



SWISS
PARENTERALS LTD.

**INNOVATIVE
FORMULATIONS**
FOR A BETTER AND
HEALTHIER TOMORROW



SWISS PARENTERALS OVERVIEW



Incorporated in 1997; part of the Eris Lifesciences Group – a publicly listed Indian pharmaceutical company with a market capitalization of ~ USD 2,500 million

EU-GMP and **PIC/s** approved sterile manufacturing facilities in Ahmedabad, India

The only Indian-origin CDMO providing the **entire basket of sterile injectable dosage forms** - General Injectables (Vials, Ampoules, Cartridges), Pre-Filled Syringes, Lyophilised Injections, Dry Powder for Injections (General, Ceph, Penicillins & Penems), Sterile Ear/Eye Drops, and Inhalation Anesthetics

State-of-the-art manufacturing facility for Oral Solids (Tablets and Capsules), Semi Solids and Oral Liquids in Ahmedabad

Track record of over 25 years in exporting a range of **190+ sterile formulations across 70+ markets** in Asia-Pacific, Latin America, Africa, Middle East and the EU

Extensive **Dossier Bank** in Sterile Injectables – 900+ active and 1,200+ filed

OUR FLAGSHIP PRODUCTS

Ferric Carboxymaltose (FCM) Injection



Methylprednisolone DPI



Sevoflurane and Isoflurane



Enoxaparin PFS

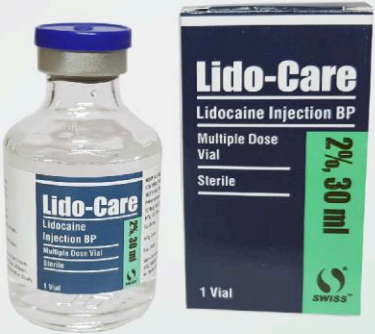


OUR BREADTH OF STERILE DOSAGE FORMS - ILLUSTRATIVE

Liquid Ampoule



Liquid Vial



Liquid Cartridge



Prefilled Syringe



Lyophilised Vial



Inhalation Anaesthetics



OUR BREADTH OF STERILE DOSAGE FORMS - ILLUSTRATIVE

Dry Powder for Injection

Cephalosporins



Penicillins



Sterile Ophthalmic Drops



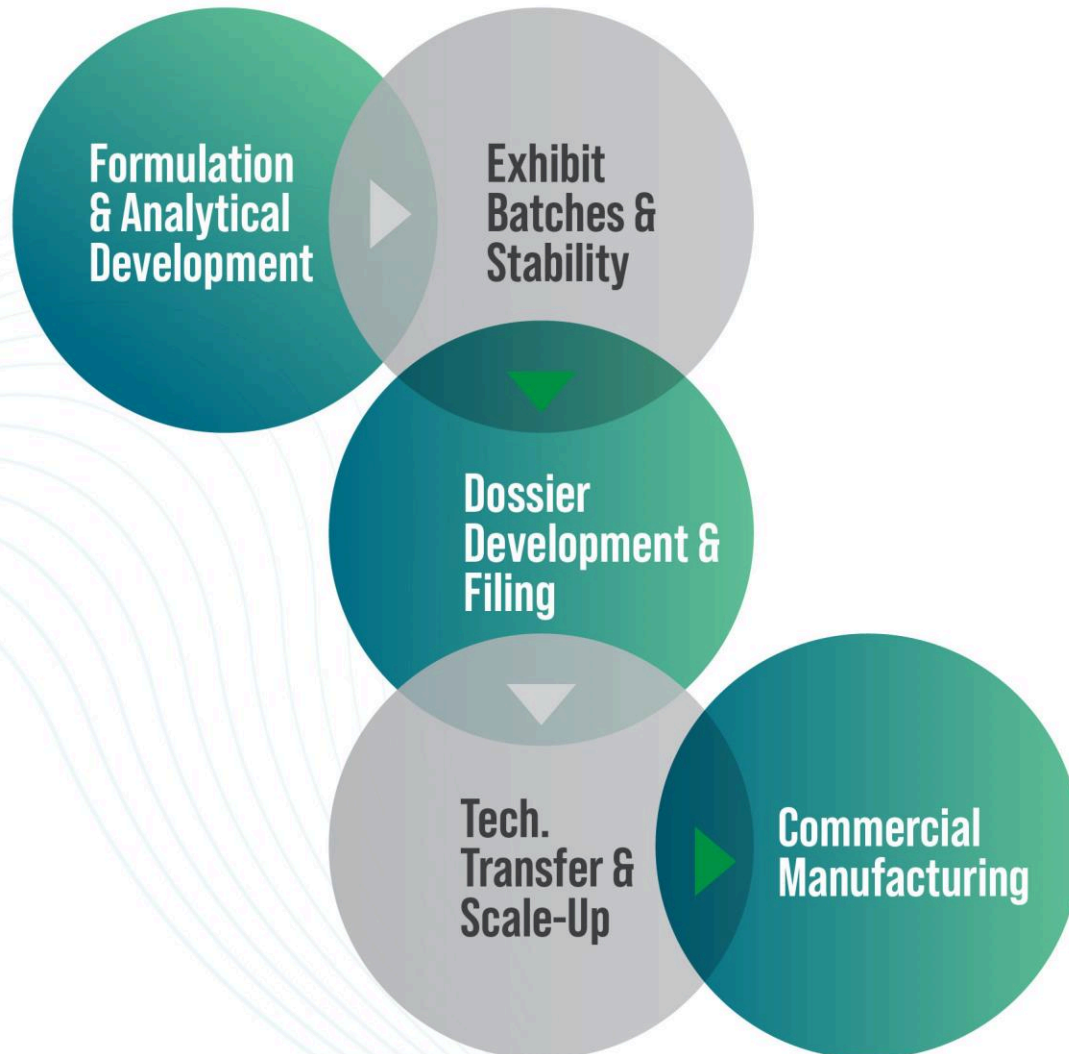
Carbapenems



General



ONE STOP SHOP FOR PRODUCT DEVELOPMENT, TECHNOLOGY TRANSFER & MANUFACTURING



ACROSS A WIDE RANGE OF DOSAGE FORMS

- Sterile Liquid Vials
- Sterile Liquid Ampoules
