CRAMSN
Research Park

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Delivering Excellence, Driven by Science

Research | Development |
Manufacturing |
Commercial Supplies

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www.cramsn.com

About CRAMSN

CRAMSN is a One-Stop-Shop CRO, CMO and CDMO service partner for the pharmaceutical industry. We differentiate ourselves with the world class R&D and manufacturing capabilities enabling partners to transform their Ideas from Concept to Commercial. CRAMSN's ability to offer end-to-end solutions or support standalone programs with efficiency, quality, and consistency enables faster go-to-market strategies and improved access for patients while placing sustainability and social responsibility at the core of our ambitions.

Vision:

- To be the '**Trusted Strategic Service Partner**' for the Global Pharmaceutical ecosystem by providing Innovative and Novel solutions from Drug Discovery to Commercial phase.

Mission:

To be the **Partner of Choice** in CRO, CDMO & CMO domains by providing

- Best in class infrastructure & Quality systems
- Experienced & competent scientific workforce
- Dedicated world class project management service for seamless delivery
- Regulatory services & support
- Commercial manufacturing capabilities - milligrams to Tonnes

We add accelerated value to customers by playing a pivotal role in the value chain of improving human health with a strong focus on Sustainability.

State-of-the-art & fully-integrated facilities

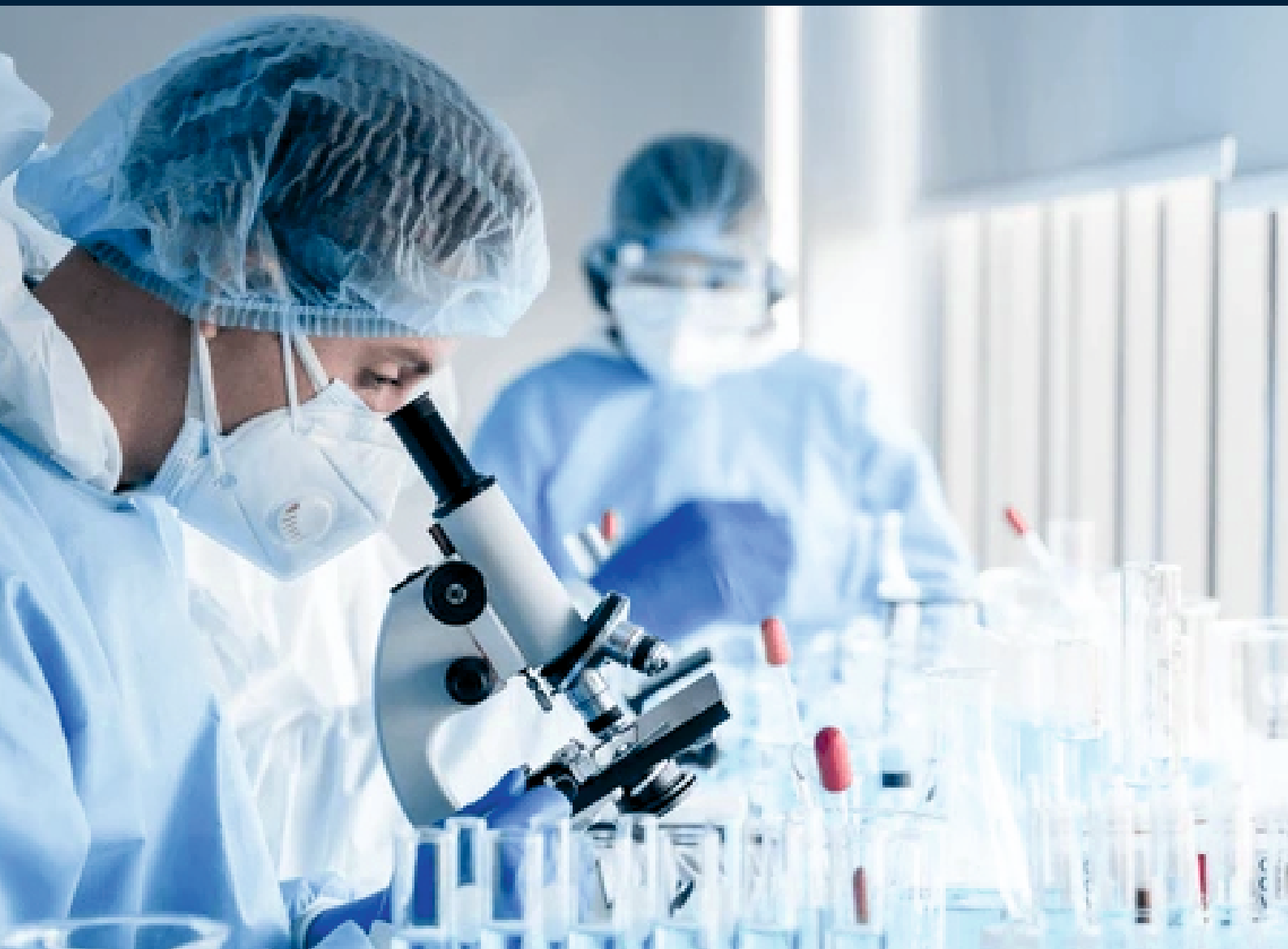
2 R&D Centers

17 API Units

8 FDF Units

Advantage CRAMSN

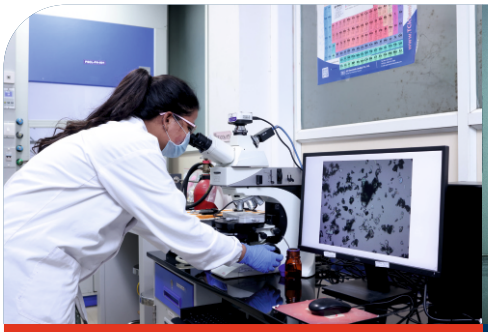
- CRAMSN is a comprehensive service provider, offering end-to-end support from early development through commercial phase programs.
- Extensive expertise in Conventional, Complex, and Niche Chemistries, including Oncology, Prostaglandins, Steroids, Peptides, and Oligonucleotides.
- Innovative, safe and cost-effective solutions for both Drug Substance (DS) and Drug Product (DP) needs.
- Advanced, digitally driven tools and technologies, including eLNB, LIMS, DoE, QbD, SAP, ISMS, QMS, PM tools, and Pharma 4.0.
- Specialized in crystallization studies for polymorph, salt, and co-crystal screening.
