



BULK DRUG MANUFACTURES ASSOCIATION (INDIA)

C-25, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD, TELANGANA-500018

Email: ed@bdmai.org, info@bdmai.org Ph:040-23706718/4804

Circular No. BDMA/084/2026

Date: 28th Sep 2026

Dear Sir,

Sub: Presentations made during Annual General Meeting of BDMAI

We would like to express our sincere thanks and appreciation to all our members for their active participation in the AGM of the Association held on 26th September 2026, which provided an excellent opportunity for members to interact with senior officials and industry peers.

During the meeting, the Drug Controller General of India (DCGI) and senior officials from CSIR-IICT, Hyderabad made informative and insightful presentations covering key regulatory reforms and opportunities for industry–research collaboration.

For the information and reference of our members, we are pleased to enclose the following two presentations:

- a) Update on Key Regulatory Reforms by CDSCO
- b) CSIR-IICT–Industry Connect – Capabilities, Technologies, Opportunities for Collaborative Innovation

We hope that these presentations will be useful to our members in understanding the latest regulatory developments and exploring opportunities for technological collaboration, innovation and R&D with CSIR-IICT.

Once again, we thank all our members for their continued support and active participation in the activities of BDMA

With regards

M Roja Rani

Executive Director

CSIR-IICT

CSIR-Indian Institute of Chemical Technology

Hyderabad, India



**CSIR-IICT–Industry Connect: Capabilities, Technologies & Opportunities
for Collaborative Innovation**



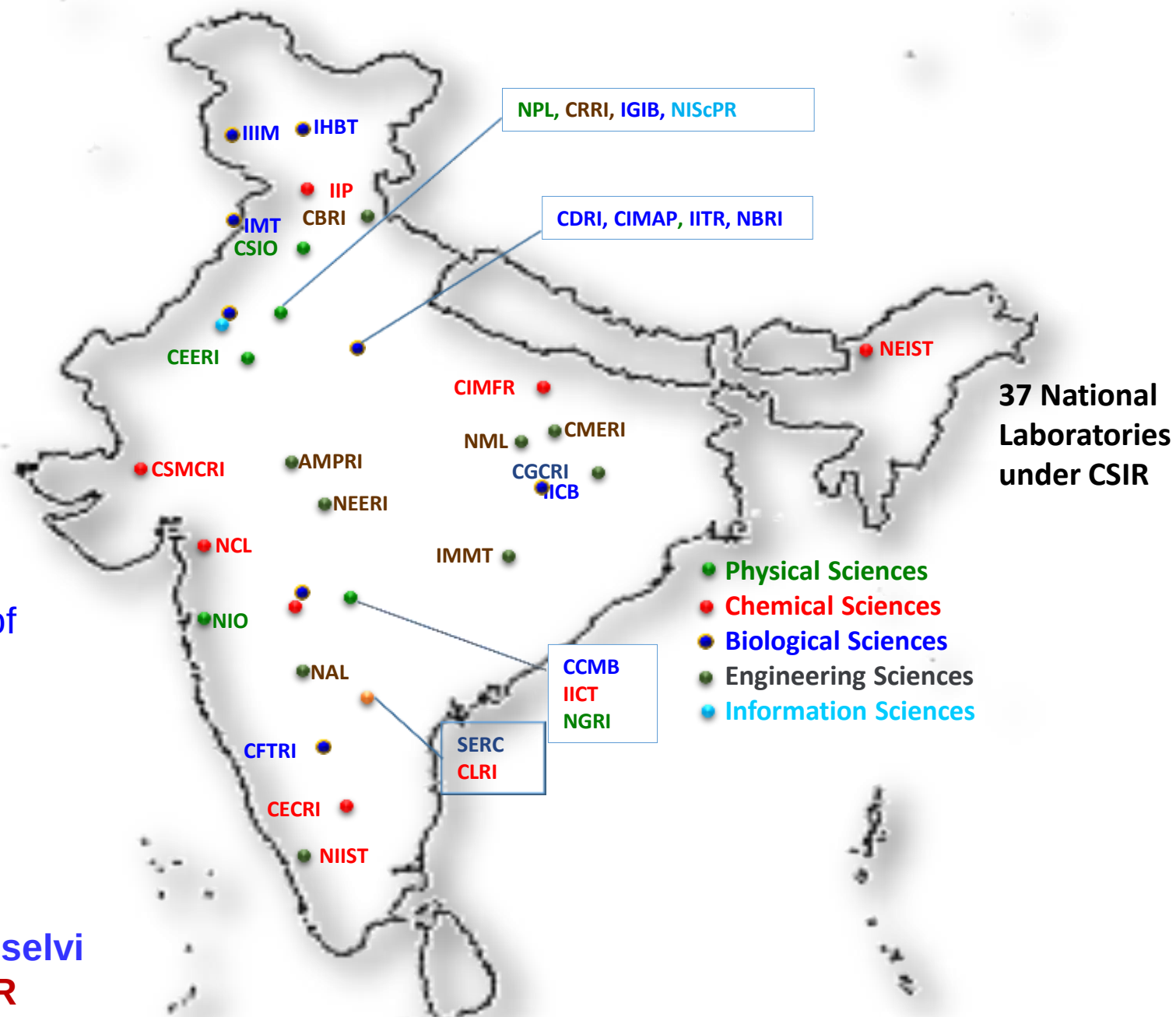
President:
Prime Minister of India



Vice President:
Union Cabinet Minister of
Science & Technology



Dr. Kalaiselvi
DG, CSIR



...Industrial Outlook and Academic Ambience
...80+ years of existence



160+ Scientists
300+ Support staff
1200+ Researchers

1659 Patents Registered
575 in India
1064 Abroad



460+ PhDs Awarded
461+ Present strength

Research Publications
450+ average / year



Organic Synthesis & Process Chemistry

- Process Development- APIs, KSMs
- New Chemical Entities Synthesis
- Impurity Synthesis & Profiling
- Route Selection & Optimization
- Multistep & Asymmetric Synthesis
- Flow Chemistry
- Parallel Synthesis
- Biotransformation

Catalysis & Fine Chemicals

- Homogenous & Heterogeneous Catalysis
- Environmentally benign catalytic processes
- Carbon capture & utilisation
- Small molecule activation & selective conversion
- Vapour phase catalytic reactions

Polymers & Functional Materials

- Specialty polymers
- Organic and Hybrid Coatings, Paints and Adhesives
- Functional and nano materials
- Solar Energy harvesting materials
- Materials for energy storage

Chemical Engineering & Process Technology

- Process Knowhow, Design, Development and Scale-up
- Process Improvements – Industrial Process
- Development of Scalable Flow Processes

Applied Biology

- Cancer Biology
- Stem Cell Biology & Regenerative Medicine
- Recombinant Proteins
- Structural & Functional Proteomics
- Pharmacology & Regulatory Toxicology

Natural Products & Medicinal Chemistry

- Natural Product Chemistry
- Medicinal Chemistry
- Hit-to-Lead Optimization
- Phytopharmaceuticals
- Nutraceuticals
- Synthesis of small molecules
- Computational Chemistry
- Standardization of Medicinal Plants

Oils, Lipid Science & Technology

- Extracting Processing Methodologies
- Biolubricants
- Surfactants
- Castor oil-based products
- Specialty Oleochemicals
- By-product of Vegetable Oils

Fluoro & Agro Chemicals

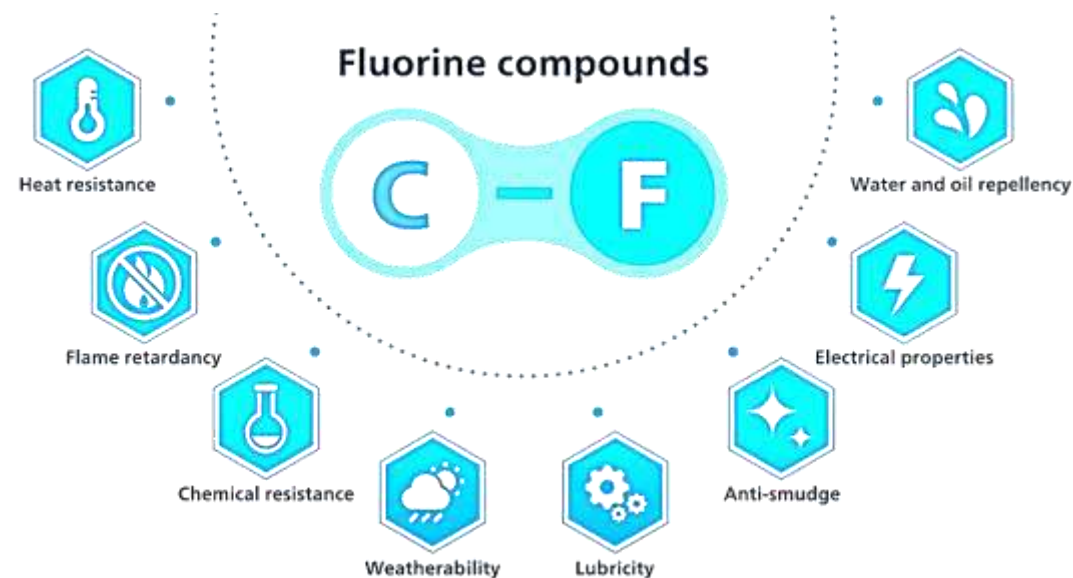
- Agrochemicals
- Plant Based Crop Protection Chemicals
- Fluorochemicals
- Pheromone Application Technology

