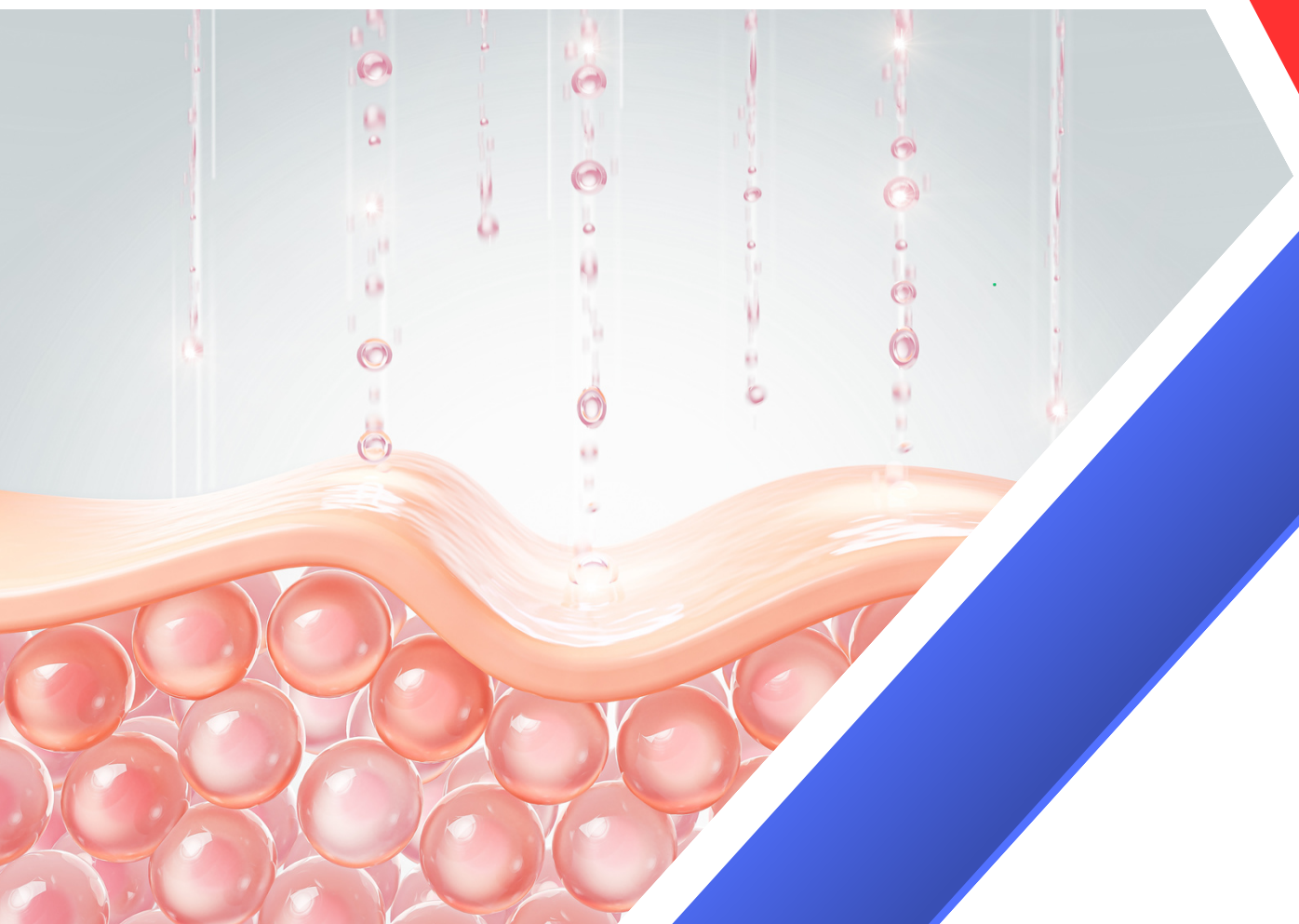
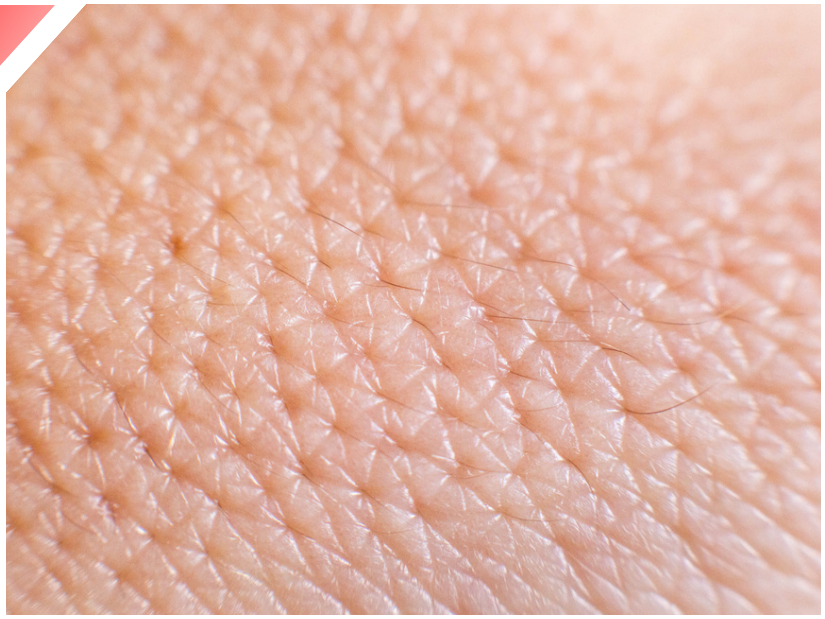
cutyx™

