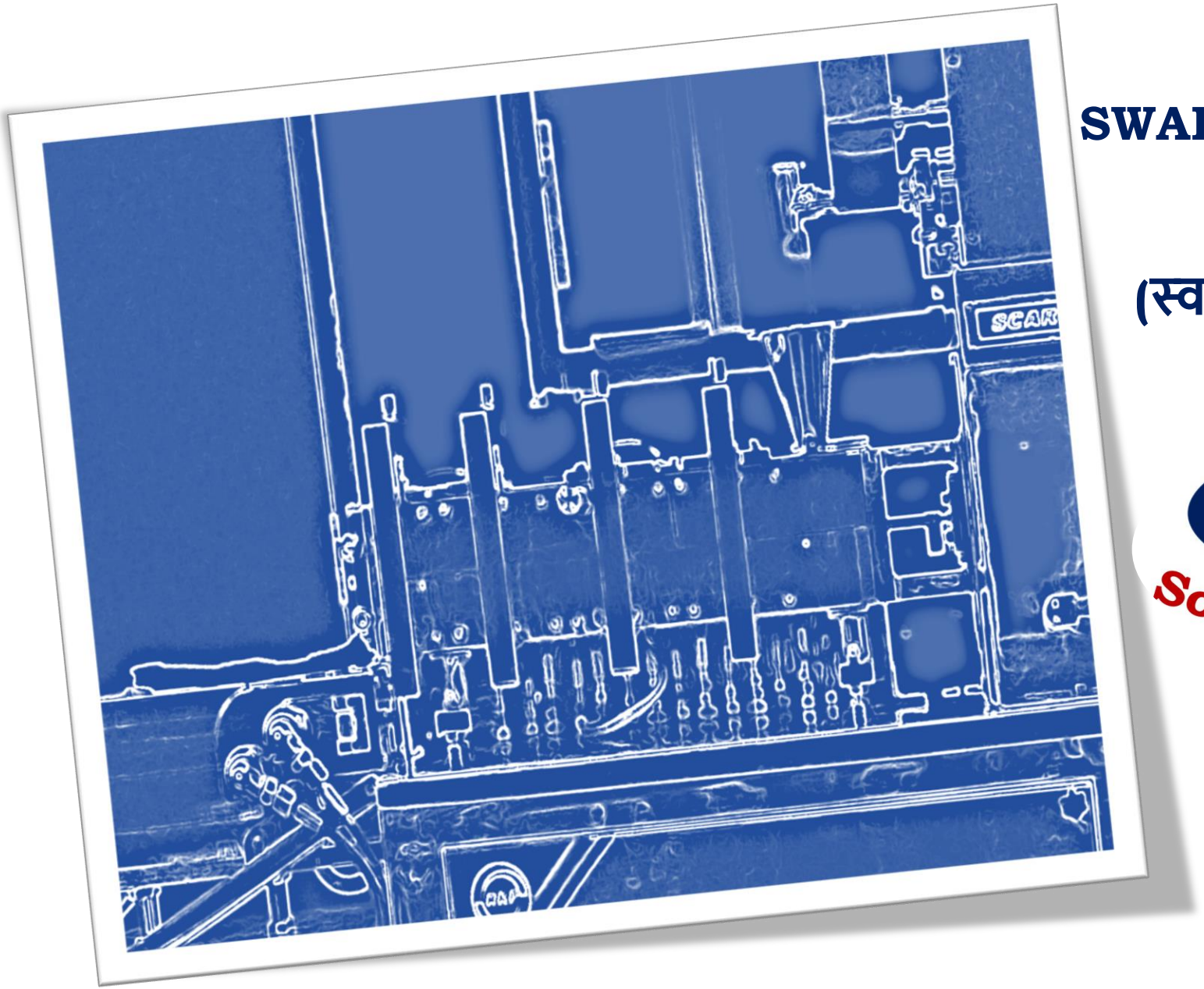

SWALAVA ENTERPRISES PVT. LTD.