Analytical & Structural Chemistry

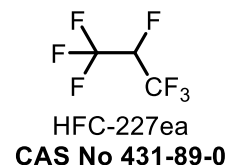
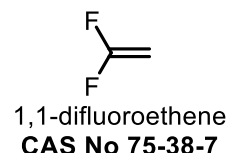
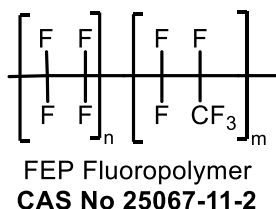
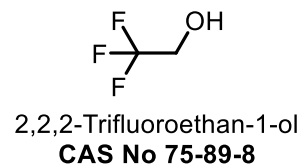
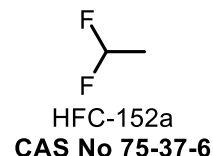
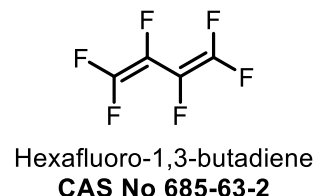
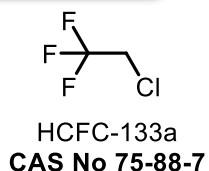
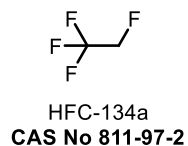
- NMR Spectroscopy
- Mass Spectrometry
- X Ray Crystallography
- Thermal & Surface Analysis
- Photochemistry and Phytophysics

CSIR-ICT Expertise in Fluorochemicals

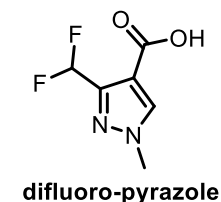
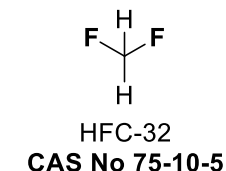
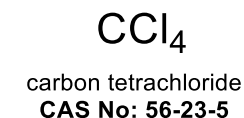
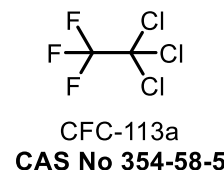
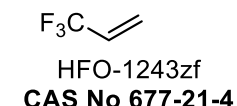
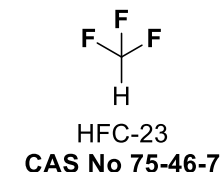
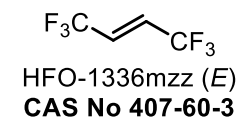
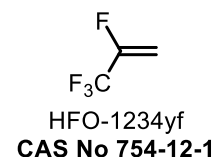
- ❖ Expertise in handling **Anhydrous HF**
- ❖ Catalytic Vapor Phase Fluorination reactions
- ❖ Thermal & Photo Halogenation reactions
- ❖ Pyrolysis reactions in continuous mode
- ❖ Support for Process Data Generation & Reactor Design
- ❖ **Only Academic laboratory in India for R&D in Fluorochemicals**



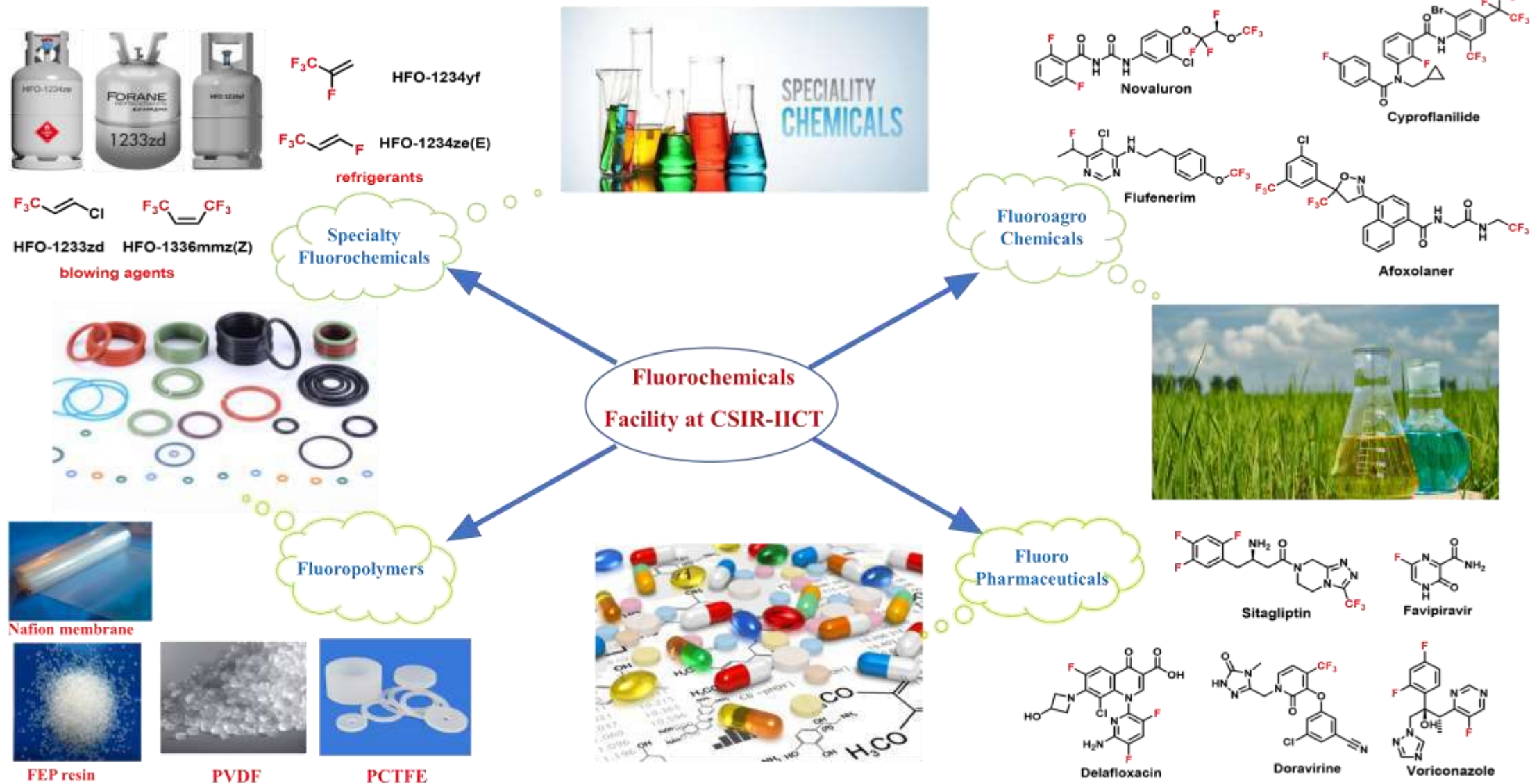
Technologies Licensed



New Processes Developed

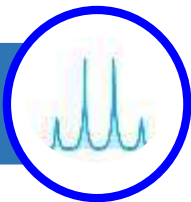


Market Potential





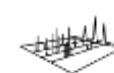
**Centre for NMR &
Structural Chemistry**



Electron Microscopy



**Chromatography,
Separations, Elemental &
Thermal Analysis Unit**



**Quantum Chemical
Calculations / design**



**X-ray
Crystallography**



**Analytical
Facilities**

**Analytical
Instrumentation**



Mass Spectrometry



Laser Spectroscopy



ACHARYA P.C. RAY KILO LAB



Pilot Plant Complex, Moulali
CSIR-Indian Institute of Chemical Technology

PILOT PLANT FACILITIES AT PPC MOULALI, CSIR-IICT



50 L Triple-Walled Glass Reactor



20 L & 50 L Rotary Flask Evaporators

Specification: 50 L Triple-Walled Glass Reactor

MOC: Borosilicate 3.3 Glass

Capacity: 50 L

Temperature: -42°C to 250°C

Pressure: Atmospheric (ATM)

