The Veeda Newsletter

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Partners in Creating

a healthier tomorrow

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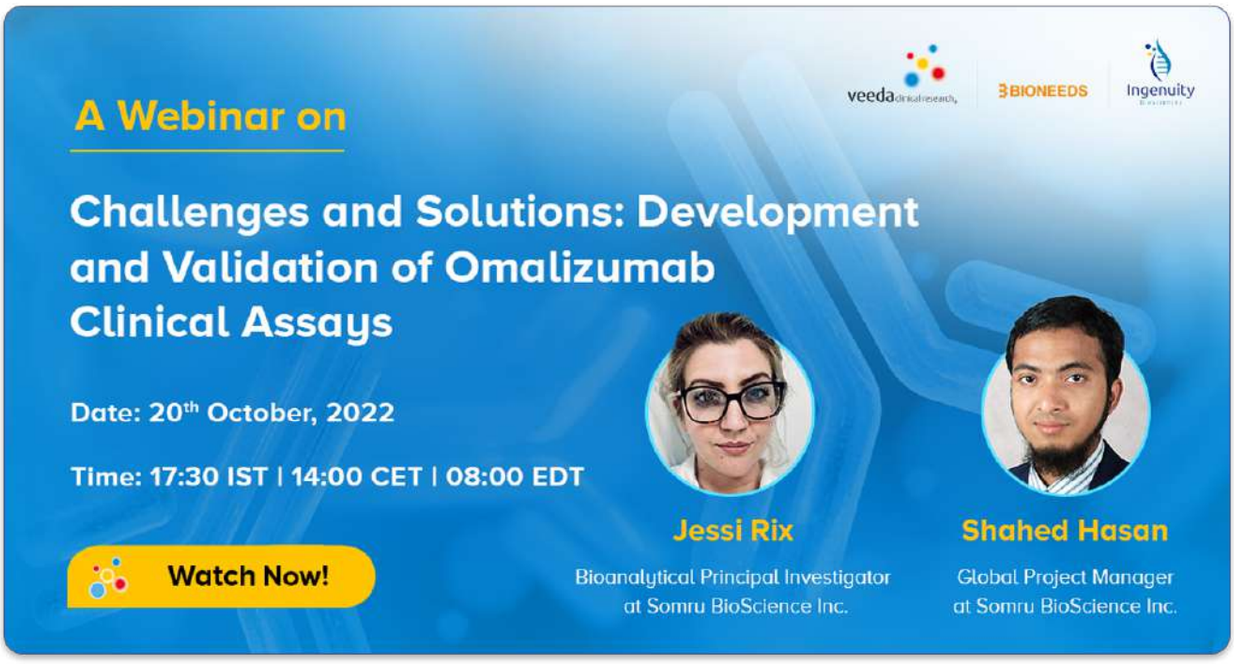
Here is a glimpse of our team successfully concluding the World Vaccine Congress 2022 in Barcelona

Watch our latest webinar on Omalizumab Clinical Assay today



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FDA Pathway Supports Long-Term Stability, Diversity of Safe and Nutritious Infant Formula Supply in the U.S.

The FDA is continuing, under certain conditions, to exercise enforcement discretion relating to the importation and sale in domestic commerce of certain infant formula products as part of its effort to provide stable, longer-term access to safe and nutritious infant formula across the country. The FDA is communicating directly with, and has made available to manufacturers, the steps to take to continue marketing certain formulas under enforcement discretion while they work to meet all U.S. regulatory requirements. In July 2022, the agency committed to developing a new framework for continued and expanded access to infant formula products for U.S. parents and caregivers.

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5 FDA decisions to watch in the fourth quarter

Though 2022 has been a down year for the biotechnology sector, notable decisions from the Food and Drug Administration have provided a few bright spots.Two gene therapies came to market, providing a lift for a field that's been slowed by recent setbacks. The cancer drug Enhertu was approved for a newly defined tumor type known as "HER2-low." The regulator also cleared a new medicine for ALS and a first-of-its-kind inflammatory disease drug.The fourth quarter could yield some other medical milestones. An Alzheimer's drug that unexpectedly succeeded in a large trial last week is under review.

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Chair of the European Network of Paediatric Research at EMA re-elected

The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) has re-elected Pirkko Lepola of the Finnish Investigators Network for Pediatric Medicines (FinPedMed) as chair of its coordinating group. Mrs Lepola will continue to co-chair the Enpr-EMA coordinating group for the next three years together with Gunter Egger, scientific officer in EMA's paediatric medicines office. The vote took place during the annual meeting of the Enpr-EMA coordinating group in October 2022.

