Amikacin	15 mg/kg q.d	
Last-line alternatives		
Imipenem/ cilastatin	0.5 g t.i.d	Consider only in patients with early culture results indicating the presence of multi-drug resistant organisms.
Meropenem	1 g t.i.d	
Ceftolozane/ tazobactam	1.5 g t.i.d	
Ceftazidime/ avibactam	2.5 g t.i.d	
Cefiderocol	2 g t.i.d	
Meropenemvaborbactam	2 g t.i.d	
Plazomicin	15 mg/kg o.d	

b.i.d = twice daily; t.i.d = three times daily; q.d = every day; o.d = once daisy.

Table 4: Suggested regimens for antimicrobial therapy for urosepsis

Antimicrobials	Daily dose	Duration of therapy
Cefotaxime	2 g t.i.d	7-10 days Longer courses are appropriate in patients who have a slow clinical response
Ceftazidime	1-2 g t.i.d	
Ceftriaxone	1-2 g q.d	
Cefepime	2 g b.i.d	
Piperacillin/tazobactam	4.5 g t.i.d	
Ceftolozane/tazobactam	1.5 g t.i.d	
Ceftazidime/avibactam	2.5 g t.i.d	
Gentamicin*	5 mg/kg q.d	
Amikacin*	15 mg/kg q.d	
Ertapenem	1 g q.d	
Imipenem/cilastatin	0.5 g t.i.d	
Meropenem	1 g t.i.d	

** Not studied as monotherapy in urosepsis*

Table 5: Suggested regimens for antimicrobial therapy for urethritis

Pathogen	Antimicrobial	Alternative regimens
Gonococcal Infection	Ceftriaxone: 1 g i.m. or i.v.*, SD Azithromycin: 1 g p.o., SD	• Cefixime 400 mg p.o., SD plus Azithromycin 1 g p.o., SD In case of cephalosporin allergy: • Gentamicin 240 mg i.m SD plus Azithromycin 2 g p.o., SD • Gemifloxacin 320 mg p.o., SD plus Azithromycin 2 g p.o., SD • Spectinomycin 2 g i.m., SD • Fosfomycin trometamol 3 g p.o., on days 1, 3 and 5 In case of azithromycin allergy, in combination with ceftriaxone or cefixime: • Doxycycline 100 mg b.i.d, p.o., 7 days
Non-Gonococcal infection (non-identified pathogen)	Doxycycline: 100 mg b.i.d, p.o., 7 days	Azithromycin 500 mg p.o., day 1, 250 mg p.o., 4 days
Chlamydia trachomatis	Azithromycin: 1.0-1.5 g p.o., SD OR Doxycycline: 100 mg b.i.d, p.o., for 7 days	• Levofloxacin 500 mg p.o., q.d., 7 days • Ofloxacin 200 mg p.o., b.i.d., 7 days

b.i.d = twice daily; t.i.d = three times daily; q.d = every day

Mycoplasma genitalium	Azithromycin: 500 mg p.o., day 1, 250 mg p.o., 4 days	In case of macrolide resistance: • Moxifloxacin 400 mg q.d., 7-14 days
Ureaplasma urealyticum	Doxycycline: 100 mg b.i.d, p.o., 7 days	Azithromycin 1.0-1.5 g p.o., SD
Trichomonas vaginalis	Metronidazole: 2 g p.o., SD Tinidazole: 2 g p.o., SD	Metronidazole 500 mg p.o., b.i.d., 7 days
Persistent non-gonococcal urethritis		
After firstline doxycycline	Azithromycin: 500 mg p.o., day 1, 250 mg p.o., 4 days plus Metronidazole: 400 mg b.i.d. p.o., 5 days	If macrolide resistant *M. genitalium* is detected moxifloxacin should be substituted for azithromycin
After firstline azithromycin	Moxifloxacin: 400 mg p.o. q.d., 7–14 days plus Metronidazole: 400 mg b.i.d. p.o., 5 days	

SD = single dose; b.i.d = twice daily; q.d = everyday; p.o. = orally; i.m. = intramuscular; i.v. = intravenous.
** Despite the lack of RCTs there is increasing evidence that intravenous treatment with ceftriaxone is safe and effective for the treatment of gonorrhoeal infections and avoids the discomfort of an intramuscular injection for patients.*