RPM: 0–180 rpm

20 L & 50 L Rotary Flask Evaporator

20 L & 50 L Rotary Flask Evaporator

Specification:

MOC: Borosilicate 3.3 Glass

Capacity: 50 L

Operating Parameters:

Temperature: 20°C to 180°C

Pressure: Full Vacuum

RPM: 0–160 rpm



63 L Glass-Lined Reactor



Continuous Nutsche Filter & Dryer

63 L Glass-Lined Reactor

MOC: Borosilicate 3.3 Glass

Capacity: 50 liters

Operating Parameters:

Temperature: -42°C to 250°C

Pressure: ATM

RPM: 0–180 rpm

Continuous Nutsche Filter & Dryer

Specification:

MOC: Teflon-lined Stainless Steel

Capacity: 50 L

Operating Parameters:

Temperature: 35°C to 150°C

Vessel Pressure: -1 to 5 bar

Jacket Pressure: 2 bar

RPM: 0–100 rpm, flame-proof motor with VFD



PILOT PLANT FACILITIES AT PPC MOULALI, CSIR-IICT



100 L SS High-Pressure Autoclave



**50 L Hastelloy High-pressure
Autoclave Reactor**

100 L SS High-Pressure Autoclave Reactor

Specification:

MOC: SS-316L

Capacity: 100 L

Minimum Stirring Volume: 10 L

Operating Parameters:

Temperature: -40°C to 300°C

Maximum Pressure: 100 bar

RPM: 0–500 rpm

VFD with Digital Indicator

50 L Hastelloy High-Pressure Autoclave Reactor

Specification:

MOC: Hastelloy C-276

Capacity: 50 L

Minimum Stirring Volume: 5 L

Operating Parameters:

Temperature: -40°C to 300°C

Maximum Pressure: 100 bar

RPM: 0–500 rpm

VFD with Digital Indicator

PILOT PLANT FACILITIES AT PPC MOULALI, CSIR-IICT



20 L SS Distillation Column



Vacuumed Hot Air Oven Dryer

Specification: 20 L SS Distillation Column

MOC: SS-316L with suitable lining for handling fluorine compounds

Capacity: 20 L

Operating Parameters:

Temperature: -40°C to 200°C

Maximum Pressure: 10 bar

Specification: Vacuumed Hot Air Oven Dryer

MOC: SS-316L

No. of Trays: 12 Nos.

Operating Parameters:

Maximum Temperature: 800°C

Working Temperature: 700°C

PILOT PLANT FACILITIES AT PPC MOULALI, CSIR-IICT



20 L Reactor & Distillation



50 L Centrifuge

Specification: 20 L Reactor & Distillation

MOC: Borosilicate 3.3 Glass, 7 mm thick

Capacity: 20 L

Operating Parameters:

Temperature: -40°C to 200°C

Maximum Pressure: Full Vacuum to 0.7 bar

RPM: 0–250 rpm

VFD with Digital Indicator

50 L Centrifuge

Specification:

MOC: Teflon-lined Stainless Steel

Capacity: 50 L

Operating Parameters:

Temperature: 37°C

Pressure: ATM

RPM: 0–10,000 rpm

VFD with Digital Indicator



Facility for
Continuous
Processing
Technologies



CSIR IICT presents

From Laboratory
Innovation to Industrial
Scale-up

Way to Industry

FROM INNOVATION TO INDUSTRIAL IMPACT



The Continuous Processing Platform at CSIR-IIICT is being developed as an integrated infrastructure for chemical process development, process intensification, continuous synthesis, scale-up and technology translation.

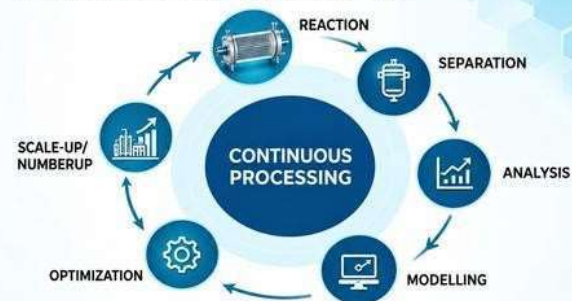
3 CHEMICAL TECHNOLOGIES
Already transferred at laboratory scale to industry partners.

OUR CAPABILITIES



Core Competencies

BUILDING A NEXT-GENERATION



ANALYTICAL & PROCESS MONITORING



MEASURE → UNDERSTAND → OPTIMIZE → SCALE

Laboratory Approach

BUILDING A NEXT-GENERATION CONTINUOUS PROCESSING ECOSYSTEM

CSIR-IIICT is establishing a comprehensive Continuous Processing Platform to accelerate the development, optimization, scale-up and industrial translation of chemical processes.

01



COMMERCIAL CONTINUOUS FLOW REACTORS

Establishment of a versatile reactor infrastructure for liquid-phase, gas-liquid, multiphase, catalytic and intensified chemical processes.

02



CONTINUOUS SYNTHESIS

Development and demonstration of continuous processes for the preparation of industrially relevant chemicals with emphasis on efficiency, safety, productivity and reproducibility.

03



LAB-TO-PILOT SCALE-UP

Translation of laboratory-scale chemistry into continuous operation and progressive scale-up through systematic process optimization and engineering.



Digital Engineering & computational capabilities

CFD / FLOW FIELD VISUALIZATION

Computational modelling for reactor design, flow analysis and process optimization



COMPUTATIONAL CAPABILITIES



Infrastructure for continuous Processing Platform

1 Reactors



2 Down-streaming Equipment



3 Pumps and Accessories



4 Analytical and Characterization Instruments



Exclusive Infrastructure & Facilities (Non-Exhaustive List)



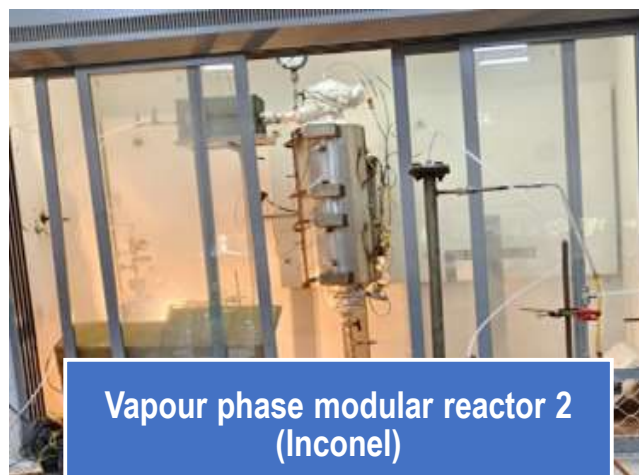
Cryogenic Fractional Distillation
Unit For Purification Of Gases



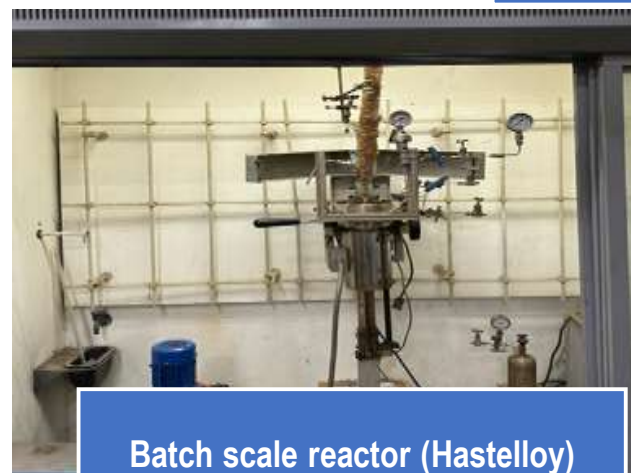
Lab Scale Pyrolyser



Pilot scale reactor/pyrolyser (Haste-
alloy reactor tube with electrical
heating and scrubber)



Vapour phase modular reactor 2
(Inconel)



Batch scale reactor (Hastelloy)

■ Coating Evaluation Facilities

- Adhesion Testing Units
- Scratch Resistance Testing Unit Impact Tester
- Cylindrical Mandrel
- Salt Spray Testing Units
- Accelerated Weather-o-meter
- Different Viscometers
- Humidity Cabinets
- Taber Abrasion
- Dry Abrasion and Washability Tester
- Color spectrophotometer and coating testing