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Cough syrups by India's Maiden Pharma linked to 66 deaths in Gambia, WHO issues alert

The World Health Organization has issued an alert for four "contaminated" medicines manufactured by an Indian pharmaceutical company that have been "potentially linked" with acute kidney injuries and 66 deaths among children in The Gambia. WHO Director-General Tedros Adhanom Ghebreyesus told reporters Wednesday, "The four medicines are cough and cold syrups produced by Maiden Pharmaceuticals Limited in India.

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Two years after FDA refusal, infusion device issues sink Supernus' Parkinson's filing

Questions about an infusion device have scuttled Supernus Pharmaceuticals' attempt to win approval of a Parkinson's disease therapy. The complete response letter marks the second time in two years that the FDA has knocked back a filing for approval of the continuous treatment of motor fluctuations.Supernus acquired the apomorphine infusion pump in 2020 and quickly filed for approval of a candidate that it is pitching as potentially the first non-surgical continuous dopaminergic stimulation device.

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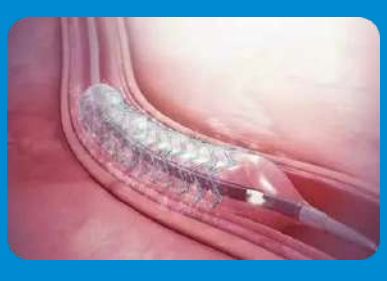
NPPA clarifies notified ceiling prices of coronary stents announced in March applicable till further orders

The National Pharmaceutical Pricing Authority (NPPA) has clarified that the trade margin it has fixed through an order on March 30, 2022 will be applicable without any change in the notified ceiling prices, till further orders. The clarification comes after a few companies selling the coronary stents requested the price regulator to give clarity on the current trade margin for these products in the country. The NPPA has discussed the request in the backdrop of the notifications on coronary stents and the provisions pertaining to trade margin from the year 2017 to 2022, in the Authority meeting held on September 27, 2022.



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NPPA further extends price revision of heparin injection, LMO and oxygen inhalation

The National Pharmaceutical Pricing Authority (NPPA) has further extended the revised ceiling price of two strengths of heparin injection, and the price fixed for liquid medical oxygen (LMO) and oxygen inhalation for three months, till December 31, 2022. The price regulations were introduced during Covid-19 pandemic in order to ensure continuous availability of these products. The revised ceiling prices of Heparin Injection 5000IU/ml and 1000 IU/ml were earlier extended for the fourth time, for a period of six months till September 30, 2022.

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Commerce ministry begins anti-dumping probe against antibiotic metronidazole imported from China

The Union ministry of commerce and industry has initiated an anti-dumping investigation against antibiotic metronidazole imported from China following a complaint filed by Aarti Drugs Limited. Metronidazole is used in treatment of bacterial infections and parasitic infections. It is used in cases of amoebiasis (amoebic dysentery), trichomoniasis (STD), giardiasis (beaver fever), gingivitis (gum inflammation), acute ulcerative, anaerobic vaginosis (vaginal inflammation) caused by overgrowth of natural bacterial found in the tracts.

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Commerce ministry agrees to include pharma sector under RoDTEP scheme

The Union commerce and industry ministry has agreed to include pharmaceutical sector under Remission of Duties and Taxes on Exported Products (RoDTEP) scheme to ensure sustainability and competitiveness of drug exporters in the global market.Piyush Goyal, Union minister of commerce and industry, at the Exporters Conclave in Chennai on October 16, 2022, agreed to extend benefits of RoDTEP scheme to drug exporters to make them competitive globally. Pharmaceutical industry has been left out of the RoDTEP scheme notified by the Directorate General of Foreign Trade (DGFT) through a circular on August 17, 2021.

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NPPA expert panel fixes retail price for diabetes drug combination dapagliflozin & sitagliptin

The Multi Disciplinary Committee (MDC) of Experts advising the National Pharmaceutical Pricing Authority (NPPA) has fixed the retail price of anti-diabetes drug combinations comprising sitagliptin and dapagliflozin, which met patent expiry of late, on a total of 10 applications from marketers including Lupin Ltd, Mankind Prime Labs, Unison Pharmaceuticals, Sun Pharma Laboratories, among others.The MDC, in a latest meeting held on October 19, considered seven applications for retail price fixation of four fixed dose combinations (FDCs) of sitagliptin and metformin tablets and three applications of two FDCs of dapagliflozin, sitagliptin and metformin tablets.