- Sterile Liquid Cartridges
- Sterile Dry Power Inj. – General
- Sterile Dry Powder Inj. –
Betalactams
- Prefilled Syringes
- Lyophilised Injectables
- Sterile Eye Drops
- Sterile Eye Ointments
- Oral Solid Dose
- Oral Liquids
- Semi Solids

FORMULATION DEVELOPMENT - OUR EXPERTISE

OUR SERVICES

- Contract Research, Formulation Development, Tech Transfer
- Non-Infringing Formulation Strategy
- Analytical Method Development and Transfer (if required)
- Stability & Validation
- Bioequivalence
- Clinical Research Support
- Regulatory Strategies - support to Dossier Development, Query Resolution and Registration

OUR TECHNOLOGIES/ DOSAGE FORMS

- **Sterile Injections** - Solutions, Long acting injections (Microsphere/ Liposomal), Suspensions, Emulsions, Dry-Powder, Lipid Complex, Lyophilized, Pen Devices (With Cartridges)
- **Topical Semisolids** - Gels, Ointment, Creams
- **Oral Solid Dosage** - Tablets and capsules
- **Oral Liquids** - Solutions, Suspensions, Syrups
- **Ophthalmic** - Drops, Solutions, Suspensions, Gels and Ointments
- **NDDS**
- **NCEs**

OUR R&D AND ANALYTICAL INFRASTRUCTURE

**40-member
R&D team based out
of a 11,000 square feet
R&D Center with
designated sections for
Formulation Development,
Analytical Development,
Tech. Transfer, Stability &
Research Quality
Assurance**

LIST OF KEY INFRASTRUCTURE/EQUIPMENT

Formulation Development

- Assembly lines for Injectable, Solid Oral, Liquid Oral and Semisolid dosage form
- Fluidized Bed Dryer, Granulator, Compression, Auto-coating Machine
- Lyophilizer Machine
- Ampoule & Vial filling and Sealing Machine
- Blister Packing Machine

Analytical Development

- Chromatography: G.C., UPLC, HPLC
- UV Spectroscopy
- Dissolution Apparatus
- Viscometer
- Stability Chamber, Cooling Chamber, Deep Freezer