■ Coating and Polymers Processing Facilities

- Sintering & Drying Oven,
- High-Pressure Reactors,
- High-Speed Disperser,
- Triple and rubber roll mill,
- Attritor mill, Dyno mill, Red Devil Shaker,
- Free Film Casting Facilities & Spray Booth
- Spin Coating Unit, Automated Film Applicator,
- Spray Drier,
- Hot Press,
- UV Curing Counter,
- Low Temperature Drying Unit

■ Polymers & Hybrid Materials Characterization Facilities

- Gel Permeation Chromatography (GPC) coupled with HPLC
- Rheometer
- Dynamic Mechanical Thermal Analysis (DMA)
- Differential Scanning Calorimetry (DSC)
- ThermoGravimetric Analysis (TGA)
- Particle Size Analyser (Nano range)
- Video-controlled Contact Angle Analyser & Goniometer
- Electrochemical Impedance Spectroscopy (EIS)
- Electrochemical Work Station
- Four-probe Source Meter
- Cyclic Voltammeter
- Universal Testing Machine (UTM)
- Karl Fischer Titrimetric Analysis
- UV visible Spectroscopy
- Infrared Spectroscopy (IR) Thermal Conductivity Measurement Unit

- Reaction engineering labs (batch & continuous flow reactors)
- Multiphase & hydrodynamic cavitation reactor systems
- Polymer processing & composite fabrication facilities
- Membrane separation units (UF, RO, HFMC systems)
- CO₂ capture and gas absorption pilot plants
- Electrochemical reactors for hydrogen production (electrolysis units)
- Thermal processing units (furnaces, pyrolysis systems)
- Water treatment pilot plants (mineral enrichment systems)
- Pilot-scale systems for fluorination
- HF-compatible equipment (Inconel, Hastelloy)
- Vapour-phase catalytic and continuous flow reactors
- High-pressure/high-temperature reactors
- Corrosion-resistant and controlled-atmosphere processing units
- Insectary and insecticide screening facility
- Semiochemicals behaviour study facility
- Biopesticide development unit
- State of the art formulation facility for agrochemicals
- Photochemical reactors; electrochemical reactors
- Chromatographic analysis: GC
- Materials characterization: XRD
- Thermal analysis: TGA
- Gas analysis systems (CO₂ capture efficiency, H₂ detection)
- Membrane characterization & performance testing setups
- Process Analytical Technology (PAT) tools for real-time monitoring
- Sensor integration & data acquisition systems
- AI/ML-enabled multivariate data analysis platforms
- Gas Chromatography-Electroantennographic Detection (GC-EAD)
- Gas Chromatography-Mass Spectrometry (GCMS)
- Liquid Chromatography-Mass Spectrometry (LCMS) & HPLC
- Wind tunnel

- Chromatographic analysis: GC
- Materials characterization: XRD
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- Gas Chromatography-Mass Spectrometry (GCMS)
- Liquid Chromatography-Mass Spectrometry (LCMS) & HPLC
- Wind tunnel
- Solution state NMR: 300-700 MHz
- Solid state NMR : 500 and 700 MHz
- 600 and 700 MHz with Cryoprobe
- Qualitative and Quantitative
- ¹H, ¹³C, ³¹P, ¹⁹F, ¹⁵N NMR Services
- 2D – NMR studies, COSY, ROSEY, NOESY
- Low temperature NMR
- Dual source (Cu & Mo) Single Crystal XRD
- Powder X-ray diffractometer
- DSC, TGA analysis
- Polymorphism
- Crystallization
- Phase identification
- Quantitative Analysis
- Customized XRD studies
- UV-Vis-Nir Spectrometer
- Fluorescence Spectrometer
- Scanning Electron Microscope
- Pump/Probe Spectrometer
- Upconversion Spectrometer

Why Choose TTFC?

TTFC bridges research and industry by enabling smooth technology transfer and IP commercialization. It empowers MSMEs and startups with expert support, ready-to-use technologies, and faster market access.

Eligibility Criteria

- ✓ MSME Udyam Registration certificate
- ✓ Self Declaration
- ✓ Bank Mandate
- ✓ Original copies of corresponding bills and vouchers

CSIR-IICT Technology Transfer Facilitation Centre (TTFC)

MSME INNOVATIVE SCHEME



Bridging Innovation with Industries

MSME-SCIP PROGRAMME

The MSME-SCIP Programme by the Ministry of MSME strengthens MSMEs by bridging technical knowledge and supporting IP commercialization through a dedicated network of Technology Transfer Facilitators.

Sanctioned by Ministry of MSME, Govt. of India

OUR COMPREHENSIVE SERVICES

1. IP Access/Acquisition Fee Reimbursement
2. Foreign Trademark & Design Registration
3. Technology Assessment & IP Valuation
4. Tailored Technology Transfer & Licensing
5. TRL Enhancement Consultancy
6. Commercialization Support & Industry Linkages
7. Capacity Building on IP & Tech-Transfer

IP ACCESS/ACQUISITION FEE REIMBURSEMENT

Funding Ratio: Reimbursement encompasses a maximum of 70% of the total eligible cost, with the remaining 30% borne by the MSME

IP Access/Acquisition Reimbursement

S.No.	Component	Max Limit (INR) 70% of cost
1	Indian Patent	₹10 Lakhs
2	Foreign Patent	₹15 Lakhs
3	Copyright or Trademark	₹2 Lakhs
4	Biomaterial or Tangible Research Property	₹10 Lakhs
5	Datasets	₹3.5 Lakhs
6	Know-how or Trade Secrets	₹10 Lakhs

Foreign Trademark & Design Registration

S.No.	Component	Max Limit (INR)
1	Foreign Trademark	₹1.5 Lakhs
2	Foreign Design	₹1.5 Lakhs

Key Benefits

- ✓ Supports MSMEs in IP commercialization
- ✓ 70% cost coverage for IP acquisition
- ✓ International IP protection support
- ✓ Easy online/offline application process

Reimbursement to following MSME's by IICT-TTFC [FY 2025-2026]

S. No	Name of MSME	Udyam ID	Technology Transferred	License Fee paid	IICT-TTFC Reimbursement
1	Devi BioCNG Private Limited, Hyderabad	UDYAM-AR-15-0000049	Anaerobic gas lift reactor (AGR)	Rs 10,00,000	Rs 7,00,000
2	Devi BioCNG Private Limited, Hyderabad	UDYAM-AR-15-0000049	Thermochemical valorization	Rs 10,00,000	Rs 7,00,000
3	Kaashyap Envergy Infrastructures private Ltd	UDYAM-TS-20-0108654	Anaerobic gas lift reactor (AGR)	Rs 10,00,000	Rs 7,00,000
4	Sattvam life Sciences Pvt. Ltd.	UDYAM-KR-03-0498202	Process Know How The development of Bio-pesticide by CSIR- IICT	Rs 3,00,000	Rs 2,10,000
5	Bionest Orgaanic	UDYAM-TS-02-0298000	Biodegradable table wear from agri biomass	Rs 5,00,000	Rs 3,50,000
6	ARK Bio Energy Private Limited	UDYAM-TS-09-0147774	Anaerobic Gas Lift Reactor (AGR)	Rs 10,00,000	Rs 7,00,000

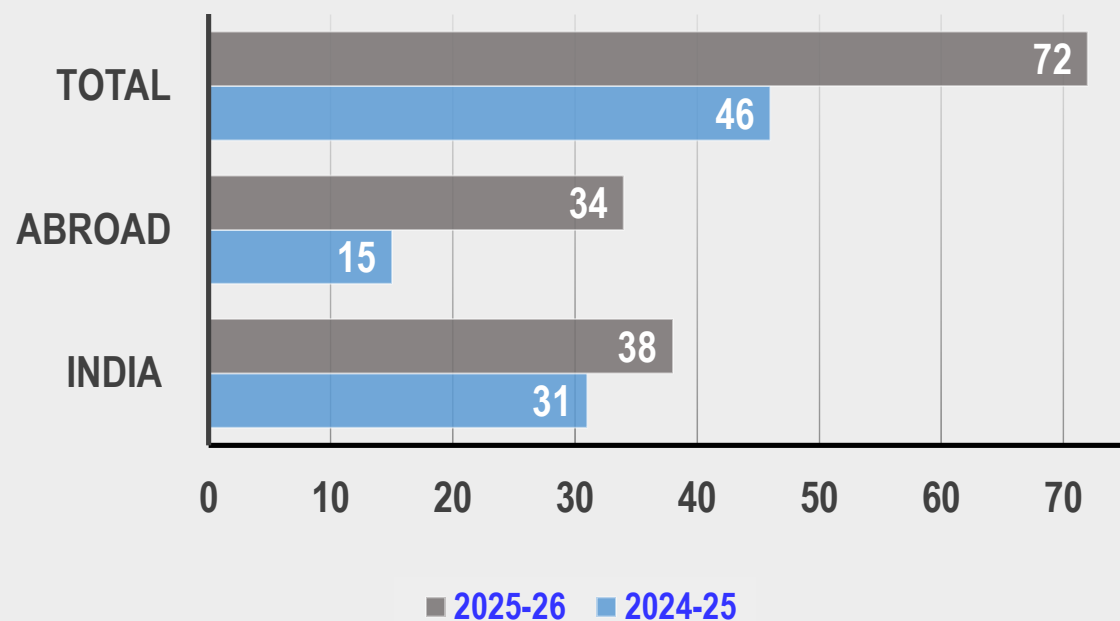
Total : Rs 33,60,000

IICT-TTFC has fully utilized the sanctioned funds for reimbursement to eligible MSMEs under the MSME Innovative Scheme.

