SORTIS PHARMA

CPHI SHANGHAI 2026

Hall / Booth: _____

YOUR STRATEGIC CDMO PARTNER

From *Molecule* to Market

Powered by Innovation · Driven by Excellence

Research-Driven

NCEs, Generics & 505(b)(2) NDAs — end-to-end formulation expertise

CDMO Excellence

Pre-formulation to exhibit batch manufacturing and tech transfer

Global Partnerships

Flexible collaboration models tailored to your development needs

DOSAGE FORM EXPERTISE

Oral Solids

Tablets · Capsules · Granules · Pellets · Powders · Sachets

Oral Liquids

Solutions · Syrups · Suspensions · Drops · Emulsions · Dry Powders for Reconstitution

Injectables

Solutions · Suspensions · Lyophilized Products · Infusions · Prefilled Syringes · Depot Formulations

Semisolids / Topicals

Creams · Ointments · Gels · Lotions · Pastes

Sortis Pharma Healthcare Pvt. Ltd.
TSIIC, M-30 Medical Device Park, Sultanpur, Sangareddy
Hyderabad, Telangana, India

www.sortispharma.com
Hyderabad, India

WHO WE ARE

About Sortis Pharma

A research-driven pharmaceutical development company based in Hyderabad, India

Sortis Pharma Healthcare is a **research-driven pharmaceutical company** based in Hyderabad, India. We develop high-quality products across multiple therapeutic areas and turn pharmaceutical concepts into market-ready products through scientific innovation, development expertise, and flexible collaboration models.

We support and collaborate with clients worldwide by providing **integrated solutions across the entire product development lifecycle** — enabling a seamless transition from development to market launch.

Our services encompass formulation development, analytical method development, stability studies, technology transfer, exhibit batch manufacturing, regulatory support, and commercialization readiness.

NCEs NEW CHEMICAL ENTITIES	**Generics** ANDA PORTFOLIO
505(b)(2) NDA PATHWAY	**Differentiated** DOSAGE FORMS

COMPLETE CHECKLIST

Capabilities at a Glance

Everything we deliver across the development lifecycle

- ✓ Pre-Formulation Studies
- ✓ Formulation Development
- ✓ Analytical Method Development & Validation
- ✓ Stability Studies (Accelerated & Long-term)
- ✓ Comparative Product Evaluation
- ✓ Process Optimisation
- ✓ Scale-Up Studies
- ✓ Exhibit Batch Manufacturing
- ✓ Technology Transfer
- ✓ Regulatory Filing Support

OUR EXPERTISE

Pharmaceutical Development Services

End-to-end support from concept to commercialisation

Pre-Formulation & Formulation Development

Comprehensive pre-formulation studies, physicochemical characterisation, and full formulation development across all dosage forms — oral solids, liquids, topicals, and injectables.

Analytical Method Development & Validation

Development and ICH-compliant validation of analytical methods for API characterisation, finished product testing, and stability-indicating method.

Stability Studies

ICH-guided accelerated, intermediate, and long-term stability programmes. Stability study conditions are selected based on product characteristics and intended market distribution.

Scale-Up & Exhibit Batch Manufacturing

Process optimisation, scale-up studies, and exhibit batch manufacturing to support regulatory filings and technology transfer activities.

Regulatory Filing Support

Comprehensive regulatory documentation support including CTD dossier preparation, ANDA, NDA 505(b)(2), and international regulatory submissions.

Technology Transfer & Commercialisation

Seamless technology transfer to manufacturing partners with full documentation packages. End-to-end support for commercial readiness and market launch preparation.

PRODUCT PORTFOLIO

Development-Ready Products

Available for technology transfer, licensing, co-development & commercialisation partnerships

PORTFOLIO HIGHLIGHTS

Our portfolio includes a diverse range of oral solid and oral liquid formulations. All products are available for licensing, co-development, technology transfer, and commercialization partnerships.

Oral Liquid Portfolio

Solutions & Suspensions — Formulation Optimised

Product	Strength / Concentration	Form	Status *
Bilastine Oral Solution	2.5 mg/mL	Oral Solution	✓ Available
Levetiracetam Oral Solution	100 mg/mL	Oral Solution	Development Under Progress
Aripiprazole Oral Solution	1 mg/mL	Oral Solution	Development Under Progress

Oral Solid Portfolio

Tablets — Multiple Therapeutic Areas

Product	Strength(s)	Therapeutic Area	Status
Bilastine Tablets	20 mg	Allergy / Antihistamine	✓ Available
Dapagliflozin Tablets	5 mg & 10 mg	Diabetes / SGLT2 inhibitor	✓ Available
Rivaroxaban Tablets	10 mg & 20 mg	Anticoagulant	✓ Available
Rifaximin Tablets	200 mg & 550 mg	Antibiotics / GI	Development Under Progress
Rosuvastatin + Ezetimibe Tablets	Combination	Cardiovascular / Lipid	Development Under Progress
Bempedoic Acid Tablets	180 mg	Cardiovascular / Lipid	Development Under Progress
Tofacitinib Tablets	5 mg & 10 mg	Immunology / JAK inhibitor	✓ Available
Eltrombopag Olamine Tablets	25 mg, 50 mg & 75 mg	Haematology / Thrombocytopenia	Development Under Progress
Sacubitril + Valsartan Tablets	24/26 mg, 49/51 mg, 97/103 mg	Cardiovascular / Heart Failure	Development Under Progress

* Multiple products have completed formulation optimisation with successful accelerated stability data which are within specification limits. Products can be advanced to pilot bio studies, exhibit batches, technology transfer, and commercialisation based on partner requirements.