OUR STERILE MANUFACTURING FOOTPRINT

**Unit I - General Liquids, Dry Powder, Lyophilised,
PFS, Ophthalmics, Anaesthetics**

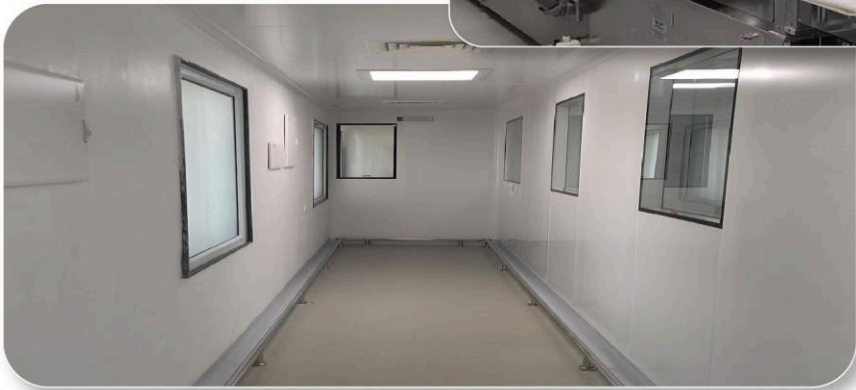


Dosage Form	Units p.m.
Liquid Ampoules	8 million
Liquid Vials	3.6 million
Dry Powder Vials	2.6 million
Prefilled Syringes	1.3 million
Lyophilised Vials	8,00,000
Ophthalmic Drops	1.3 million
Ophthalmic Ointments	1.5 million
Inhalation Anesthetics	2,00,000

* Capacities based on a two-shift operation

OUR STERILE MANUFACTURING FOOTPRINT

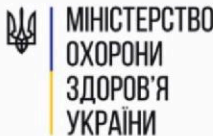
Unit 2 - Betalactams Dry Powder Ampoules - Cephalosporins, Penicillins, Carbapenems



Dosage Form	Units p. m.
Cephalosporins	4.2 million
Penicillins	3.6 million
Carbapenems	2.6 million

* Capacities based on a two-shift operation

STERILE MANUFACTURING - REGULATORY ACCREDITATIONS



UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION



UNITED NATIONS
GLOBAL MARKETPLACE



МИНИСТЕРСТВО
ЗДРАВООХРАНЕНИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ



The Federal Democratic Republic of Ethiopia
Ministry of Health



Medicines Control Authority of Zimbabwe



EAEU
Eurasian
Economic
Union



Direction de la Pharmacie, du Médicament
et des Laboratoires de Côte d'Ivoire



ORAL SOLIDS AND SEMI-SOLIDS MANUFACTURING FOOTPRINT

Unit in Ahmedabad - Oral Solids (Tablets & Capsules), Oral Liquids, Ointments, Sterile Ampoules



Dosage Form	Units p. m.
Oral Solids - Tablets	180 million
Oral Solids - Hardgel Capsules	20 million
Ointments	7 million
Sterile Ampoules	3 million
Oral Liquids	1.5 million

* Capacities based on a two-shift operation

REGULATORY AFFAIRS - KEY COMPETENCIES/ SERVICES

Powered by a 30-member Regulatory team that has developed 2,200+ dossiers for 80+ markets

Dossier Preparation and Submission Preparing and submitting dossiers for drug approval in compliance with regulatory requirements

Filing in E-CTD, ACTD, CTD, and Country-Specific Formats
Experienced in handling submissions in electronic (e-CTD), ASEAN Common Technical Dossier (ACTD), Common Technical Document (CTD), and other region-specific formats as may be required