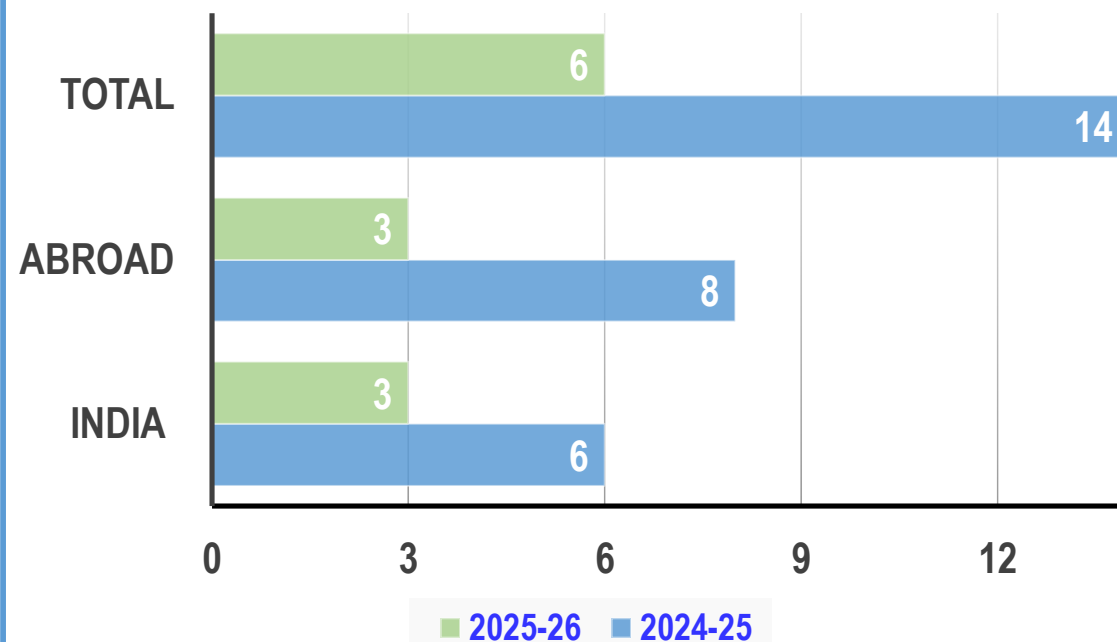
Successfully Filed a Trademark for TTFC Logo



Patent Filed

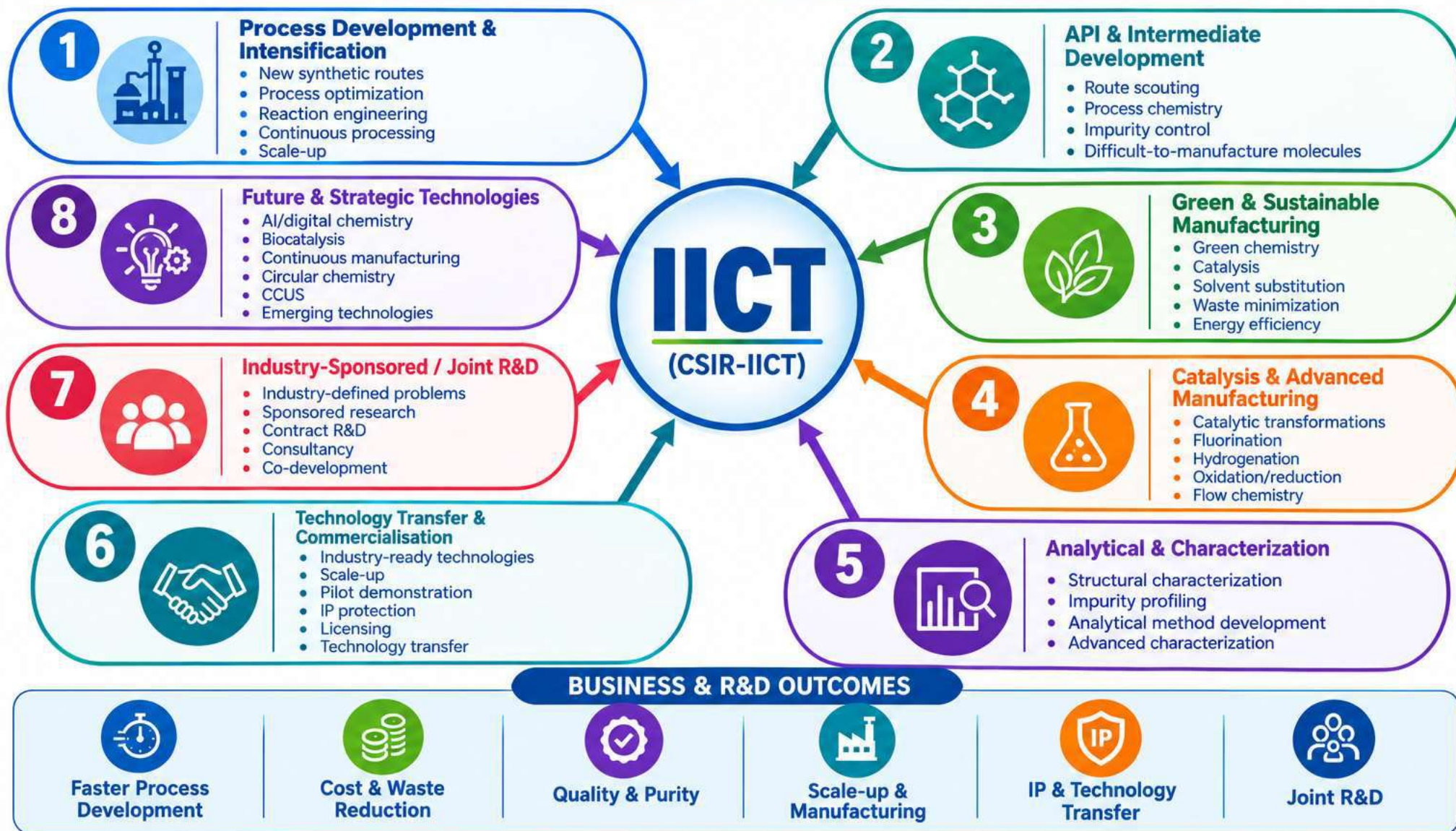


Patent Granted



WHERE CAN THE BULK DRUG INDUSTRY COLLABORATE WITH CSIR-IICT?

Industry Needs → CSIR-IICT Expertise → Collaborative Outcomes



Best Practices

Ease of Doing Business

- **Single point of contact**
- **Quick response to queries**
- **Simple templates of (NDA, MCA & MoU)**
- **Time-bound decision making**
- **Streamlined IP policy**

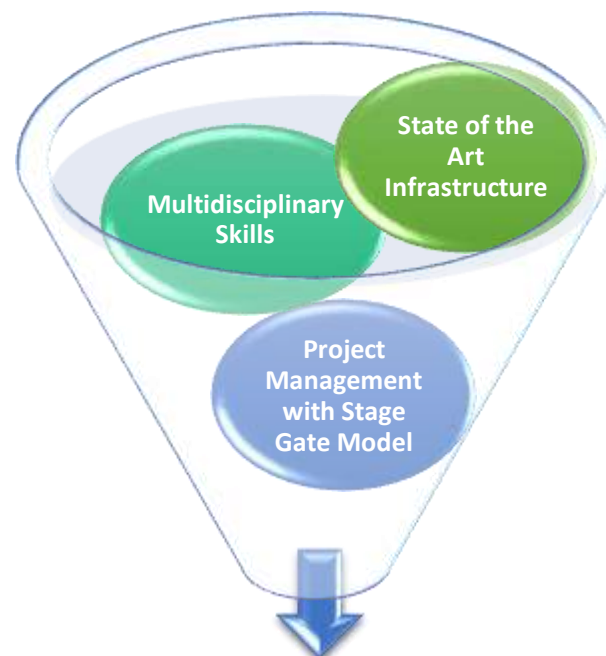
Will of Doing Business

- **Customized Business Models**
- **Flexibility on Non-exclusive licensing**
- **Stringent follow up & coordination**
- **Timebound delivery**

Feedback and Response

- **3 Tier Project management strategy**
- **Weekly review with Stage Gate Model**
- **Getting client feedbacks**
- **Constant status updates to client**

USP of IICT



Concept to Commercialization

Full Value for Money

Business Models

Technology Licensing (of Intellectual Property Rights)

Sponsored Research / Fee for Service

Consultancy Services

Technical Services

Training and Skill Development

Collaborative Research Model



Dr. Pravin R. Likhari

Scientist-G & Chair,

Business Development & Research Management (BDRM)

CSIR–Indian Institute of Chemical Technology (CSIR-IICT)

Hyderabad – 500 007

Ph: +91-40-27193992

Email: plikhar.iict@csir.res.in,



Thank you all !!

