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A panorama in the world of health sciences

NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH DEEMED UNIVERSITY | JUL-DEC 2022 Vol VIII Issue 2

Managing Editors View

Dr. Cyril Sajan
Assistant Professor

It is our pleasure to share issue 2 volume 7 of Pharmahorizon. This issue comprises important information regarding new drug approval namely Cariprazine hydrochloride bulk and Cariprazine capsules and Tipiracil hydrochloride bulk and FDC of Trifluridine along with its side effects and contraindications in patients.

Artificial Intelligence (AI) is increasingly being used in the pharmaceutical industry to improve drug discovery and development, as well as to optimize clinical trials and improve patient outcomes.

AI can also be used to optimize clinical trials by identifying the most promising patient populations to enroll in, predicting patient outcomes, and monitoring patient safetyBlockchain technology has the potential to improve transparency, efficiency, and patient safety in the pharmaceutical industry

A recent study has shown a new biomarker molecule to identify Alzheimer's Neurodegeneration in Blood and it also improve clinical confidence and risk prediction in Alzheimer's disease diagnosis. This will help the physician to diagnose Alzheimer in early stage.

Futibatinib is an anticancer agent with demonstrated anti-tumour activity in mouse and rat xenograft models of human tumours with activating FGFR genetic alterations. Activities performed by our students, staff and Publication done are included in this issue. We welcome your suggestions, contributions and feedback at editorpharmahorizon@gmail.com

NEW DRUG APPROVAL

Liothyronine sodium bulk and Liothyronine sodium tablets 5mcg & 20 mcg

Indication:

- Hypothyroidism:
- Initial dosage: 25 mcg orally once daily.
- Titration: Increase by 25 mcg/day every 1 to 2 weeks, if needed
- Maintenance dosage: Usually in the range of 25 to 75 mcg once daily.
- Thyroid uptake with thyroid suppression: Usual dosage: 75 to 100 mcg/day for 7 days, and radioactive iodine uptake is evaluated before and after liothyronine administration. The radioiodine uptake will drop significantly after liothyronine administration if the thyroid function is normal. A 50% or greater suppression of uptake indicates a normal thyroid-pituitary axis.

Side effect: Cardiac dysrhythmia, Increased blood pressure, Myocardial infarction, Palpitation, Tachycardia, Dermatitis herpetiformis, Flushing, Intolerant of heat, Loss of hair, Hyperthyroidism, Poor glycemic control, Diarrhea, Increased appetite, Muscle weakness, osteoporosis, Slipped upper femoral epiphysis, Headache, Insomnia, Pseudotumor cerebri, Tremor, Irregular periods, Dyspnea.

Contraindications & Caution:

- Hypersensitivity to liothyronine or any extraneous constituents of the preparation.
- Uncorrected adrenal cortical insufficiency
- Untreated thyrotoxicosis

Pregnancy: The weight of an adequate body of evidence suggests this drug poses minimal risk when used in pregnant women.

Source:

1. List of new drugs approved in the year 2022

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO. WEB/elements/download_file_division.jsp?num_id=ODg5Ng==

2. Pralsetinib Capsule 100mg

Indication:

- Medullary thyroid carcinoma, Advanced or metastatic, RET-mutant: Usual dosage: 400 mg orally once daily on an empty stomach.
- Non-small cell lung cancer, Metastatic, RET fusion-positive disease: Usual dosage: 400 mg orally once daily on an empty stomach.
- Thyroid cancer, Advanced or metastatic RET fusion-positive disease, in patients who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate): Usual dosage: 400 mg orally once daily on an empty stomach.

Dosage in Renal Failure

- Mild or moderate impairment (CrCl 30 to 89 mL/min): No differences in pralsetinib pharmacokinetics were observed; no specific dose adjustments are provided.
- Severe impairment (CrCl less than 15 mL/min): Pharmacokinetics of pralsetinib has not been evaluated in this population; no specific dose adjustments are provided.

Side effect: Edema, Hypertension, Rash, Abdominal pain, Constipation, Decrease appetite, Diarrhea, Nausea, stomatitis, taste sense altered, Xerostomia, ALT/SGPT level raised, Musculoskeletal pain, Dizziness, Headache, Peripheral neuropathy, Cough, Dyspnea, Pneumonia, Pneumonitis, Fatigue, Fever, Tumor Lysis Syndrome.

