CRAMS

@ Global Pharma Healthcare Pvt. Ltd.

- Formulation & API Development
- Analytical Development
- Regulatory support & Stability Studies
- Technology Transfer

Global Pharma

About us

Global Pharma Healthcare Pvt Ltd (R&D Unit) is one of India's leading API - F R&D Contract Research and Manufacturing Services provider supporting R&D programs from process development to clinical supplies. Our multi-disciplinary skills include capabilities in synthetic medicinal chemistry, custom synthesis, process R&D, F R&D upto BA/BE Studies with regulatory support.

Global Pharma Healthcare Pvt Ltd (R&D Unit) delivers significant value to its customers worldwide by leveraging its scientific skills, cost competitiveness and some of the best practices in confidentiality and protection of intellectual property.

For more than two decades, we have been providing a wide range of pharmaceutical formulations in several therapeutic forms to a variety of markets in Southeast Asia, Central America, LATAM, CIS and Africa.

We are ISO 45001:2018, ISO 9001:2015, ISO 14001:2015, ISO 27001:2013 certified.

We are accredited by CDSCO & DSIR Govt. of India.

ISO 9001:2015 | ISO 14001:2015 | ISO 27001:2013

Infrastructure

1. 16000 Sq. ft. area for Research & Development of finished formulations.
2. Low Humidity areas to handle specific products.
3. Batch sizes from 30g to 3000g.
4. Walk-In Stability Chambers.
5. To produce API from gram level and upto 1kg.
6. Sterile processing area with class 100.
7. Aseptic process.
8. Terminal Sterilization.

Product Development services

- Formulation development [F.D]
- Process development [P.D]
- Process Validation batch [P.V]
- Scale Up batch
- Process optimization [P.O]
- Exhibit Batch [E.B]
- Customized development
- In-built quality with regulatory compliance
- Harmonized market (US/EU/CA/AUS)
- Abbreviated New Drug Application [ANDA][505(j)]
- Development of innovative value added generic formulations
- Improve bioavailability of formulations
- Analytical method development (AMD)
- Analytical method validation (AMV)
- Partial Dossier development
- Prototype development
- Registration strategies to meet the customer requirements
- Regulatory & IP support
- Tailor made product development services
- Ophthalmic & Otic products.

We Offer

- We do CRAMS for formulation / API.
- Formulation development on various dosage forms.
- Analytical Development and Validation of methodologies.
- Process Validation and technology transfer.
- Supply and execution of method transfer protocols.
- Documentary and regulatory support.
- Stability facilities to accommodate a range of ICH conditions.
- Bio Equivalence Studies*
- Contract Manufacturing and finished product supplies.

*Dedicated Partners

Stability Studies

We provide stability testing for all types of commercial and pre-market drug products.

- We offer standard storage conditions, meeting ICH guidelines, along with any specialized storage conditions your product may require.
- Stability protocol design.
- Long-Term stability testing.
- Accelerated stability testing.
- Forced degradation studies.
- Photostability.
- Process capabilities-Sterile Manufacturing.
- Compatability studies.

Dosage forms


TABLETS


CAPSULES


SYRUP & SUSPENSION


OINTMENTS


CREAMS


GELS


EYE DROPS


INJECTABLES


API

Contact us

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