Central Drugs Standard Controls Organisation (CDSCO)

KEY REGULATORY REFORMS UPDATE

Drug Approvals · Scientific Review · Medical Devices

CDSCO, under guidance of MoHFW, initiated Drug Regulatory Reforms journey as a focused activity in 2023. Since then multiple major and minor reforms have been implemented and many more are in pipeline. Reforms have been taken to support stakeholders through “Ease of Doing Business” and help fast and innovative drug development in India. The following slides will show some of the major reforms and their impact on various application approval timelines, as one of the main success indicators. Many more are in pipeline which, once completed, will change the complete Drug and Medical Device regulatory framework in India and will significantly impact global healthcare supply chain

DRUG REGULATORY REFORMS – IMPLEMENTED & OPERATIONALIZED

Drug Approval Process Reforms - *Implemented*

Reducing barriers from lab to market

01

Reforms in Drug Approval Process

✓ LAUNCHED

Waiver of Permission to Manufacture New Drug for Examination/Testing (T-Lic)

Dated 20.01.2026 providing system of intimation instead of obtaining permission (NoC) from Central Drugs Standard Control Organization (CDSCO) for manufacture of majority of drugs up to pre-Clinical stage

Impact -

Reduction in drug development timelines, faster market access:

Amendments expected to reduce drug development timelines by at least 90 days; statutory processing period for test licences reduced to 45 days.

Waiver of Permission for BA-BE Studies for Export Purpose (Intimation Mechanism)

New Drugs and Clinical Trials Rules were amended vide G.S.R. 50(E) dated 21.01.2026, providing a system of prior intimation for conducting BA/BE studies for export purpose in defined cases already approved in the country or any one of the countries namely, USA, EU, Japan, Australia, Canada and United Kingdom of a drug subject to certain conditions

Impact -

- **Faster Study Initiation (Prior Intimation vs. Prior Permission).**
- **Reduced Regulatory Hurdles for Exports.**
- **India's improved Generics standing in the world.**
- **Increased number of international studies in India because of high predictability – increased business opportunity and ease of doing business**

Waiver of Local Clinical Trials (Certain Drug Categories from Specified Countries)

Specified countries (USA, UK, Japan, Australia, Canada and EU) under the Rule 101 of New Drugs and Clinical Trial Rules given waiver of local clinical trial for approval of new drugs. Around 30% applications for CT have been given waiver.

Impact -

- Provides faster access of medicines to Indian patients for Orphan Drugs, Gene and cellular therapy products, New drugs used in pandemic situations, New drugs for special defense purpose, and New Drugs having significant therapeutic advance.

Simplification of Export NOCs (Online, 1-year Validity)

Export NOCs for unapproved drugs are being issued online with 1-year validity/exhaustion of the sanctioned amount whichever is earlier instead of earlier practice of issuing quantity specific NOC.

Impact -

- **Reduced administrative burden.**
- **Flexibility for exporters.**

Auto-generated Certificates for Medical Devices for Export (Neutral Code, Market Standing, Conviction)

Streamlined the system for auto generated neutral code, market standing certificate and conviction certificate for the medical device manufacturers for export purpose on 09.04.2025

Impact -

- Reduced administrative burden.
- Flexibility for exporters.

Simplification of Dual-Use NOCs (Annual NOC, Reduced Checklist)

Streamlined the process of online issuance of NOCs for dual use products by changing from the consignment-based NOCs to an annual NOC and further the checklist of the application has also been reduced

Impact -

- Predictability & Planning
- Reduced Administrative Burden
- reduced paperwork.

Deemed Approval for Post-Approval Applications for Global Clinical Trials (30-day Rule)

Post approval applications for additional site and change in PI for Global Clinical Trials are considered deemed to be approved if no objection is received from the CDSCO within 30 days with the condition that it is approved by Ethics Committee. It has been effective since 26th December 2024

Impact -

- Reduces delays for sponsors, making India a preferred destination

Scientific Review Process Reforms - *Implemented*

Building capacity for deeper scientific regulation

Digital Dash Board :

Status of every submitted application for approval is visible at every level on SUGAM

Impact -

- Better monitoring and supervision
- Effective Timeline Management

Engagement of Non- Governmental Subject Experts in SECs (IND and CGTPs)

CDSCO has already started involving non-governmental subject experts as members of the Subject Expert Committees (SECs) especially related to Investigational New Drugs (IND) and Cell, Gene, and Tissue Therapy Products (CGTPs), to strengthen scientific evaluation and regulatory oversight in this emerging domain.

Impact -

- Improved scientific rigor
- Enhanced patient safety
- Faster decisions
- Global credibility

Internal Expertise for Clinical and Pre-Clinical Protocol/Data Review

Taken relevant expertise on loan from ICMR as shared resource
(3 days a week)

Impact -

- Stronger scientific review

Human Resource Reforms [220 (Drug) + 219 (MD)] New Posts, Recruitment Rules, UPSC Proposals)

220 posts, including 140 Posts of Drugs Inspectors, have been created in 2022. Furthermore, 219 posts have been created in Medical Devices Vertical. New Recruitment Rules (RRs) for Drugs Inspector (Drugs Vertical) have been notified on 11.11.2025 and for Drugs Inspector (Medical Devices Vertical) have been notified on 06.11.2024.

Impact -

Enhancing regulatory capacity

- *The proposal has been sent to UPSC for recruitment of 186 posts of Drugs Inspector (Drugs Vertical)*
- *The proposal for 20 posts of Drugs Inspector (Medical Devices Vertical) is with UPSC, Written exam has been completed, awaiting interview of successful candidates*
- *The proposal for 22 posts of Assistant Drugs Controller (I), Medical Devices is also with UPSC*

Training Cell & Skill Development

- Over the past three years, CDSCO has undertaken several initiatives including induction training programs for newly recruited personnel, both in CDSCO and State Regulators, **advanced thematic trainings on biologics, medical devices, clinical trials, pharmacovigilance, and quality management systems including GMP, GDP, etc., as well as refresher programs for in-service officers.** CDSCO in association with Drug manufacturing associations has also organized various workshops **across the country for the industries.**
- Currently 13 virtual online training modules on GMP have been created and uploaded on training portal, additional 18 modules are under final stages.
- The whole training initiative is focused around upgrading required knowledge for Regulators, both CDSCO and States and for industry employees
- Various training sessions are being conducted in collaboration with THSTI, CII, FICCI, WHO on regular basis for stakeholders including central and state regulators

Impact -

- **Stronger regulatory workforce.**
- **Greater uniformity in regulation.**
- **Improved industry compliance.**

Medical Devices Regulation Reforms - *Implemented*

Enabling innovation and strengthening oversight

CHANGES TO ADDRESS MD Vertical's INDEPENDENCE AND DOMAIN EXPERTISE

1	Separate dedicated vertical with its separate leadership has been created in CDSCO which is fully operational
2	New Recruitment Rules (RR) has been approved for Medical Device (MD) regulators bringing all relevant educational qualifications including engineering degrees like Biomedical, Mechanical, Electrical, Computers engineering.
3	UPSC has already initiated recruitment process for 20 Drugs Inspectors-MD, 22 Assistant Drugs Controllers - MD and 9 Deputy Drugs Controllers - MD with revised RR
4	Essential qualifications for MD regulators have been included in revised RR for Drugs Controller General notified on 20 th April 2026
5	Medical Device Technical Advisory Group (MDTAG) has been operationalized and 2 meetings have happened till date