(स्वलवा इंटरप्राइजेज प्राइवेट लिमिटेड)

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About Swalava, capabilities & Services

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Swalava is a Contract Research Organization (CRO) providing services in..

- **Product / process development using HME Technology.....**
  a. Pharmaceutical ***(potent and non-potent* product)**
  b. Herbal & Nutraceutical
- **Product / Process development using Twin Screw Processor.....**
  a. Melt Granulation
  b. Wet Granulation

HME capability for Potent and Non-Potent product /process development

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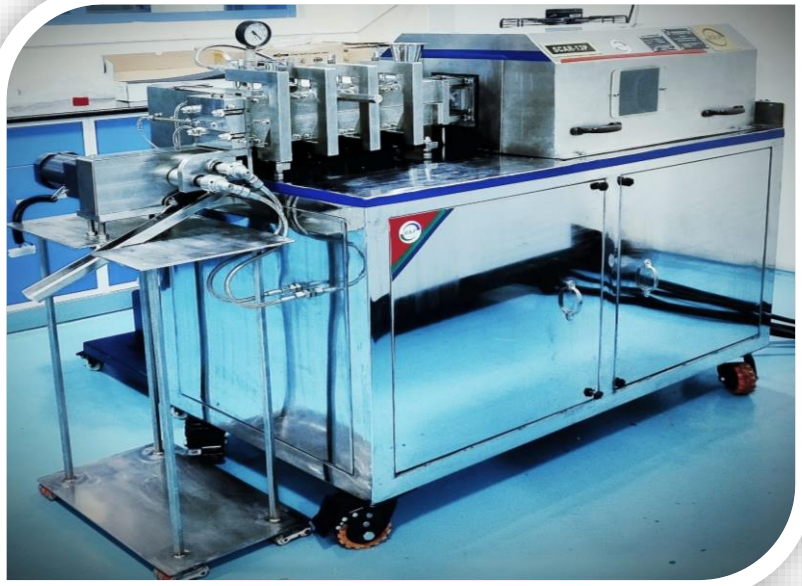

Services: Product development using HME

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Pharmaceutical Product

- Solubility Enhancement

"Enhancing bioavailability of your poorly soluble API (BCS Class II & IV) leading to better Therapeutics efficacy"

- Modified Release
- Taste Masking
- Dispersions (Emulsion/Suspension/ Gels/Cream)

Services for High Potent API (HPAPI) and non-potent API.

Herbal & Nutraceutical Products:

- Solubility Enhancement
- Taste Masking
- Dispersions (Emulsion/Suspension/ Gels/Cream)
- Encapsulation of essential oils and Flavours
- Improving dispersiability of Herbals extracts
- Herbal Product Stability enhancement
- Reducing bioburden of herbals

Advantages of HME process...

- Solvent free process
- Continuous process
- Better mixing for viscous material
- Thermodynamically stability than spray drying
- Cost Effective process
- Smaller foot print for manufacturing
- Energy efficient

Services: Product development using Twin Screw Processor for Continuous Granulation (Wet & Melt)

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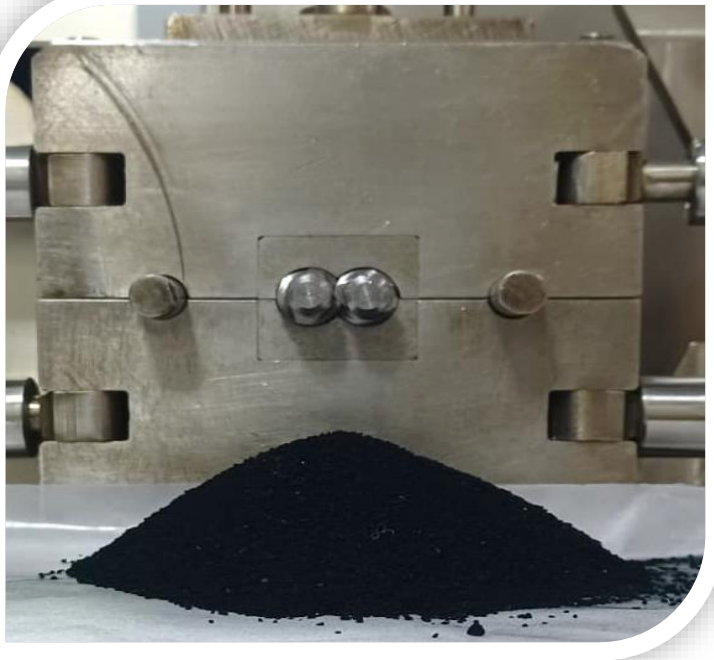
Melt Granulation