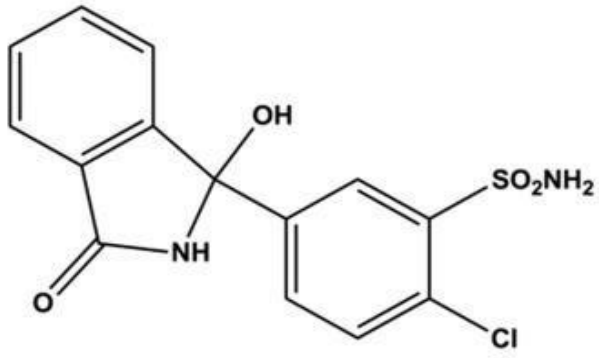
Table 6: Suggested regimens for antimicrobial therapy for chronic bacterial prostatitis

Antimicrobial	Daily dose	Duration of therapy	Comments
Floroquinolone	Optimal oral daily dose	4-6 weeks	
Doxycycline	100 mg b.i.d	10 days	Only for *C. trachomatis* or mycoplasma infections
Azithromycin	500 mg once daily	3 weeks	Only for *C. trachomatis* infections
Metronidazole	500 mg t.i.d.	14 days	Only for *T. vaginalis* infections

b.i.d = twice daily; t.i.d = three times daily.

Chlorthalidone [Monograph]

Category : Diuretic



Dose: 100 to 200 mg daily.
Mechanism of action: Inhibition of the Na+/Cl- symporter
Inhibition of the reabsorption of Na+ &Cl- at DCT
Higher sodium and chloride ion content in nephron Alters the osmotic gradient Elevated intra tubular volume and sodium concentration Diuretic effect (increased excretion of sodium and fluid)

Decreased intravascular water and solute concentration Reduced hydrostatic pressure
Reduction in blood pressure Shifting of fluid from outside to inside of the tubules

Pharmacokinetics
Absorption
Bioavailability - Absorbed from the *GI tract.*
Onset - Diuretic action begins around *2.6 hours after dosing.*
Duration - Up to 72 hours.
Distribution - *Plasma Protein Binding*
About 75%; 58% is bound to albumin**.**
Elimination — Elimination Route — 30–60% excreted unchanged in urine.
Half-life — 40–60 hours**.**
Stability — Storage — Oral Tablets — Tight, light-resistant containers at 20–25°C.
Indications :
1.Hypertension,
2.Edema,
3.Edema in pregnancy
4. Edema in heart failure
5. Edema secondary to nephrotic syndrome
6. Diabetes insipidus
7. Renal tubular acidosis
8. Renal calculas formation
Adverse drug reactions
anorexia, stomach irritation, nausea, emesis, cramping, loose stools, constipation, and pancreatitis, paresthesias, dizziness, and headaches.
Monitoring parameters
1. Serum electrolytes —
- Hypokalemia
- Hypochloremia
- Hyponatremia
- Hypomagnesemia
- Hypercalcaemia

2. Fluid status and Blood pressure
3. Hyperuricemia – gout (uric acid levels)
4. Hyperglycaemia
5. Hyperlipidaemia

Warnings
- Lupus erythematous
- Hypotensive agents
- Hypersensitivity reactions

Interactions
1. Alcohol, opiates, barbiturates – increases risk of postural hypotension
2. Amphetamine – decrease excretion of some amines
3. Amphotericin B , Corticosteroids, Corticotropin – additive / potentiated potassium loss
4. Anticoagulants (oral) – antagonists
5. Anti diabetic agents (sulfonylureas) , Insulin – secondary failure of antidiabetic agent
6. Cholestryramine / colestipol resin – may bind thiazide reduce their GI absorption

Contraindications

- Hypersensitivity to chlorthalidone or sulfonamides-derived medications
- Significant electrolyte derangement (severe hypokalemia, severe hyponatremia)
- Anuria
- Advanced chronic kidney disease

- Orthostatic hypotension
- Syncope
- Geriatric population (age greater than 65 due to risk of hyponatremia)
- Pregnancy.

Description: White to yellowish-white, crystalline powder; almost odourless; tasteless. Solubility: Practically insoluble in water, in solvent ether and in chloroform; slightly soluble in alcohol; soluble in methyl alcohol and in solutions of alkali hydroxides.

Standards: Chlorthalidone is 2-chloro-5-(3-hyd-roxy-1-oxoisoindolin-3-yl) benzenesulphonamide. It contains not less than 98.0 percent .