Cutyx Research



Introduction



Cutyx Research is dedicated to reshaping the pharmaceutical industry through exceptional consulting and R&D services.

Our expertise lies in advancing the development of transdermal patches, oral films, topical products and complex dosage forms.

Committed to empowering our clients, we provide innovative solutions that drive patient compliance, reduce costs, accelerate pharmaceutical development, and elevate overall therapeutic outcomes.

28+

Years of cumulative experience

20+

Complex projects delivered

4+

Greenfield setups

Dr. Dhaval Pethani

Co-Founder &
Chief Technology Officer

Dr. Pradeep Dabhi

Co-Founder &
Chief Scientific Officer

Company Overview

About Us

Boasting a cumulative experience of 28 years, our team stands as a testament to unwavering dedication in the pharmaceutical realm. Our journey includes significant stints in renowned pharmaceutical companies, focusing on regulated markets.

We specialize in the nuanced domains of formulation and analytical development, consistently steering projects from concept to commercial fruition. Our proficiency extends to the specialized realm of transdermal patches, oral films, topical products and drug-device combinations.

At the core of our capabilities is a mastery of In vitro permeation or release testing, handling extractables and leachables concerns, conducting comprehensive drug-device testing, and undertaking advanced characterization studies.

At Cutyx, we take pride in our proven ability to deliver excellence in pharmaceutical development, setting the stage for innovation and success.

Vision

To become a global leader in revolutionizing pharmaceutical innovation, through our cutting-edge expertise

Mission

To empower businesses with innovative transformative solutions in complex dosage forms, that drive sustainable growth

Experts' Profile

Dr. Dhaval Pethani
Co-Founder & Chief Technology Officer, Cutyx Research
Expert Committee Member, Center for Research on Complex Generics - USFDA

Dr. Dhaval Pethani is a highly accomplished Formulation Scientist with about 14 years of experience in research and development focused on Transdermal systems, ODF and Topical creams, ointments, gels, lotions, solutions, swabs; for the regulated markets. Dhaval's extensive experience with complex drug delivery systems, including transdermal patches, films, and drug-device combination products, has consistently yielded successful outcomes across all phases of product development, from early-stage product development to commercialization. Dhaval possesses comprehensive knowledge of cGMP requirements for transdermal and topical manufacturing facilities and has successfully navigated inspections of various regulatory Agencies. Dhaval is skilled also in new equipment design, Factory Acceptance Testing (FAT), machine qualifications, and related areas. Dhaval earned his Doctorate in Pharmaceutical Sciences and a Master's degree in Pharmaceutics and Pharmaceutical Technology from L.M. College of Pharmacy, Ahmedabad, India.