Medical Devices (MD) Regulation

✓ LAUNCHED

INCREASING OPERATIONAL EFFICIENCY & DECREASING APPROVAL TIMELINES

	INCREASING OPERATIONAL EFFICIENCY & DECREASING APPROVAL TIMELINES
1	MD Rules were the first 100% digital Regulatory System in India – an updated database is being prepared on continuous basis
2	Auto-generated Certificates for Medical Devices for Export (Neutral Code, Market Standing, Conviction)
3	Exemption from Licensing for Class A Medical Devices (Non-Sterile, Non-Measuring)
4	Auto-Allocation of Applications: System-driven allocation of applications to reviewers ensures equitable workload distribution, faster processing, and enhanced accountability.
5	Online Risk Classification Module: Digital tool for classification of medical devices improves transparency, consistency, and ease of access
6	Development of Tooltips and Guidance for Applicants: tooltips and guidance related to submission of applications provided in the application forms to assist in filing

	EASE OF DOING BUSINESS AND INDUSTRY SUPPORT
1	Development Guidance for Software as Medical Device (SaMDs) has been released for helping industry
2	Total no. of Manufacturing units of Class A & B devices licensed : ~ 3327 Total no. of Manufacturing units of Class C & D devices licensed : ~ 1077 Import license applications (Class A, B, C & D) approved: ~ 12490
3	Creation of MedTech Mitra platform with aim to foster development of affordable and accessible Medical Devices/ In-Vitro Diagnostics by providing strategic handholding support to innovators/start-ups. Technical Advisory Committee Meetings conducted: 47 meetings Total application received: 847 Nos. Applications addressed: 742 Nos. Regulatory support provided: 605 Nos.
4	Release of compendium of standard In-vitro diagnostics (IVDs) evaluation protocol (39) in coordination with ICMR

Medical Devices (MD) Regulation

✓ LAUNCHED

	CAPACITY BUILDING
1	The Training cell of CDSCO already conducted the annual training programme in Medical Device regulations for 155 regulators during last 03 years, both from Central and State regulatory authorities
2	CDSCO in cooperation with CII has initiated workshop for industry associations/stakeholders to have direct interaction on the challenges faced during implementation of MDR-2017. 03 such workshops were already completed in 2025 in different places of the country.
3	India is an Affiliate member of International MD Regulatory Forum (IMDRF)
4	Essential qualifications for MD regulators have been included in revised RR for Drugs Controller General notified on 20 th April 2026
5	Complete MD Regulatory value chain is part of Digital Drugs Regulatory System (DDRS) being developed as new platform for country's regulatory system

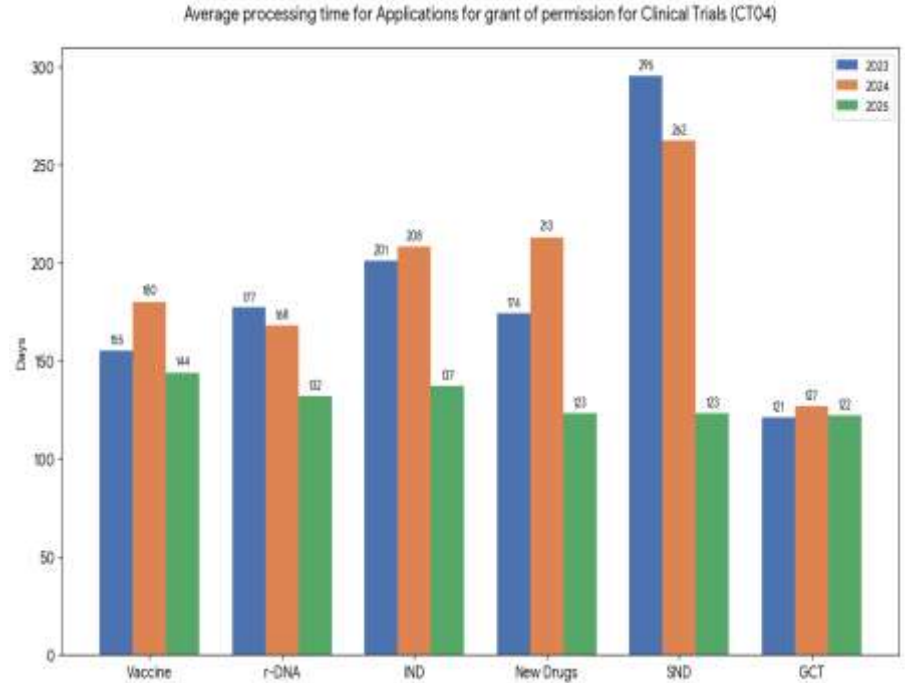
IMPACT OF REFORMS

APPROVAL TIMELINES

- ONE OF THE MAJOR ASKS OF INDUSTRY HAS BEEN IMPROVEMENT IN APPROVAL TIMELINES FOR DIFFERENT APPLICATIONS
- CDSCO HAS BEEN ABLE TO ADDRESS THE CONCERN THROUGH COMBINATION OF MULTIPLE DIFFERENT INITIATIVES LIKE – Digitization, close monitoring, capacity building, process rationalization etc.
- THERE IS FURTHER SCOPE OF IMPROVEMENT – WORK IS IN PROGRESS.
- YoY APPROVAL TIMELINES IN SOME OF THE CASES IS GIVEN IN THE FOLLOWING SLIDES

Clinical Trials Application Approval Timelines

Clinical Trials Application Approval Timelines			
DIVISION	2023	2024	2025
	Number of Days		
Vaccine	155	180	144
r-DNA	177	168	132
IND	201	208	137
New Drugs	174	213	123
SND	295	262	123
GCT	121	127	122

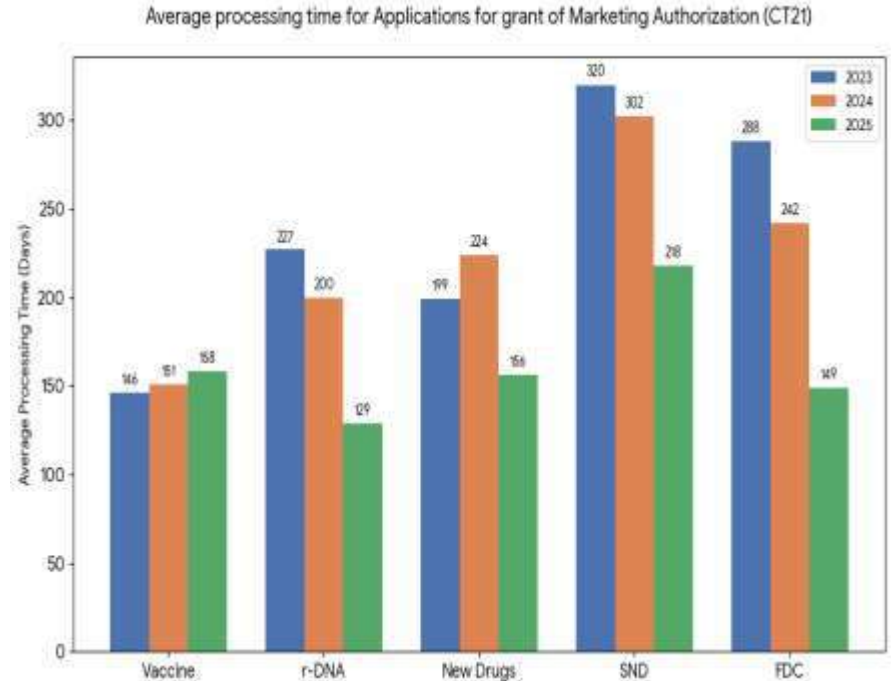


Source : Sugam Approval Data

r-DNA – Biosimilars; IND – Investigational New Drug; SND – Subsequent New Drugs; GCT – Global Clinical Trials

Marketing Authorization Approvals

Marketing Authorization Approvals			
DIVISION	2023	2024	2025
	Number of Days		
Vaccine	146	151	158
r-DNA	227	200	129
New Drugs	199	224	156
SND	320	302	218
FDC	288	242	149