Wet Granulation

Product Development Service and Activities

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Sr. no.	Development Activities	Description of Activities	No. of Trials	Total material Qty. required*	Type of Development	
1	Feasibility or POC trials	Assess technical feasibility (Screening of polymer/s, excipients and process condition)	5-10	0.1 – 1 kg	Partial	End-to-end
2	Prototype or trials	Develop prototypes formulations by HME, meeting the broad specification	10-30	2 – 5 kg		
3	Long run Trials	Understanding the stability of the process run. (Run time 1-3 hrs)	1-3	1 – 6 kg		
4	Pilot bio batch and stability	Manufacturing of the Pilot bio batch at identified manufacturing site	1-3	1 – 5 kg		
5	Optimization Trial	DoE run to define design space for composition and process	6-20	1 – 2 kg		
6	Scale up and Engineering batch	Scale up on same scale of HME (long run) or higher scale HME at commercial scale	5-10	Depends on scale of the HME machine	Scale up	
7	Commercial manufacturing	Exhibit batch manufacturing at identified manufacturing site	3	Depends on scale of the HME machine		

**** The drug loading would be 10 – 70 % based on the product requirement***

Process Development Service and Activities

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Sr. no.	Development Activities	Description of Activities	No. of Trials	Total material Qty. required*
1	Feasibility or POC trials	Feasibility trial on HME using the composition provided by client	5-10	0.1 – 1 kg
2	Only Process development	Developing process on HME using the composition provided by client	10 -20	2 – 3 kg
3	Troubleshooting	Trouble shooting for the process by providing HME process solution	Not applicable	Not applicable

**** The drug loading would be 10 – 70 % based on the product requirement***

Our Special Capabilities based services:

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1. PROCESSING OF VERY THERMOLABILE API

We has expertise in handling thermolabile API (degrade/decomposes > 90%) for solubility enhancement using HME and meeting the regulatory requirement of the product.

2. PROCESSING OF MATERIAL IN HME USING PRESSURISED GAS

We have experience in processing material using pressurised gas Carbon-di-oxide or Nitrogen inside the HME. This unique process help to reduce the processing temperature and thereby prevent drug degradation and also help to improve the milling efficacy of the difficult to mill material and achieve very low particle size.

3. CONVERTING CRYSTALLINE API TO AMORPHOUS USING HME

Converting an Crystalline API to Amorphous form resulting into patent circumventing pathways as well as possibility of claiming own IP.

4. LIFECYCLE MANAGEMENT

Converting Spray drying process to an efficient and simple HME process.

Our Consultation services:

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1. **DEVELOPMENT SERVICE:** HME based Product/Process development on HME equipment at your facility

2. **SCALE-UP & TECHNOLOGY TRANSFER:** Scale-up support for the product developed on the lab scale HME to commercial which includes scale-up calculation, optimization on scale-up equipment and during exhibit batches.

3. **TROUBLESHOOTING:** During development, scale-up & commercial batches which include and not limited to screw configuration, screw speed, feed rate and barrel temperature set up.