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Victoria's new centre for clinical trials

A clinical trials centre will be built in Melbourne's new multibillion dollar medical precinct, as the Victorian government defends its move to shutter a purpose-built quarantine site.The state government is partnering with the University of Melbourne to establish the centre in the suburb of Arden as part of a plan to build a medical precinct and upgrade the Royal Melbourne and Royal Women's hospitals in Parkville. After touring the Peter MacCallum Cancer Centre on Wednesday, Premier Daniel Andrews announced the trials hub would be integrated into Arden campus's north tower and include 20 patient and 20 laboratory spaces.

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IIL to invest Rs. 700 crore in Hyderabad for new animal vaccine facility

Indian Immunologicals Limited (IIL), a one health company and one of the largest producers of vaccines in Asia, will invest about Rs 700 crore to set up a new animal vaccine manufacturing facility in Genome Valley, Hyderabad, the “Vaccine Hub of the World”, to meet the vaccine security of the nation against economically important diseases such as foot and mouth disease (FMD) and other emerging diseases. The facility will create total employment for around 750 people. IIL, a subsidiary National Dairy Development Board (NDDB) is already one of the largest manufacturers of FMD vaccine in the world and is the leading supplier of FMD vaccine to the Government of India’s National Animal Disease Control Programme (NADCP).

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VINS Bioproducts completes phase-II clinical trials for COVID-19 antidote VINCOV-19

VINS Bioproducts, in collaboration with the Centre for Cellular and Molecular Biology (CCMB) and the University of Hyderabad (UoH), has completed the phase-II clinical trial for VINCOV-19, an antidote and cure for COVID-19, a statement from VINS Bioproducts has claimed.According to the statement, VINCOV-19 is now ready for market authorisation and for simultaneous phase-III clinical trials.The phase-II clinical trials were conducted across multiple centres in India and included more than 200 patients.

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India's first clinical trial for menstrual cramps using cannabis-based medicines

New Delhi-based startup HempStreet is conducting a year-long clinical trials to help women suffering from Primary Dysmenorrhea in collaboration with Amrita School of Ayurveda. The university was founded in 2004 and is based out of Kerala.HempStreet intends to use this randomized controlled trial to assess cannabis-based medicines' clinically reported analgesic effect in Primary Dysmenorrhoea, a condition characterized by painful menstrual cramps in the lower abdominal region.

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Walmart steps into clinical trials claiming ability to improve diversity

The business project was announced through the Walmart Healthcare Research Institute, which will work alongside clinical research organizations (CROs), pharmaceutical companies and academic medical centers to help recruit patients to clinical trials.The initial stages of the project will concentrate on recruitment for the studies on chronic conditions and ‘innovative treatments,’ where it would aim to improve access to such trials for underserved communities.As part of the move into clinical trial recruitment space, Walmart launched the ‘MyHealthJourney’ digital tool, which is delivered to patients through a digital health application.

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Idera Pharmaceuticals Acquires Aceragen

Idera Pharmaceuticals, Inc. ("Idera," the "Company," "we," "us," or "our") (Nasdaq: IDRA) today announced it has completed the acquisition of Aceragen, Inc. ("Aceragen"), a privately-held biotechnology company addressing rare, orphan pulmonary and rheumatic diseases for which there are limited or no available treatments. The combined cash of the two companies is expected to provide runway into Q3 2023, funding the advancement of Aceragen's pipeline, including ACG-701 and ACG-801, through important 2023 clinical milestones. The Company estimates annual peak sales potential of $650 million from the three current lead programs.

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H.I.G. Capital Acquires Morningside Healthcare and Morningside Pharmaceuticals

H.I.G. Capital, a global alternative investment firm, announced on Oct. 3, 2022 that its portfolio company Aspire Pharma has acquired Morningside Healthcare and Morningside Pharmaceuticals, a UK provider of niche generic and branded specialty pharmaceuticals. The financial terms of the transaction have not been disclosed.Morningside is focused on developing and licensing niche generic pharmaceutical products, marketing over 160 stock keeping units across more than 80 product families and multiple therapeutic areas.

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Hillenbrand completes acquisition of Linxis Group

Hillenbrand, Inc., completed its acquisition of Linxis Group, a supplier of specialized equipment for the food, pharma and cosmetics industries. Linxis Group will be a part of the Coperion Food, Health and Nutrition division headed by Kevin Buchler as president, food, health and nutrition division, and Tim Cook as chief strategy and business development officer, Linxis. "We look forward to having a dedicated and committed partner at our side that will support and enhance the growth path we started several years ago," Mr. Cook said.