Complex regional pain syndrome (CRPS)

It is a rare disease with chronic pain that usually affects an arm or a leg. Complex regional pain syndrome (CRPS) typically develops after an injury, a surgery, a stroke or a heart attack. The pain is out of proportion to the severity of the initial injury.

AEITOLOGY:
The cause of CRPS isn't completely understood. It's thought to be caused by an injury to or difference in the peripheral and central nervous systems. CRPS typically occurs as a result of a trauma or an injury.

CRPS occurs in two types, with similar signs and symptoms, but different causes:

- **Type 1.** Also known as reflex sympathetic dystrophy (RSD), this type occurs after an illness or injury that didn't directly damage the nerves in the affected limb. About 90% of people with CRPS have type 1.
- **Type 2.** referred as causalgia, develops after injury to major peripheral nerve.

Many cases of CRPS occur after a forceful trauma to an arm or a leg. This can include a crushing injury or a fracture. Other major and minor traumas — such as surgery, heart attacks, infections and even sprained ankles — also can lead to CRPS. It's not well understood why these injuries can trigger CRPS. Not everyone who has such an injury will go on to develop CRPS. It might be due to an interaction between your central and peripheral nervous systems that isn't typical and different inflammatory responses.

COMPLICATIONS:
If CRPS isn't diagnosed and treated early, the disease may progress to more-disabling signs and symptoms.

- **Tissue wasting (atrophy).** The skin, bones and muscles may begin to deteriorate and weaken if you avoid or have trouble moving an arm or a leg because of pain or stiffness.
- **Muscle tightening (contracture).** You also may experience tightening of the muscles. This may lead to a condition in which the hand and fingers or the foot and toes contract into a fixed position.

SYMPTOMS:
Signs and symptoms of CRPS include:

- Continuous burning or throbbing pain, usually in the arm, leg, hand or foot
- Sensitivity to touch or cold
- Swelling of the painful area

- Changes in skin temperature — alternating between sweaty and cold
- Changes in skin colour, ranging from white and blotchy to red or blue
- Changes in skin texture, which may become tender, thin or shiny in the affected area
- Changes in hair and nail growth
- Joint stiffness, swelling and damage
- Muscle spasms, tremors and weakness (atrophy)
- Decreased ability to move the affected body part

Symptoms may change over time and vary from person to person. Pain, swelling, redness, noticeable changes in temperature and hypersensitivity (particularly to cold and touch) usually occur first. Over time, the affected limb can become cold and pale. It may undergo skin and nail changes as well as muscle spasms and tightening. Once these changes occur, the condition is often irreversible.

ACUTE STAGE: Usually within weeks of injury, affected limb is having swelling, redness, burning sensation with increased diaphoresis of affected limb.

DYSTROPHIC STAGE: It is within months of injury, where skin of limb is cool and diaphoretic. Pain spread throughout the limb and sudek's atrophy of bone can be seen in x-ray.

ATROPIC STAGE: Usually after the years of injury, skin become shiny and pale. Atrophy of muscle and bone in affected limb with constant pain even after treatment.

DIAGNOSIS:

Diagnosis of complex regional pain syndrome (CRPS) is based on a physical exam and medical history. There's no single test that can definitively diagnose CRPS, but the following procedures may provide important clues:

- **Bone scan.** This procedure might help find bone changes. A radioactive substance injected into one of your veins allows your bones to be seen with a special camera.
- **Sweat production tests.** Some tests can measure the amount of sweat on both limbs. Uneven results may indicate CRPS.
- **X-rays.** Loss of minerals from your bones may show up on an X-ray in later stages of the disease.
- **Magnetic resonance imaging (MRI).** Images captured with an Magnetic resonance imaging (MRI) test may show tissue changes that rule out other conditions.

TREATMENT:

There's some evidence that early treatment might help improve symptoms of CRPS. Often, a combination of different treatments, tailored to your specific case, is necessary.

PHARMACOLOGICAL THERAPY - medications to treat the symptoms of CRPS.

- **Pain relievers.** — such as aspirin, ibuprofen (Advil, Motrin IB, others) and naproxen sodium (Aleve) — may ease mild pain and inflammation.
- **Antidepressants and anticonvulsants.** Sometimes antidepressants, such as amitriptyline, and anticonvulsants, such as gabapentin (Gralise, Neurontin), are used to treat pain that originates from a damaged nerve (neuropathic pain).
- **Corticosteroids.** Steroid medications, such as prednisone, may reduce inflammation and improve mobility in the affected limb.
- **Bone-loss medications.** to prevent or stall bone loss, such as alendronate (Binosto, Fosamax) and calcitonin (Miacalcin).