Contraindications & Caution: Specific contraindications have not been determined.

Pregnancy: Available evidence is inconclusive or inadequate for determining fetal risk when used in pregnant women.

Source:

- **List of new drugs approved in the year 2022**

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO. WEB/elements/download_file_division.jsp?num_id=ODg5Ng==

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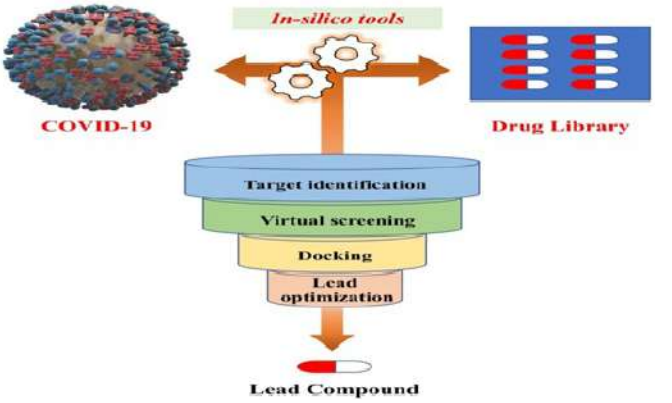
IN-SILICO TESTING



• In silico testing refers to computer-based simulations and modeling techniques used to predict the safety, efficacy, and pharmacokinetics of drugs. In the field of pharmacy, in silico testing has become an increasingly valuable tool in drug development and regulatory approval processes.

• There are several types of in silico testing techniques, including molecular docking studies, quantitative structure-activity relationship (QSAR) modeling, and pharmacokinetic modeling. Molecular docking studies can help predict the interactions between drug molecules and target proteins, while QSAR modeling can predict the activity of a drug based on its chemical structure. Pharmacokinetic modeling can predict how a drug will be absorbed, distributed, metabolized, and excreted in the body.

• In silico testing can also be used to predict drug toxicity, identify potential drug-drug interactions, and optimize drug dosing regimens. By using computational techniques to predict drug properties, researchers can reduce the number of experiments needed to evaluate a drug's safety and efficacy, leading to faster and more cost-effective drug development.

Reference: Ekins S, Mestres J, Testa B. In silico pharmacology for drug discovery: methods for virtual ligand screening and profiling. Br J Pharmacol. 2007 Sep;152(1):9-20.

BIOPRINTING

• Bioprinting is a rapidly advancing technology that involves the fabrication of three-dimensional (3D) structures using living cells, biomaterials, and other biological components. In pharmacy, bioprinting has the potential to revolutionize drug discovery, drug delivery, and tissue engineering.

• One application of bioprinting in pharmacy is the development of personalized medicine. With the ability to precisely deposit living cells in specific patterns and configurations, bioprinting can create tissues and organs that more closely mimic the complexity of human anatomy and physiology. This can help researchers develop drugs that are more effective and have fewer side effects.

• Bioprinting can also be used to create drug-delivery systems that can target specific areas of the body. By creating structures with specific porosity and other properties, bioprinting can help researchers create drug delivery vehicles that can release drugs at a controlled rate or in response to specific triggers.

• Another potential application of bioprinting in pharmacy is tissue engineering. Bioprinting can be used to create 3D structures that can be used to replace or repair damaged tissues and organs. This can help improve patient outcomes and reduce the need for organ transplants.

Reference: https://ispe.org/pharmaceutical-engineering/july-august-2017/3d-printing-bioprinting-pharmaceutical-manufacturing

Carbamazepine Induced Rashes with Drug rash with eosinophilia and systemic symptoms (DRESS Syndrome): A Case Report