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Cytiva Acquires CEVEC, Boosts Cell Line Development Capabilities

Cytiva has acquired CEVEC Pharmaceuticals, a Germany-based provider of high-performance cell line development and viral vector manufacturing technologies, in a move that strengthens Cytiva's capabilities to offer biomanufacturing solutions.With this acquisition, Cytiva gains CEVEC's scalable producer cell lines for vectors based on adeno-associated virus and adenovirus, two widely used vectors for gene therapy delivery, according to an Oct. 6, 2022 company press release. Cytiva also gains producer cell lines (PCLs) enabled by CEVEC's ELEVECTA technology, which promotes yield, scalability, and robustness in the manufacturing process.

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Marksans acquires capacity from Tevapharm India

Marksans Pharma entered into a Business Transfer Agreement with Tevapharm India yesterday, to acquire its business relating to the manufacture and supply of bulk pharma formulations in Goa, as a going concern on a slump sale basis, a statement from Marksans Pharma has notified.The statement said that the transaction is in cash consideration, and is expected to be finalised by 1st April, 2023, subject to the usual closing conditions. Marksans has agreed to retain the site employees with the existing terms of employment.

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Bharat Biotech gets patent for single dose conjugate vaccine Typbar-TCV for typhoid fever

Dismissing a pre-grant opposition filed by Pune-based Serum Institute of India (SII), the Indian Patent Office has granted a patent application filed by Hyderabad-based biotechnology firm Bharat Biotech International Ltd for its single dose conjugate vaccine Typbar-TCV, for typhoid fever among children and adults. Typbar TCV is the only approved vaccine for children and infants less than two years of age as well as adult, and the first typhoid conjugate vaccine in the world which has been pre-qualified by World Health Organisation (WHO), claims the company.

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TMT Law Practice underscores need for making UCPMP mandatory with penal action for violators

TMT Law Practice has underscored the need for making the Unified Code for Pharma Marketing Practices (UCPMP) mandatory and penalizing the violators. The Prevention of Corruption Act (PCA), 1988 should be amended to include commercial bribery between two private entities. Benefits provided to health care providers (HCPS) like cash, gifts, travel, speaker fees and sponsorships should be prohibited with criminal liability. Following the move by the Union government to appoint a high-level Committee to examine the marketing practices of pharmaceutical companies, Sanjay Kumar, partner TMT Law Practice said that even the National Medical Commission (NMC), the erstwhile Medical Council of India (MCI) rules should have penal consequences for accepting any cash or kind by doctors whether in public or private service.

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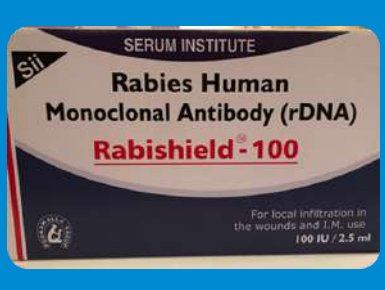
SII gets patent for improved process for production of monoclonal antibody for rabies vaccine

The Pune-based Serum Institute of India (SII) has received a patent approval from the Indian Patent Office for its application for improved process for production of monoclonal antibody for rabies vaccine with improved potency in a review petition, after it was rejected through an order on July 27, 2021.The company filed a patent application on September 26, 2015, for improved feeding strategies and purification processes for monoclonal antibody production, for an invention which provides a method for manufacturing a rabies monoclonal antibody (HuMab 17C7).



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Goa to host 9th World Ayurveda Congress & Arogya Expo from December 8-11

The 9th World Ayurveda Congress (WAC) & Arogya Expo, billed as the biggest event in traditional wellness system, will be held in Panaji, the capital city of Goa from December 8-11, seeking to give a transformational push to Ayurveda to bring it into global focus.Another objective of the event, being held in Goa for the first time, is to create an accessible and affordable healthcare system that is in harmony with modern medicine practices.'Ayurveda for One Health' is the focal theme of the event this year at Kala Academy, being organised by World Ayurveda Foundation, an initiative of Vijnana Bharati.

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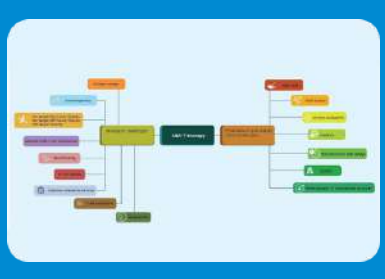
India enjoys big cost advantage in CAR-T cell therapy compared to US and EU

India has an edge in chimeric antigen receptor (CAR)-T cell therapy in terms of cost and positive patient outcome compared to US and Europe where the fee is exorbitant. Currently, CAR-T is free of cost in India because of a major ongoing phase III clinical trial, said Dr. Sharat Damodar, chairman, oncology services & oncology collegium, clinical director, MSMC, sr. consultant & head of adult haematology & bone marrow transplant unit, Narayana Health City. In fact, CAR-T cell therapy began a decade ago in the US and has proven to be advantageous for patients who relapse following leukaemia or lymphoma treatment.