Dr. Pradeep Dabhi
Co-Founder & Chief Scientific Officer, Cutyx Research
Expert Committee Member, Center for Research on Complex Generics - USFDA

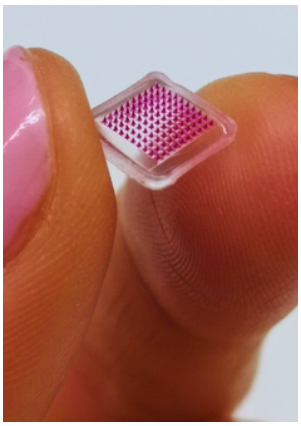
Dr. Pradeep Dabhi is an accomplished Analytical Development Scientist focused on Complex dosage forms, particularly Transdermal patches, intravaginal rings (IVR) & Topical products. With about 14 years of experience in analytical development across the spectrum of complex dosage forms, Pradeep has played a pivotal role in numerous research and development endeavors, including ANDAs and NDA 505 (b)(2) projects related to Topical and Transdermal Drug Delivery Systems. Pradeep has a strong background in analytical method development, qualification, validation, and transfer, as well as in-vitro release and skin permeation testing (IVRT/IVPT) alongwith statistical evaluations, extractables and leachables (E&L) and elemental impurities. In addition, Pradeep has extensive regulatory CMC knowledge, including both early and late-stage submissions, and responses to regulatory deficiencies. Pradeep holds a Doctorate in Pharmaceutical Sciences and a Master's degree, M.S.(Pharm.) from NIPER-Ahmedabad, India.

Our Expertise

Expertise in Transdermal, ODF and Topical Products

Equipped with a profound comprehension of the strong principles of Chemistry, Manufacturing, and Controls (CMC), we have honed our expertise in various related domains. These include material selection and testing, formulation design, manufacturing process development & validation and analytical development. Additionally, we possess a thorough understanding of regulatory guidelines and work meticulously to ensure adherence to these requirements, guaranteeing the products meet all regulatory standards.



- Product lifecycle experience
- Cost-cutting keen eye
- PAT prowess for swift manufacturing processes
- Robust R&D and plant team networking
- Rapid analysis, upping efficiency
- Market intelligence
- Regulatory savvy in CMC requirements
- Strategic supplier relationship (material and equipment)
- Turnkey solutions for Product development
- Dynamic duo of Formulation and Analytical development

Our Experience

US NDA/ANDA and EU Product development exposure

Patches
- Hormonal Patches
- Non-hormonal Patches
- Pain management patch, NDA 505(b)(2)
- Dementia patch, NDA 505(b)(2)

Films
- Oral films
- Sublingual films
- Buccal films

Topical Products
- Creams
- Ointments
- Gels
- Solutions
- Lotions

Complex Products
- Intra vaginal rings
- Microneedle patches

cGMP facilities and Greenfield Projects

Exposure to three US FDA approved cGMP facilities and one Greenfield facility setup
- Production of hormonal products
- Production of non-hormonal products
- Production of controlled substances
- Greenfield project for setup of transdermal and oral films manufacturing facility

Exposure to latest technologies
- Harro Höfliger converting line
- Delta ModTech converting line
- Optimags Commercial Coating
- Mathis Commercial Coating