Drug rash with eosinophilia and systemic symptoms (DRESS) syndrome is an uncommon but potentially fatal condition that develops in response to anticonvulsants that produce arene oxide, such as phenytoin and carbamazepine. Upon first contact with the offending medications, there have been numerous reports of cross reactivity among the anticonvulsants. There are, however, few studies describing the emergence of DRESS syndrome following the discontinuation of previously well-tolerated carbamazepine and the DRESS-induced induction of CBZ hypersensitivity. The medicine carbamazepine is frequently used. Hepatic abnormalities, ranging from an asymptomatic increase in liver function tests to severe liver failure, are frequently linked to it. When a generalized reaction is present, it is the most severe. Due to the low occurrence of side effects after prolonged usage, carbamazepine (CBZ), an effective anticonvulsant for partial and secondary generalized seizures, has become a preferred medication. Skin rash, CNS symptoms like sleepiness and vertigo, hepatic dysfunction, and, very rarely, hematological disorders make up the majority of the documented negative effects of CBZ.

Case description: A 65 year old male with the known case of hypothyroidism, was diagnosed with Trigeminal Neuralgia, but was on irregular medication for it and was administrating Zeptol (300 mg) (1-0- 1) (Carbamazepine) for a month, for the treatment of seizures. CBZ was typically given for the treatment of seizure. The patient started developing breathlessness and rashes 10 days back, the patient then visited the local hospital and was then given Tab Avil (Pheneramine) (25 mg) as an anti-allergic drug for the rashes on his body.

Treatment: The identification and withdrawal of the causative medication is the mainstay of treatment for all patients with DRESS. Introducing new medications, including empirical use of antibiotics, should be avoided, if possible. Since the cross-reactivity among aromatic antiseizure medications is well documented, patients with DRESS triggered by carbamazepine or other aromatic antiseizure medications should be treated with nonaromatic agents (eg, valproic acid, topiramate, gabapentin). Supportive care includes fluid, electrolyte, and nutritional support. Adjunctive measures include gentle skin care with emollients and warm baths/wet dressings.

Conclusion: In conclusion, DRESS syndrome is a rare medication reaction that, if left untreated, could be lethal. It should be taken into account when making a differential diagnosis for patients who have a common rash and are taking medication. Due to the widespread use of anticonvulsants in many disorders, DRESS syndrome is a clinical condition that, despite its rarity, should be treated as if it were a fatal sickness in situations where the same class of medications had been used previously. Because DRESS syndrome is a very uncommon occurrence. IVIG, cyclophosphamide, cyclosporine, and immunosuppressant's have all been successful in treating patients of corticosteroid-resistant DRESS. The involved drug and other drugs in the same class (e.g., aromatic, nonaromatic) must be strictly avoided, and identification of a substitute drug is part of the management of concomitant psychiatric disorder (eg, VPA for CBZ-induced DRESS).

REFERENCES: Neha R Gulati., et al. "Carbamazepine Induced Rashes with DRESS Syndrome: A Case Report". Acta Scientific Pharmacology 3.12 (2022): 13-16.

FDA Approves Jesduvroq (daprodustat) for Anemia Caused by Chronic Kidney Disease for Adults on Dialysis

Food and Drug Administration (FDA) has approved Jesduvroq (daprodustat), an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the once-a-day treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months. Jesduvroq is the first innovative medicine for anemia treatment in over 30 years and the only HIF-PHI approved in the US, providing a new oral, convenient option for patients in the US with anemia of CKD on dialysis. The FDA approval is based on results from the ASCEND-D trial, assessing the efficacy and safety of Jesduvroq for the treatment of anemia of CKD in patients on dialysis. Safety Information for Jesduvroq includes a boxed warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Jesduvroq increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE). No trial has identified a hemoglobin target level, dose of Jesduvroq, or dosing strategy that does not increase these risks. Use the lowest dose of Jesduvroq sufficient to reduce the need for red blood cell transfusions. Jesduvroq has not been shown to improve quality of life, fatigue, or patient well-being. Jesduvroq is not indicated for use as a substitute for red blood cell transfusions in patients who require immediate correction of anemia or for treatment of anemia of chronic kidney disease in patients who are not on dialysis.

Jesduvroq, a HIF-PHI, belongs to a novel class of oral medicines for the treatment of anemia of CKD in adult patients on dialysis. Inhibition of oxygen-sensing prolyl hydroxylase enzymes stabilises hypoxia-inducible factors, which can lead to transcription of erythropoietin and other genes involved in the correction of anemia, similar to the physiological effects that occur in the human body at high altitude. Jesduvroq provides an oral treatment option for adult patients with anemia of CKD on dialysis. Jesduvroq is a tablet available in 5 dosage strengths: 1mg, 2mg, 4mg, 6mg, 8mg.