- Highly experienced in providing regulatory support for IND, NDA, and CTD filings.
- Utmost respect for IP and data security, ensuring confidentiality and protection.
- All 25 manufacturing facilities (API and Formulations) are accredited multiple times by stringent regulatory bodies worldwide.
- Fast decision-making backed by strong financial stability.



Drug Substance Solutions

Service offerings in:

- Small molecules
- Peptides & Oligos
- Steroids & Hormones
- HPAPIs
- Labeled compounds
- Prostaglandins
- Iron-Carbohydrate nano particulate complexes
- Flow chemistry
- Polymeric molecules



CRO

- Med-Chem
- Route scouting
- Library generation
- Process Development
- Lead optimization
- Synthesis & Supply of preclinical / clinical quantities (Tox & cGMP Supplies)
- IND enabling

CDMO

- Route assessments
- Process Optimization (DoE & QbD Studies)
- Process engineering & Safety studies
- Analytical Method development and validations
- Polymorph, Salt & Co-Crystal screening studies
- Scale up studies, Technology Transfer & Manufacturing
- Registration & validation batches
- NDA enabling

CMO

- Technology Transfers
- Familiarization studies
- Scale-up studies
- Validation batches
- Commercial manufacturing up to multi MT scale

Drug Substance Capabilities

- Handling of molecules with multi-step synthesis, involving 30+ stages.
- Expertise in managing chiral molecules with multiple chiral centers through resolution/asymmetric synthesis.
- Capable of performing cryogenic (-80°C to -100°C), high-temperature (up to 180°C), and high-pressure (upto 10 kg) reactions.
- Specialized in synthesizing Oligonucleotides in batch sizes of 10-20 µmol.
- Capable of synthesizing Peptides with more than 30 Amino Acid sequence, from mg to kg scale under cGMP conditions.
- Expertise in handling HPAPI molecules upto OEB5 band (<0.1 µg/m³).
- Two dedicated manufacturing facilities for handling HPAPIs from grams to multi-tons.
- Support from preclinical to commercial phase (mg to MT scales) with cGMP.
- Regulatory compliance and support for IND/NDA/CTD filings.
- Project lifecycle management to ensure quality and on-time deliverables.
- Development of innovative, novel, cost-effective, and eco-friendly processes.
- Strict adherence to EHS recommendations.