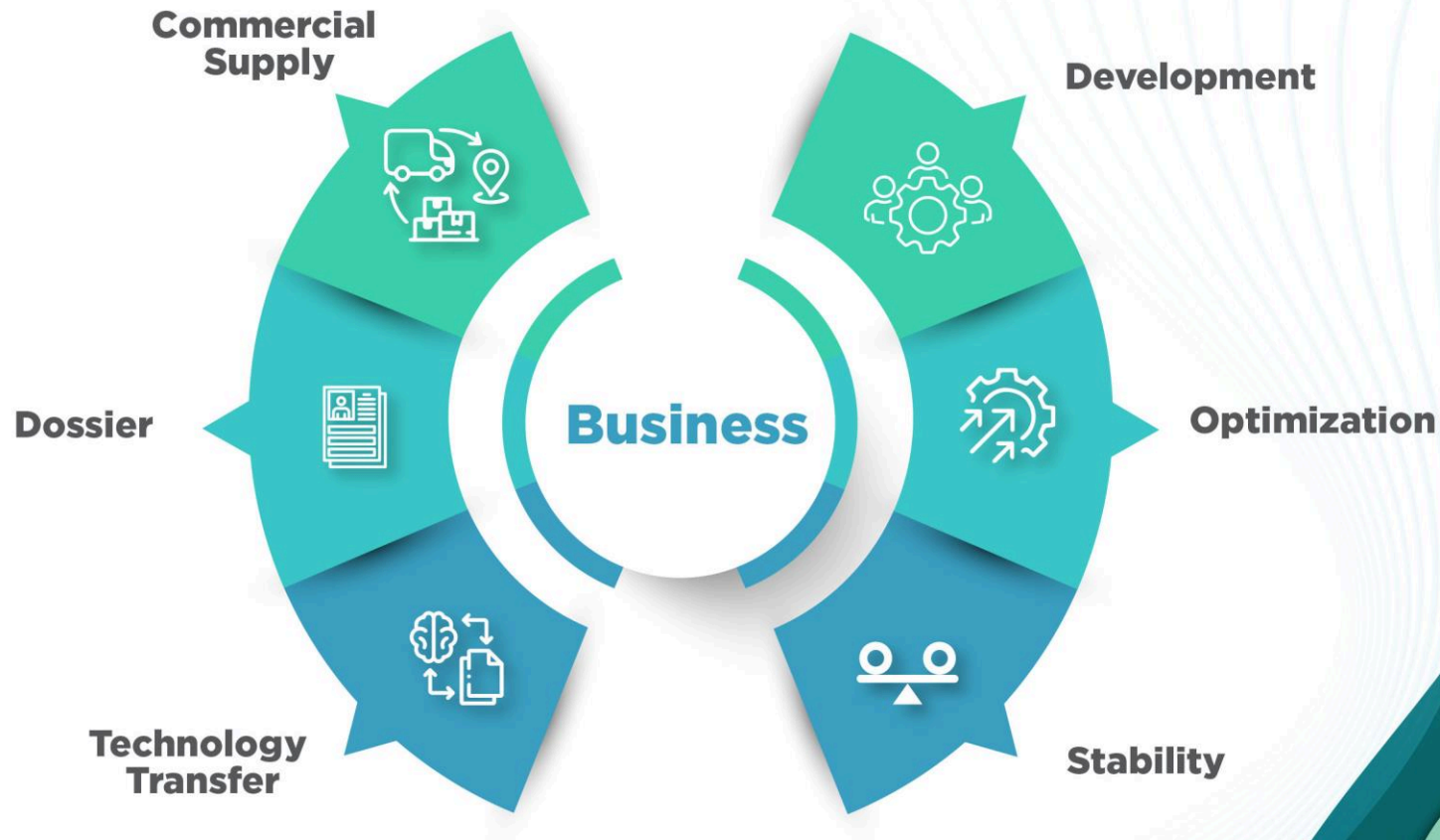
Query Response Support - Client and Regulatory Authorities
Ongoing dialogues with Clients, Regulatory Agencies and MoHs for query resolution

Review of Technical Documents Based on Regulatory Queries
Reviews of technical documents to ensure compliance with regulatory requirements and queries raised

Support for Variation Filing Applications
For approved products, to ensure compliance with regulatory changes and/or product modifications



OUR BUSINESS MODELS FOR COLLABORATION



FEE FOR SERVICE MODEL

- Activity based Milestone structure.
- CRO, CMO & CDMO

CO-DEVELOPMENT

- Identify products to develop in partnership - predefined scope and territorial rights

OUTLICENSING

- Out-licensing of existing/ pipeline Swiss products to marketing partners

We Deliver an End-to-End Solution starting with API Sourcing to Formulation/ Analytical Development, Stability Studies, Dossier Preparation & Manufacturing for Global Markets

CONTACT US



Write to us for Inquiries

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COMPANY PROFILE