Source: https://www.drugs.com/newdrugs/fda-approves-jesduvroq-daprodustat-anemia-caused-chronic-kidney-adults-dialysis-5966.html

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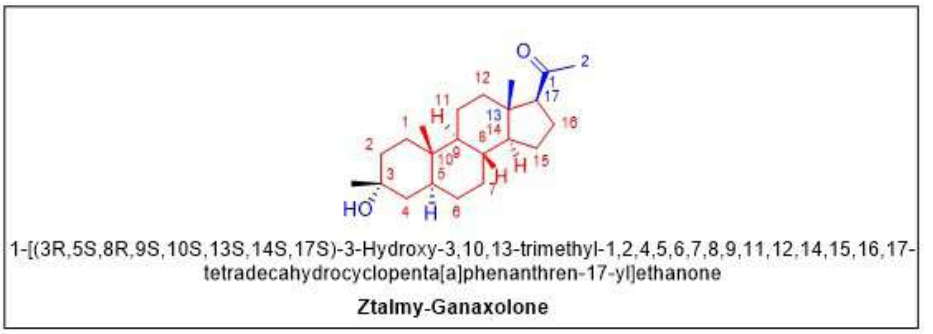
FDA Approves Jesduvroq (daprodustat) for Anemia Caused by Chronic Kidney Disease for Adults on Dialysis



Pharmacology: Ganaxolone is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients ≥2 years old. Pharmacokinetics and pharmacodynamics:Absorption Following oral administration of ZTALMY, ganaxolone is absorbed with a time to maximum plasma concentration (Tmax) of 2 to 3 hours.When ZTALMY was administered with a high-fat meal, the Cmax and AUC increased by 3-and 2-fold, respectively, when compared to administration under fasted conditions. ZTALMY was administered with food in the clinical efficacy study. Ganaxolone is approximately 99% protein-bound in serum. The terminal half-life for ganaxolone is 34 hours. Ganaxolone is metabolized by CYP3A4/5, CYP2B6, CYP2C19, and CYP2D6 Following a single oral dose of 300 mg [14C]-ganaxolone to healthy male subjects, 55% of the total radioactivity was recovered in feces (2% as unchanged ganaxolone) and 18% of the total radioactivity dose was recovered in urine (undetected as unchanged ganoxolone)

Mechanism of action:

- The specific mode of action through which ganaxolone produces its therapeutic benefits for the treatment of seizures associated with CDD is not fully understood, but it is believed that its anticonvulsant properties are a result of enhancing the activity of the gamma-aminobutyric acid type A (GABAA) receptor in the central nervous system (CNS) through positive allosteric modulation.
- Spectrum of Activity:
- ZTALMY is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. (1).

Drug interactions:

- Cytochrome P450 inducers will decrease ganaxolone exposure. It is recommended to avoid concomitant use with strong or moderate CYP3A4 inducers; if unavoidable, consider a dosage increase of ZTALMY, but do not exceed the maximum recommended dosage

Conclusion:

- Ganaxolone's unique mechanism of action as a synthetic form of allopregnanolone hormone provides a promising approach to treating rare genetic seizure disorders in both pediatric and adult patients. By targeting the brain's GABA receptors, ganaxolone can potentially reduce seizure frequency and improve seizure control, offering hope to patients who previously had limited treatment options. Furthermore, ongoing clinical trials evaluating ganaxolone's efficacy and safety will help establish its potential as a viable treatment option for rare genetic seizure disorders. If the results of these trials are positive, ganaxolone could potentially offer a new avenue for patients and healthcare providers in managing these challenging conditions. Overall, ganaxolone represents a promising development in the field of neurology and holds significant potential to improve the lives of those affected by rare genetic seizure disorders
- References:

- FDA approves drug for treatment of seizures associated with rare disease in patients two years of age and older | FDA
- Ganaxolone: Uses, Interactions, Mechanism of Action | DrugBank Online

1. RECOMMENDATION

Induction of labour is recommended for women who are known with certainty to have reached 41 weeks (greater than or equal to 41 weeks +0/7 days) of gestation (moderate-certainty evidence).