- **Sympathetic nerve-blocking medication.** Injection of an anaesthetic to block pain fibres in the affected nerves may relieve pain in some people.
- **Intravenous ketamine.** Some studies show that low doses of intravenous ketamine, a strong anaesthetic, may substantially alleviate pain.
- **Medicines to lower blood pressure.** Sometimes high blood pressure medications, including prazosin (Minipress), phenoxybenzamine (Dibenzyline) and clonidine can help to control pain.

NON- PHARMACOLOGICAL THERAPY

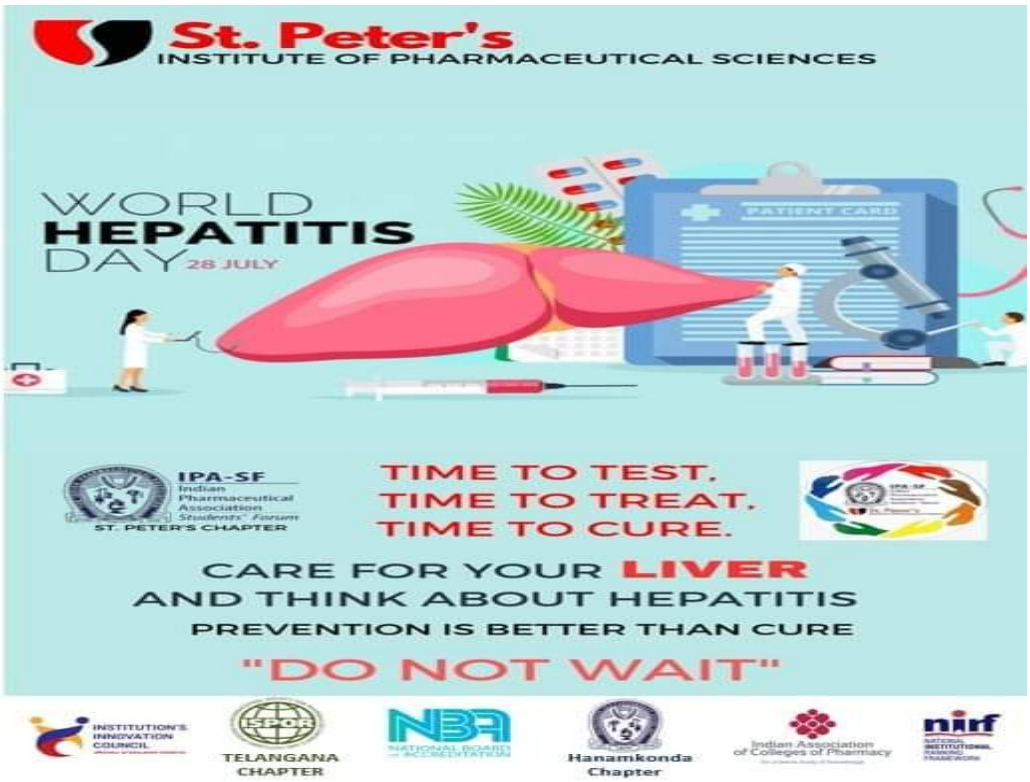
- **Heat therapy.** Applying heat may offer relief of swelling and discomfort on skin that feels cool.
- **Topical analgesics.** Various topical treatments are available that may reduce hypersensitivity, such as capsaicin cream available without a prescription, or lidocaine cream or patches (Lidoderm, ZTlido, others).
- **Physical or occupational therapy.** Exercising of the affected limbs or modifying daily activities might help decrease pain and improve range of motion and strength.
- **Mirror therapy.** This type of therapy uses a mirror to help trick the brain. Sitting before a mirror moving the healthy limb so that the brain perceives it as the limb that is affected by CRPS. Research shows that this type of therapy might help improve function and reduce pain for those with CRPS.
- **Transcutaneous electrical nerve stimulation (TENS).** Chronic pain is sometimes eased by applying electrical impulses to nerve endings.
- **Spinal cord stimulation.** Inserts tiny electrodes along spinal cord. A small electrical current delivered to the spinal cord results in pain relief.
- **Intrathecal drug pumps.** In this therapy, medications that relieve pain are pumped into the spinal cord fluid.
- **Acupuncture.** The insertion of long, thin needles may help stimulate nerves, muscles and connective tissue to increase blood flow and relieve pain.