- Knowledge of different facilities about cGMP for patch/film manufacturing and testing
- Technology transfer of patches/films to different international facilities
- In-depth knowledge of each unit operations of patch/film manufacturing process & controls
- Exposure to multiple USFDA inspections and marketing partner audits
- Exposure in Greenfield projects of R&D setup for Topicals, Transdermal, IVRT, IVPT and others

Consulting Services

Technical Consulting

- Formulation Development support
- Process Development and Scale-up Assistance
- Analytical Development and Validation Guidance
- In vitro testing guidance and deficiency response
- Manufacturing Process Optimization using QbD and CFR-Compliant Statistical Software
- Lab Setup – R&D
- Pharmaceutical Manufacturing Facility Setup (Greenfield and Brownfield)
- CMC Regulatory, Technical, and Document Review
- Due Diligence Services
- Compliance Audits
- API DMF Critical Review
- Evaluation of Innovative Platforms and Technologies
- Expertise in Developing Non-Infringing Novel Patentable Formulations
- Addressing FDA Deficiencies with scientific justifications
- Packaging Development and Drug-Device Combination Requirements
- Clinical Study Strategizing and Monitoring (Clinical Endpoint, PK, Adhesion, Irritation, and Sensitization)
- Training and development

Toxicological Evaluations

- Toxicological Assessments
- Impurity Qualifications
- In-Silico Assessments

Packaging Development

- Selection of Packaging Components
- Qualification and Characterization
- PackageTesting as per USP and ASTM
- Extractable Studies
- Compilation of Design History Files for Drug-Device Combination Products

In-vitro studies

Monitoring of In-vitro studies

We are involved in actively overseeing the initiation, progress and conduct of in-vitro experiments:

- In vitro Release testing (IVRT)
- In vitro Permeation testing (IVPT) using human cadaver, human epidermis, mucosal membranes, porcine skin, etc.
- In use stress/heat flux studies
- In vitro nail permeation studies
- In vitro feeding tube studies
- Drug release studies or dissolution testing
- Extractable and leachable studies (Sample incubation as per in use conditions)
- Adhesion testing (Peel, Tack, Shear, Release force, etc.)
- Condom compatibility studies
- Performance testing of Applicators, Pen-injectors, Vaginal Rings, Drug Devices, etc.
- Advanced Characterization Studies (SEM-EDAX, Elemental Mapping, Confocal Microscopy, Rheology)

In-vitro study monitoring and due diligence are essential processes for maintaining the quality, credibility, and ethical integrity of scientific research conducted in laboratories/CROs. We expertise in assessing the qualifications and capabilities of researchers, reviewing study protocols and reports, confirming the accuracy of data collection and analysis methods, and verifying the reliability of results, with on-time escalation to clients.

Glimpses of study monitoring for IVRT, IVPT and E&L projects:

- **In-vitro Permeation and Release Testing (IVPT/IVRT)**
  - Topical creams
  - Topical ointments
  - Topical gels
  - Transdermal Systems/patches
  - Topical patches
- **Extractable and Leachable (E&L) Studies**
  - Transdermal Patches
  - Drug device combinations
  - Vaginal rings
  - Topical products
  - Pulmonary products
  - Complex injectables

Collaborate with us

- Product development support for transdermal patches, oral films and topical products
- Deficiency response to critical queries from Regulatory Agencies
- Portfolio expansion in Transdermal, oral films and Topical dosage forms
- Early stage development and proof-of-concept for IND/NDA/505(b)2 applications
- Expansion from regional markets to Regulated markets
- Monitoring of In-vitro studies in laboratories and CROs

Cutyx Research

Contact Us

Website	www.cutyxresearch.com
Phone	+91 (79) 6712 4600
E-mail	dhaval.pethani@cutyxresearch.com pradeep.dabhi@cutyxresearch.com
LinkedIn	www.linkedin.com/company/cutyx-research-llp/
HQ address	1101 Earth Arise, Near YMCA Club, SG Highway, Ahmedabad, Gujarat 380051, IN