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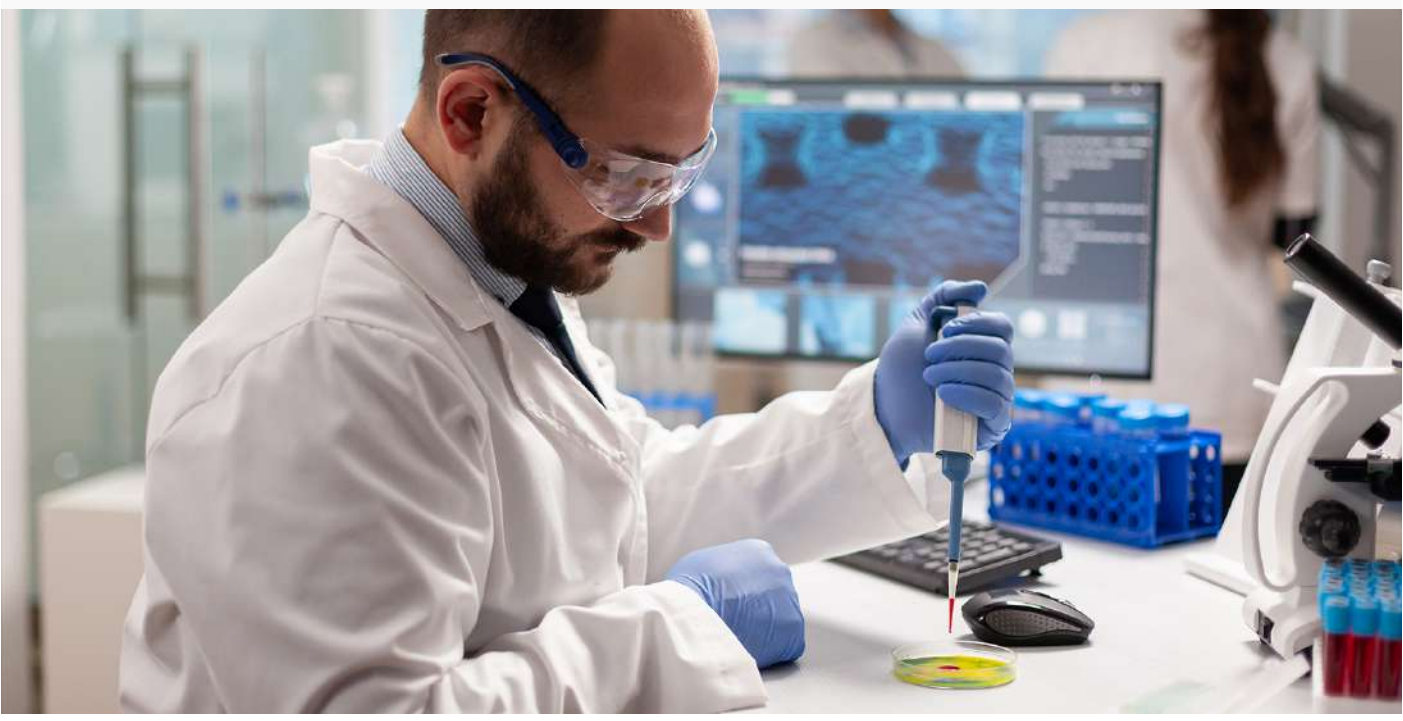

For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

Corporate Office

VEEDA CLINICAL RESEARCH LIMITED
Block 6, Magnet Corporate Park,
100 ft. Thaltej - Hebatpur Road,
Nr.Sola Bridge, Off. S.G.Highway,
Thaltej, Ahmedabad 380 054

Registered Office

Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PTC044023

OTHER ADDRESS:

- Sarkhej - Gandhinagar Highway
  Vedant Complex, S. G. Highway, nr. YMCA club,
  Ahmedabad, Gujarat 380051
- Insignia, Besides Auda Garden, Opp. Zenobia
  Residency, Sindhu Bhavan Road, Off. S. G. Highway,
  Bodakdev, Ahmedabad- 380059, Gujarat, India
- Radhe Palladium
  Panchot Cir, Kunal, Mehsana, Gujarat 384002