4. **INCREASE EFFICIENCY:** for improving the process efficiency by increasing the throughput, reducing the impurity, increase yield

5. **HANDILING AND RESPONDING TO REGULATORY QUERIES:**

6. **CONVERTING BATCH-TO-CONTINUOUS PROCESS:** Converting a batch process to continuous process for HME and Twin screw processor based granulation process (Gravimetric dispensing, continuous blending, continuous milling, continuous post blending & Lubrication).

7. **CONVERTING CONVENTIONAL BATCH-TO-CONTINUOUS PROCESS:** We support customer in converting conventional batch or semi-batch process (RMG, FBP, Roller compactor, direct compression) for tablet, capsule, granules, and powders to continuous process.

Upcoming Specialized Formulation Capability

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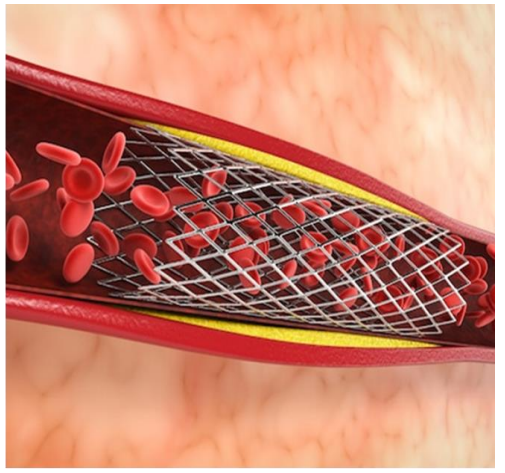
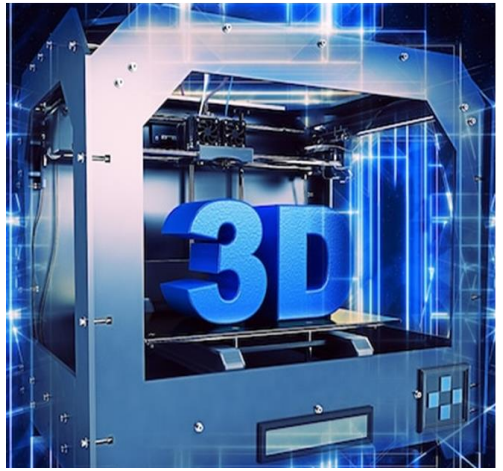
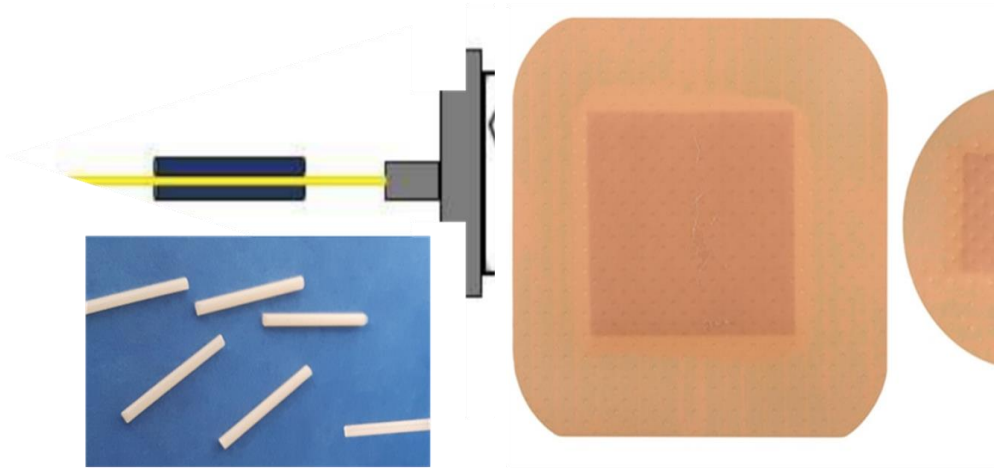
- Implants (parenteral & Dental)
- Abuse deterrent technologies
- Transdermal patches
- Fast Dissolving oral films
- Drug Eluting Stents
- Chews for Veterinary
- 3D-Printing







About our Team .....