PARTNERSHIP MODELS

Flexible Collaboration Models

We adapt to your business model — choose the engagement structure that works best for you

Fee-for-Service (FFS)

Transparent milestone-based pricing for specific development activities. Full intellectual property ownership retained by you at every stage.

End-to-End CDMO Model

Comprehensive development-to-commercialisation partnership. We manage the entire journey from pre-formulation through to market-ready product.

Co-Development Partnerships

Shared risk and reward models for mutual growth. Ideal for licensable product development with shared commercial upside.

COMPETITIVE ADVANTAGE

Why Global Partners Choose Sortis

Six pillars of pharmaceutical development excellence

01

Quality-Driven Development

Strong focus on product stability and quality across all development stages. ICH-compliant processes built into every programme from day one.

02

Strong Formulation Expertise

Deep scientific expertise across complex dosage forms — oral solids, oral liquids, semi-solids, and injectables. Proven track record in challenging molecules.

03

Flexible Business Models

Fee-for-service, end-to-end CDMO, and co-development partnerships — we structure engagements to match your strategic objectives and risk appetite.

04

Regulatory-Oriented Approach

Regulatory intelligence embedded throughout development. Expertise in USFDA, EMA, and emerging market regulatory pathways including ANDA and 505(b)(2) NDAs.

05

Technology Transfer Excellence

Comprehensive, well-documented technology transfer packages that ensure seamless handover to manufacturing partners with minimal disruption and timeline risk.

06

Commercialisation-Oriented Development

Every programme is designed with commercial viability as a core objective — from formulation design to manufacturing scalability and cost-of-goods optimisation.

MEET OUR TEAM

We welcome pharmaceutical companies, licensing organisations, investors, and CMOs seeking strategic development partnerships. Whether you are looking to in-license a development-stage asset, out-license a molecule for CDMO services, or explore co-development of a new programme — our team is here to discuss your opportunities.

FACILITY SNAPSHOT

Equipment and Capabilities Overview

Our comprehensive equipment portfolio supports development across all major dosage forms, enabling us to handle projects from early development through lab scale optimisation and pilot bio batches.

Formulation & Processing Equipment-Oral Solids

- ✓ Rapid Mixer Granulator (RMG)
- ✓ Extrusion and Spheronization equipment
- ✓ Multi-mill
- ✓ Fluid Bed Processor (FBP)
- ✓ Roll compactor
- ✓ Blenders
- ✓ Tablet compression machines
- ✓ Film coating equipment

Testing & Quality Control

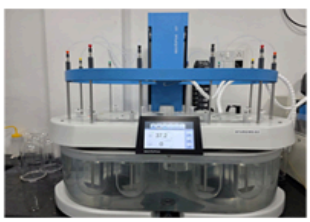
- ✓ Hardness tester and friabilator
- ✓ Disintegration test apparatus
- ✓ Halogen moisture balance
- ✓ Mechanical sieve shaker
- ✓ Viscometer and homogenizer
- ✓ Filtration units
- ✓ ICH-compliant stability chambers
- ✓ Photo-stability chambers

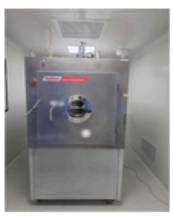
Packaging & Filling Machinery

- ✓ Blister packing machines
- ✓ Automatic capsule filling equipment
- ✓ Induction cap sealer and foot sealers
- ✓ Vial sealing machines
- ✓ Sachet sealing equipment

Sterilization & Specialized Equipment-Injectables

- ✓ Lyophilizer (freeze dryer)
- ✓ High-pressure homogenizer (GEA Panda)
- ✓ High-shear homogenizer (Megatron)
- ✓ Rotary evaporator
- ✓ Dry heat sterilizer and autoclave
- ✓ Laminar Air Flow (LAF) and isolators
- ✓ Dehumidification systems





"From Molecule to Market, Powered by Innovation."

REGISTERED OFFICE

TSIIC, M-30 Medical Device Park
Sultanpur, Sangareddy, Hyderabad
Telangana, India

DOSAGE FORMS

Oral Solids, Oral Liquids
Topicals, Semi-Solids
Injectables

SPECIALISATION

Generics, NCEs, 505(b)(2) NDAs

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