Drug Substance Infrastructure

Research and development

- Facility spread over 184,000 sq. ft.
- 40 synthetic labs with ~350 fume hoods
- Dedicated laboratories for HPAPIs, Prostaglandins, Labeled Compounds, Iron-complexes, Flow Chemistry, Peptides, Oligos, particle size engineering, and more
- Specialized engineering laboratories for process safety studies and process intensification
- Dedicated scale-up facility with reactor capacities ranging from 10L to 100L under cGMP, including a clean room facility for supplying material for phase I, II, and III trials

Analytical

- Facility spread over 45,000 sq. ft.
- Equipped with ultra-modern instruments
- Supports lab development, method transfers, validations, scale-up, and commercial manufacturing
- Facilities for solid-state and structural characterization, method development and validations, and purification support

Manufacturing

- 17 facilities with 2,400 reactors, totaling 10,000 KL reaction volume (reactor range: 20 L to 20 KL)
- 2 dedicated HPAPI facilities to handle all band widths (up to 0.01 µg/m³)

API ACCREDITATIONS

FDA · Health Canada · edqm · Hamburg BGV - HAMBURG · EUROPEAN MEDICINES AGENCY · WHO - GENEVA · OGYÉI National Institute of Pharmacy and Nutrition NIP - HUNGARY · JAZMP SLOVENIA · ANVISA - BRAZIL · Cofepris Comisión Federal para la Protección contra Riesgos Sanitarios · Australian Government Department of Health · KFDA · MOH - RUSSIA · pmda

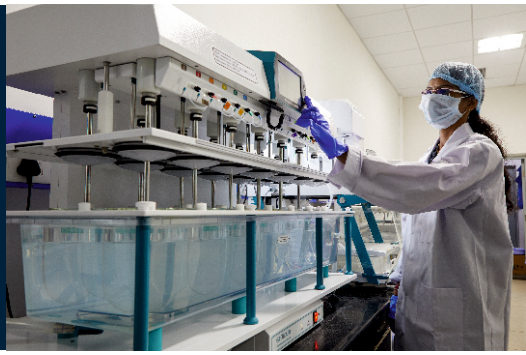
Drug Product Solutions

Service offerings in:

- Oncology, Non-Oncology, Immunosuppressant & High Potent product development
- Solid Orals
- Parenterals (Liquids & Lyo)
- Liquid Orals
- Extended/ Modified Release Injectables
- Expertise in handling the various dosage forms
- Ophthalmics
- Prefilled Syringes (PFS) & Pens

CRO

- Feasibility Studies
- Prototype formulation design
- Process identification and development studies
- Selection of a lead formulation candidate
- Preparation of test articles for IND enabling toxicology studies



CDMO

- Formulation optimization and scale-up
- Process Performance Qualification (PPQ)
- Technology transfer and scale-up
- cGMP production and filing support in eCTD format

CMO

- Commercial manufacturing
- On-time deliverables
- Lifecycle management strategies

Capabilities:

- **Solid Orals**
  - Intermittent Release
  - Extended Release
  - Sustained Release
  - Modified Release (Osmotic)
  - Multi-layered formulation
  - Sublingual
  - Pellets
  - Granules
- **Liquid Orals**
  - Oral Suspensions
  - Oral Solutions
  - Unit Dose cups
- **Ophthalmics**
- **Parenteral** (Liquids & Lyo)
  - Oral Suspensions
  - Oral Solutions
  - Unit Dose cups
- **Prefilled Syringes (PFS) & Pens**

Maximized process automation; impeccable quality

Drug Product Infrastructure

FDF Capacity per annum:

~ 12 Billion Tablets	**~ 2.0 Billion** Capsules	**~ 100 Mn.** Sachets
~ 40 Mn. (Lyo & Liquids) Parenterals	**~ 7.0 Mn.** Oral Suspension	**~ 100 Tons.** Granules

FDF ACCREDITATIONS

US FDA | BGV- GERMANY | SIDC- CZCH REPUBLIC | WHO- GENEVA | SIDC- SLOVAKIA | MHRA - UK | SAUMP- UKRAINE

MOH - ROMANIA | ANVISA - BRAZIL | INVIMA - COLOMBIA | MOH - PERU | FDA - TAIWAN | DSIR- INDIA | DEA

KSFDA - SAUDI | MOH - UAE | MOH - QATAR | MOH - JORDAN | MOH - YEMEN | PPB - KENYA | MCAZ-ZIMBABWE

TFDA - TANZANIA | FMHACA - ETHIOPIA | NAFDAC- NIGERIA | MOH- NAMIBIA | PMRT - MALAWI | NDA- UGANDA | ISO 9001 :2008

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