Vijay Kulkarni
(M.Pharm, Ph.D.)

Director, Formulation & Business Development

Dr. Vijay Kulkarni
Co-Founder of Swalava Enterprises Pvt. Ltd.

Experience: more than 16 years of experience in pharmaceutical industry working on development of solid oral dosage forms out, of which 11 years' experience in ***Hot Melt Extrusion Technology for Solubility enhancement of poorly soluble drugs and for continuous Manufacturing.***

Dr. Vijay was a Postdoc research scholar at **Dr. Michael Repka's lab, The University of Mississippi, USA,** working on Hot Melt Extrusion for various application.

Expertise and Research Area: Development of pharmaceutical and nutraceutical using HME (continuous nanoparticle, solubility enhancement, continuous granulation for IR and ER products, semisolid dispersions, Effervescent.

Rising Star Award in F&D for contribution in ***"Continuous Granulation"***, presented during **FDD 2019 Conclave, Hyderabad by Indian Express.**

About our Team .....

Rameshwar Nalawade

(M.Sc. Analytical Chemistry)

Director, Analytical, Quality & Corporate Strategy

Mr. Rameshwar
Co-Founder of Swalava Enterprises Pvt. Ltd.

Experience: more than 22 years of experience in pharmaceutical industry in Analytical Development and Quality.

Expertise and Research Area:
Analytical Development of NCE's, Characterization of **Hot Melt Extrudates** and different types of formulations. Developed and optimized analytical tools for monitoring materials produced through continuous manufacturing by Hot melt Extrusion.

Technical Transfer: Involved in strategies for Technical transfer of Analytical Methods from Research and Development to commercial manufacturing site.

Has spent over 2 decades with leading Indian pharmaceutical companies, (Ipca, Zydus Cadila, Piramal and STEERLife).

Our Scientific Adviser .....

S. Narasimha Murthy
(Ph.D., FAAPS)

Scientific Adviser,

Dr. S. Narasimha Murthy

Scientific Adviser

Dr. Murthy provides expertise in formulation development, characterization and IVPT And IVRT. He has two USFDA contracts to conduct research on Q3 characterization and IVPT protocol.

He was a Professor at the University of Mississippi for over 15 years. Transcutaneous drug product development using HME and other technology are one of the main areas of his research.

He is recipient of New Investigator award and Cumberland Researcher of the year from University of Mississippi, Global Indus Technovator award from MIT, Inducted as the Fellow of American Association of Pharmaceutical Scientists in 2017.

He was honored with Distinguished Scientist award by American Association of Indian Pharmaceutical Scientists, recognized as "Eminent Scientist" from Association of Pharmacy Professionals, bestowed with "Pharmaceutical Global Health Award" by the AAPS.

He has published over 150 research papers, over 200 scientific posters in various national and international level, authored two books and over fifteen book chapters. He has been funded by NIH, USFDA and Pharmaceutical companies.

Our Scientific Adviser .....

Dr. GIRISH KUMAR JAIN
(M.Pharm, Ph.D.)

Scientific Adviser,

Dr. GIRISH KUMAR JAIN
Scientific Adviser

Experience: Rich professional Experience of 27+ years in development and filing of different dosage forms. Filed about 250 ANDAs and 505(b)(2) NDAs with US FDA and 50+ generic products in Europe and 25+ in Australia.

Expertise and Research Area: Experience of developing and filing various dosage forms including Solid Orals, Liquid Orals, Sterile dosage forms (Injectable and Ophthalmic), Topical and Transdermal Delivery system and extensive experience in Modified Release dosage forms development. He has expertise in correlating R&D development with commercial viability.

Dr. Girish has 32 granted patents in US and 150+ patents in Europe. He was awarded Chairman's Trophy for approval and launch of the product and was involved in filing and approval of multiple FTFs.