2. RECOMMENDATION

Routine induction of labour, for women with uncomplicated pregnancies, at less than 41 weeks is not recommended (low-certainty evidence).

- Accurate gestational dating of the pregnancy is critical. WHO recommends one ultrasound scan before 24 weeks of gestation (early ultrasound) for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy and improve a woman's pregnancy experience.
- Most women will give birth by the end of the 41st week of gestation. Spontaneous onset of labour minimizes interventions, the potential for over-medicalization of a physiologic process, and may lead to a more positive birth experience.
- The GDG noted updated evidence from a large study from a high-income country that showed a modest level of perinatal benefits for low-risk women who underwent induction of labour at 39 completed weeks of gestation (slight reduction in caesarean section and perinatal morbidity). The evidence for perinatal benefits may not be generalizable to lower-resource settings.
- However, in settings where induction of labour can be carried out safely, women with uncomplicated pregnancies at full term (39 weeks and up to 41 weeks of gestation) may consider induction of labour in the context of their values and preferences. These settings should be able to provide midwifery care, fetal heart rate monitoring at frequent intervals, immediate access to caesarean section if needed, and access to pain relief. The process of joint decision-making for this and all other interventions should begin early during antenatal care (ANC) contacts.
- The GDG noted that induction of labour can increase the use of resources (i.e. induction agents, health workers, facility preparedness) and the risk of iatrogenic complications (i.e. inadvertent prematurity). The indication for induction of labour should document the specific clinical indication or state that it was undertaken at the maternal request..
- High-quality ANC and fetal surveillance should continue until the onset of labour or induction for the indication of post-term pregnancy. These recommendations pertain to women with uncomplicated pregnancies.

Source: https://www.who.int/publications/who-guidelines#

KarXT

Company: Karuna Therapeutics
Disease: Schizophrenia
Treatment type: Small molecule
Trial: Emergent-2

The value of Karuna Therapeutics, a Boston-based developer of brain drugs, rose by billions of dollars in late 2019, after its most advanced experimental medicine scored positive results in a schizophrenia study.

The study, which enrolled about 180 participants, showed that those taking Karuna's medicine, known as KarXT, experienced significant reductions in the severity of their symptoms compared to those given a placebo. Karuna also said KarXT was well tolerated, an important finding given that one of the drug's active ingredients caused concerning side effects in clinical trials a few decades ago.

Karuna now hopes to build the case for its drug through two larger clinical trials — the first of which, named EMERGENT-2, should produce results by the end of September. The trial, which is evaluating nearly 250 adult patients with schizophrenia over a five-week period, finished enrollment this spring. In a recent note, Jefferies analyst Chris Howerton wrote that his team puts the odds of the trial succeeding at 75%. If KarXT goes on to secure FDA approval, Howerton claims it should have "no issue" surpassing $1 billion in annual sales. Historically, pharmaceutical companies have struggled to develop treatments for psychiatric disorders. The Food and Drug Administration also approved two new schizophrenia medicines — one from Intra-Cellular Therapies, and the other from Alkermes in 2019 and 2021, respectively. Karuna expects EMERGENT-3, its other schizophrenia study and a trial delayed by the war in Ukraine, to produce results in early 2023.

Source: https://www.biopharmadive.com/news/biotech-10-clinical-trials-watch-2022-second-half/625359/

Sotorasib

Company: Amgen
Disease: Lung cancer
Treatment type: Small molecule
Trial: Codebreak 100

Drugmakers have spent decades trying to design a medicine that can treat cancer by blocking KRAS, a gene that's often mutated in several common tumour types. Amgen's sotorasib has a chance to become the first, which is why the drug has fast become the most valuable asset in the biotech's pipeline.

Sotorasib's most promising results so far have come in patients with advanced lung cancer — specifically for those whose non-small cell lung cancer has a specific mutation called KRAS G12C. Early data, for instance, showed treatment led to response rates roughly twice as high as what would be expected from chemotherapy.