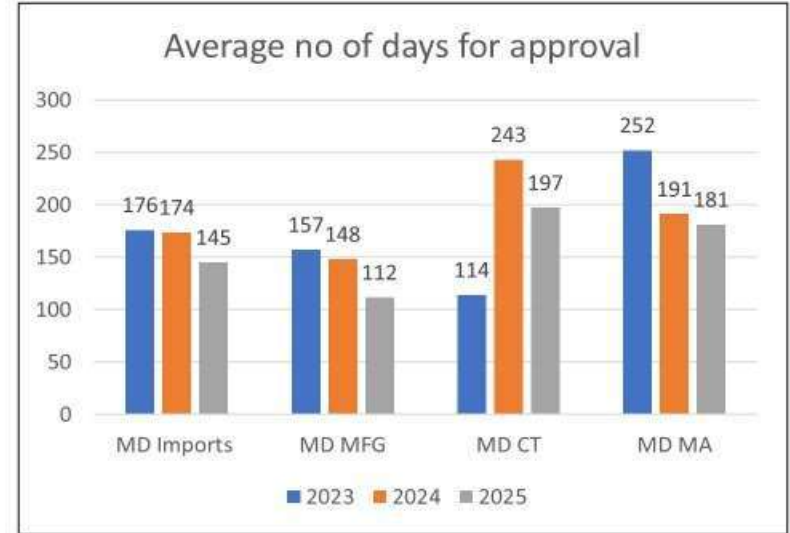


Source : Sugam Approval Data

r-DNA – Biosimilars; IND – Investigational New Drug; SND – Subsequent New Drugs; FDC – Fixed Dose Combinations

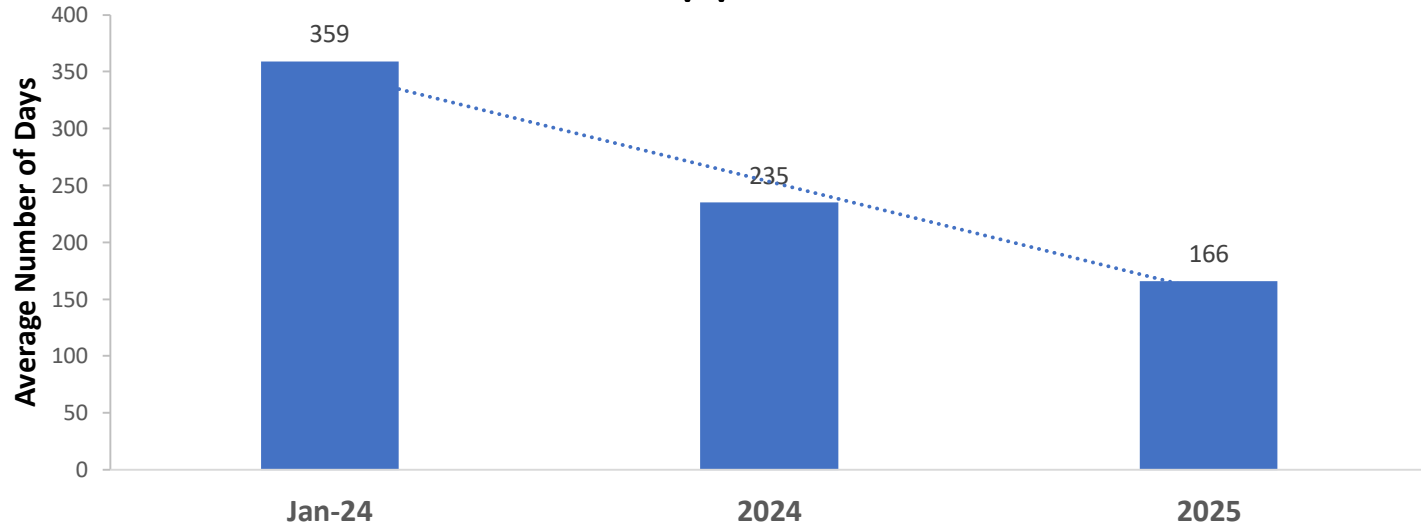
Medical Devices

Average no. of days for approval			
	2023	2024	2025
MD Imports	176	174	145
MD MFG	157	148	112
MD CT	114	243	197
MD MA	252	191	181



Source : MD Online Approval Data; MD-Medical Devices, MFG-Manufacturing, CT-Clinical Trials, MA-Marketing Authorization

Blood Bank Applications



Year	Average Time Taken (Days)
Jan-24*	359
2024	235
2025	166

* Digital Platform for Blood Bank Licensing started in Jan'24

Source : ONDLS Blood Bank Approval Data

Export NOC- Statistics

[07-March-2025* to 31st August-2026]

1. *Centralized, Digital Export NoC Application was started from 7th March 2025 to streamline, simplify and to get quick turnaround
2. Before Digital, States used to issue Export NoC, based on physical application. There was variation among states and some states used to take up to 2 months to issue the NoC
3. Post digitization, the approval timeline has reduced significantly

Total no. of applications received	45152
Number of applications approved	36123
Average no. of days to approval ^{\$}	9.44

^{\$} - Before centralized Digital platform, different states used to take anywhere between 20 days to 2 months

DRUG REGULATORY REFORMS – *WHAT IS IN PIPELINE*

STRUCTURAL REFORMS WITH LONG-TERM IMPACT – *In Pipeline*

STRUCTURAL REFORMS WITH LONG-TERM IMPACT

	REFORMS	STATUS
1	Sanction of 1500 positions to build internal scientific cadre at CDSCO	CDSCO constituted a committee consisting representatives from DoP, ICMR, MoHFW and CDSCO. Committee has given detailed proposal for creation of the scientific cadre. The said proposal has also been discussed with major stakeholders in the Private Sector. Proposal under approval at DoE
2	Use of Notified Bodies / Experts for Auditing some part of Regulatory Value Chain	Discussion with QCI on skills, competence, monitoring and financial model completed. Final proposal is awaited from QCI. Concerns have been expressed by WHO on the proposal which has been clarified with them. Pilot will be initiated in non core areas like Ethics Committee and Clinical Trial Site Audit.
3	Digital Drug Regulatory System (DDRS) – Development of Digital Platform to include India's end to end Regulatory Value Chain including CDSCO, States, PGAs, manufacturers, sellers and other stakeholders	- Bidding on GeM completed - Technical Evaluation of vendors ongoing - First Phase to be fully operational in 18 months from award of development contract 

Drug Approval Process Reforms – *In Pipeline*

Reducing barriers from lab to market

Drug Approval Timelines

In progress

Waiver of Import Permission for Drugs for Testing (Notification)

Drugs Rules, 1945 are under consideration for amendment to provide system of intimation instead of obtaining license from Central Drugs Standard Control Organization (CDSCO) for import of certain categories of drugs in Form 11 for analytical and non-clinical testing.

- **Reduction in drug development timelines, faster market access.**

Waiver for permission of BA-BE studies for Domestic Purpose

Waiver for obtaining permission for conduct of BA-BE studies for domestic purposes in certain categories of New drugs under process

- **Faster Development.**
- **Support Innovation and domestic drug development.**

Waiver of Animal Toxicity Studies for Intravenous Infusions/Injectables

Draft Published G.S.R. 45(E) dated 20.01.2026 for waiving conductance of sub-acute animal toxicity studies for intravenous infusions and injectables when the test product, in respect of its excipients, is qualitatively and quantitatively same as reference product

- **Reduce compliance burden & faster approvals**

Replace Form 29 (State FDA Approval) with Notification-Based System for Test/Analysis

Proposal to replace approval under Form 29 from State FDA for examination, test or analysis with a notified-based system.

- **Reduce State Variation**
- **Reduction in drug development timeline and faster market access**
- **DCC sub-committee formed to look at the proposal and recommend**

Exemption from NOC from RCGM (Category 1 & 2)

Draft Biosimilar Guidelines : Streamlined the process of approval to manufacture test items for examination, test and analysis by removing the requirement of obtaining NOC from RCGM (Review Committee on Genetic Manipulation) w.r.t. products falling under category 1 & 2 GE experiments. Final concurrence from RCGM/DBT is awaited

- **Reduced compliance burden.**
- **Faster market access for patients.**

Scientific Review

Building capacity for deeper scientific regulation

02

Guidance Documents (Ease of filing, Innovation & Advanced Therapies)

Multiple Guidance documents have been released to facilitate application process e.g. Subject Expert Committee Operational Guidelines (GL), Dossier Based Licensing GL, Draft Biosimilar GL, Draft Post Approval Changes GL, Stability Studies for In Vitro Diagnostics GL, Medical Device Software GL etc.

- **Global harmonization.**
- **Improved clarity for industry.**
- **Faster and Cost-Effective Development.**

Internal Scientific Reviewer Cadre (+ 1500 New positions)

The proposal regarding strengthening CDSCO by Creating: Scientific Reviewer Cadre of 1,500 scientific resources is under approval. The cadre to comprise regular employees (60%) and flexi pool (40%). The flexi pool to comprise: fixed-term contract resources, scientific and technical personnel on deputation from organizations (such as ICMR, DBT, CSIR, NIPERs etc.)

- **Improved predictability.**
- **Faster approvals of new drugs.**
- **Improved surveillance.**
- **Alignment with global standards:**

THANK YOU

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