Currently he is working at Cochlea Pharma, Mumbai, in past he has worked in Slayback Pharmaceuticals Inc., Alkem Laboratories Ltd, Wockhardt Limited, Ranbaxy Research Laboratories, Gurgaon at various capacity as President, Head of Formulation Development etc. He has multiple Scientific Publications, Presentations and Patents at National and International Journals level.

About our collaborator .....

IDRS Labs Pvt. Ltd.

IDRS Clients Across the world

Services & capabilities –Formulation development

Our Partner IDRS Labs Pvt. Ltd..

- IDRS LABS founded by experienced scientists from the pharmaceutical industry, was established in OCT 2012, having registered office at Delaware (USA) and Bangalore (India)
- Cater to large and medium pharmaceutical companies for their pharmaceutical developmental needs.
- Development project for regulated & emerging markets involving….
    - Generic and Complex generics including NCE-1, 505B2;
    - Cytotoxic, Potent,
    - NCE- formulation development for FIH
    - Phytopharmaceutical and other small molecules
    - Parenteral, Liquid and Solid oral dosage forms
    - Pre-clinical formulation development
    - Pediatric formulation development
    - Veterinary formulation development

Services and capabilities –Analytical development at IDRS Labs

- Analytical method development and validation for API and drug product
- Stability studies to support development of API and drug product
- Reverse engineering of innovator products
- Unknown impurities identification and characterization
- Cleaning method development & validation for drug products
- Method transfers to customer quality control labs

- HPLCs (UV, PDA, RI and ELSD detectors)
- Viscosity Measurement
- Differential Scanning Calorimetry
- Elemental Impurities Assessment
- DVS (Sorption/Desorption)
- Delamination Studies
- Gas Chromatography
- Leachable & Extractables
- Particle Size Analysis
- Photo stability Assessment
- Osmolality
- Dissolved and Head Space Oxygen Quantification
- Moisture Quantification
- FDM
- Solid state characterization for API and in drug product

Note: Certain capabilities are offered through collaboration

idrs

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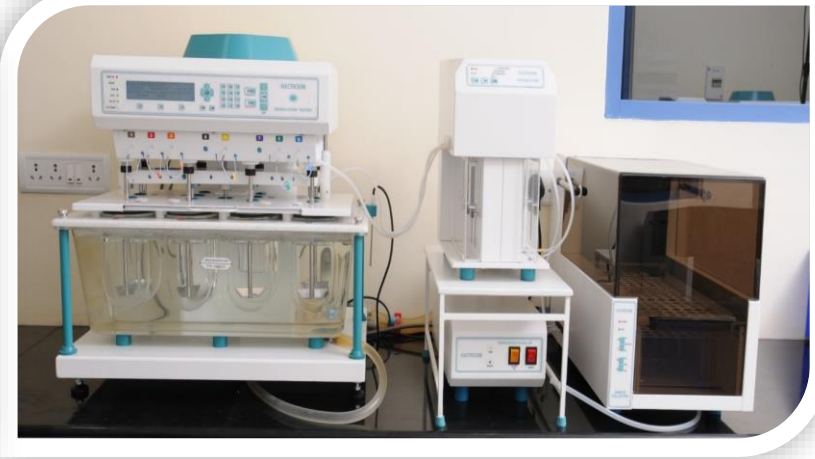
R&D Infrastructure at IDRS Labs

Formulation –Lab 1 (Oral Formulation)

Analytical Development Labs (Wet, Dissolution, Instrumentation)

Analytical Wet Lab

HPLCs



Dissolution Tester

Magnetic Stirrer with Hot Plate

Oxygen Headspace Analyzer

Dehumidifier

Formulation –Lab 1 (Oral Formulation)

Fluid Bed Processor & Tablet Coating Machine

Rapid Mixed Granulator Cone Mill Multi Mill

Blister Packaging Machine

Inweka Compression Machine

Isolator Chamber

THANK YOU

Looking forward to work with You

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Rameshwar Nalawade (MSc. Analytical)
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