In October, Amgen released a vague statement claiming, without details, that the drug had shown similar efficacy, safety and tolerability in Phase 2 testing. Those data were included in approval applications the company submitted to the FDA and EMA in December. Amgen will finally unveil those results this month when the company presents Phase 2 sotorasib results at the World Conference on Lung Cancer. The details could determine how widely the drug might be used in lung cancer and how it stacks up against would-be competitors like Mirati Therapeutics. Amgen is also testing sotorasib in combination with other medicines, among them immunotherapies, making its profile as a single treatment important.

Source: https://www.biopharmadive.com/news/biotech-10-clinical-trials-watch-2021-first-half/593069/

WORLD PHARMACIST DAY-2022

As a part of the program, Department of Pharmacy, SVDU planned for community awareness program, health check-up camp at Anguthan Village, Ta. Dabhoi on 25th September 2022 and competitions like Pharma Model, Pharma Recipe and Elocution Competition. Students had explained to villagers about life style modification, disease complications, diet chart, drug-drug interaction etc. Students had actively participated in Pharma Model, Pharma Recipe and Elocution Competition. Theme of the World Pharmacist Day was "Pharmacy united in action for a healthier world" according to International Pharmaceutical Federation (FIP). The subject was selected to "Showcase Pharmacy's positive effect on health throughout the world and to further enhance Professional Unity."

WORLD HEART DAY

On the occasion of World Heart Day, Students of Department of Pharmacy, Sumandeep Vidyapeeth produced flyers and posters to increase public awareness of heart health. Our Institute had organized a healthy heart awareness rally and a fundamental heart health awareness programme in the village "Piparia". Pharmacy Teaching staff and students actively took part in these activities. Students had elaborated about various themes, including dietary modifications, heart disease, problems, and drug-drug interactions. Students also provided the residents with several lessons on how to maintain a healthy heart. In addition, they educated the community on basic health issues. They also discussed the changes made as a result of the corona epidemic with regard to, among other things, dietary guidelines, heart disease, complications, and how to lead a healthy life.

NATIONAL PHARMACY WEEK-2022

National Pharmacy week was celebrated by Department of Pharmacy, SVDU. On 17th November, Function was Inaugurated in presence of Dr. R. Balaraman and other faculty members. The students from Department of Pharmacy had prepared posters and models subjecting to general health awareness, anatomical structure and Physiology of Human body . Department of Pharmacy, SVDU also visited Shri G. N. Patel Vidyalaya, Vadodara. Posters were presented to Students of Shri G. N. Patel Vidyalaya, Vadodara. Different models base on Animal Cell, Neuron, Heart, Kidney, Arm etc. were also explained. Our students had explained about life style modification, disease complications, diet chart, Nutrition deficiency etc to the younger ones. Health Awareness rally was also arranged at Dhiraj Hospital where Pharm D students explained to various patients about hygiene, lifestyle habits, Nutrition supplements etc.

Publications

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Awards / Recognition / Achievements

1. Mr. Shivkant Patel has been awarded excellence in reviewing articles in South Asia Journal of Research in Microbiology.
2. Dr. Dhanya B. Sen has been awarded for reviewing article in Heliyon, Elsevier Journal.
3. Dr. Dhanya B. Sen has been awarded for reviewing article in Saudi Pharmaceutical Journal.
4. Dr. Ashim Kumar Sen has been awarded for reviewing article in Heliyon, Elsevier Journal.
5. Mr. Shivkant Patel has been awarded excellence in reviewing articles in South Asia Journal of Research in Microbiology.
6. Mr. Shivkant Patel has been awarded excellence in reviewing articles in South Asia Journal of Research in Microbiology.
7. Dr. Aarti Zanwar has been awarded for judging Drawing competition on world AIDS day -2022 which was held at K.M Shah Dental College and Hospital, Sumandeep Vidyapeeth Deemed to be University, Vadodara on 1st December 2022.
8. Dr. Ghanasyam Parmar has been appreciated as Hackathon Academic Mentor at Student Start-up and innovation Policy (SSIP) at Regional Round of Azadi ka Amrit Mahotsav Hackathon-2022 which was held at KPGU, Vadodara during 7th and 8th October 22