It's possible for CRPS to recur, sometimes due to a trigger such as exposure to cold or intense emotional stress. Recurrences may be treated with small doses of an antidepressant or other medication.

Departmental Activities:

Our students visited Bulk Drug Manufacturing Association of India Technology and Training Centre, Hyderabad.

World Hepatitis Day was conducted by St. peter's institute of pharmaceutical sciences on July 26 and created awareness on hepatitis .Care for your liver and think about hepatitis prevention is better than cure.



ACADEMICS :


St.Peter's
Institute of Pharmaceutical Sciences
Vidyanagar, Manumakonda, Telangana, India - 506 001
Ph: 08702567303, Mobile: 9000001196
www.stpeters.co.in
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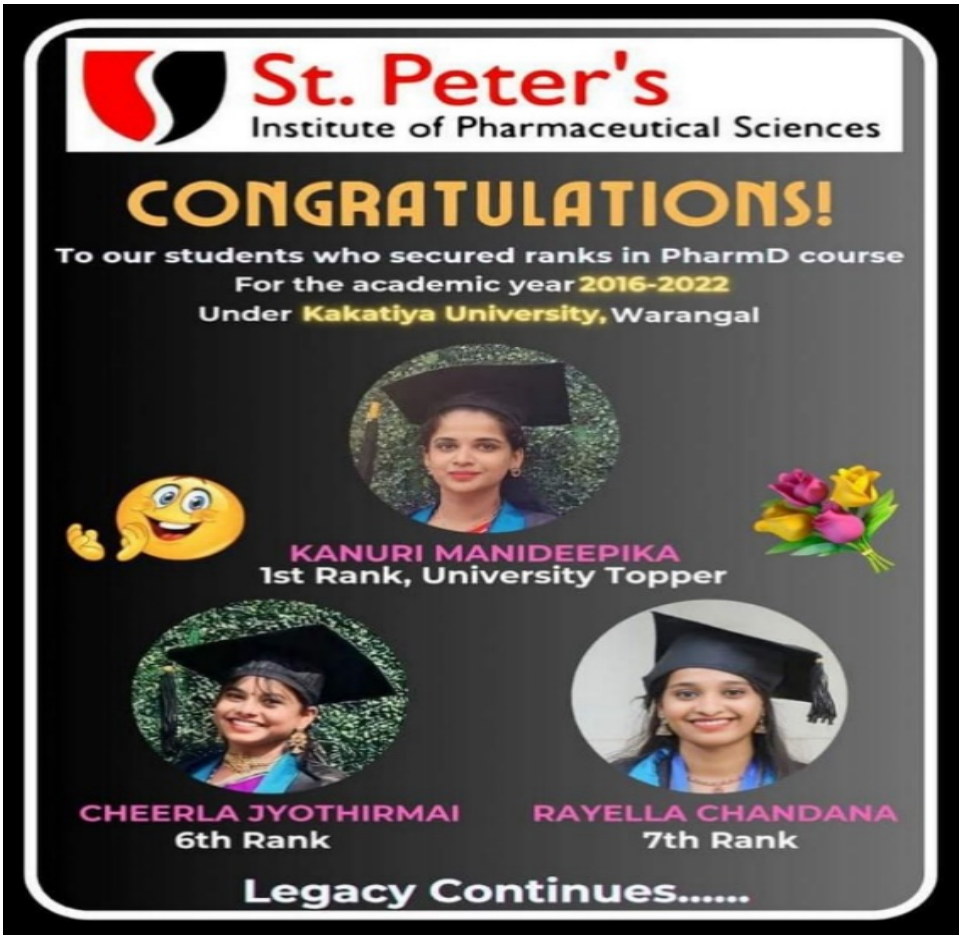
ACHIEVEMENT


St. Peter's
Institute of Pharmaceutical Sciences
CONGRATULATIONS!
To our students who secured ranks in PharmD course
For the academic year 2016-2022
Under Kakatiya University, Warangal
KANURI MANIDEEPIKA
1st Rank, University Topper
CHEERLA JYOTHIRMAI
6th Rank
RAYELLA CHANDANA
7th Rank
Legacy Continues.....