

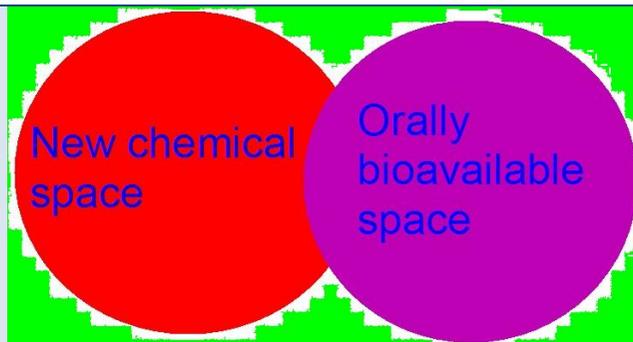
## CRYSTALIN RESEARCH

**CRYSTALIN RESEARCH** is a new scientific enterprise started at the Technology Business Incubator facility on University of Hyderabad campus. **CRYSTALIN** will leverage Scientific Inventions and Innovations through Pharmaceutical R&D and transform into platform technologies and novel drug products. We provide reliable solutions to polymorphism and crystallization problems through in-depth knowledge and expertise of the solid-state for over a decade. Our motto is to create Intellectual Property through R&D.

The business theme of Crystalin is Chalk2Salt – to take insoluble drug molecules like chalk dust and transform them into high solubility solid forms as table salt. The discovery of novel drug forms and selection of the stable formulation is guided under the expert mentorship of Professor Ashwini Nangia, author of 180 research publications and 12 patents.

<http://chemistry.uohyd.ernet.in/~an/>

Crystalin Research Pvt. Ltd.  
Room No. 5, Technology Business Incubator Facility, University of Hyderabad campus, Gachibowli, Hyderabad 500 046, AP  
Mob +91 98481 55416, 040 2301 1338  
E-mail [ashwini.nangia@gmail.com](mailto:ashwini.nangia@gmail.com)  
URL [www.crystalin.co.in](http://www.crystalin.co.in)



To thicken the pipeline of soluble drugs

**CRYSTALIN** offers the expertise and experience of academics to industry for innovative solutions to pharmaceutical solid-state issues. Over 80% drugs and 95% of top-selling drugs are administered as tablets/capsules. All drugs coming through development in the last 10 years have many polymorphs and pseudopolymorphs.

The focus of Crystalin is to use the knowledge of hydrogen bonding and crystal packing to develop novel design strategies for polymorphs and cocrystals and salts. Analytical techniques such as XRD, DSC, TGA, thermo-microscopy, DVS, NMR, HPLC, IR, NIR, Raman spectroscopy are used to characterize new solid-state forms and monitor phase transitions. The knowledge and experience is applied to solve polymorphism, solvates, hydrates, stability, filterability, cocrystal, salt, dissolution, stability and tableting issues in drugs, discover novel API polymorphs, and optimize robust crystallization protocols.

Solubility and stability of polymorphs and cocrystals, Tablet and Powder Dissolution.

## RESEARCH ACTIVITIES

The main focus of Crystalin is to harness the technological potential of pharmaceutical research and transform into novel drug products at their R&D lab. The goal is to develop Improved Chemical Entities, ICEs, at affordable cost and rapid timelines.

API characterization

DSC, TGA, HSM, IR, NIR, Raman, microscopy, XRPD, SC XRD

Form screen

Polymorphs, solvates, cocrystals and salts of APIs through novel crystallization techniques

PC/PK/PD improvement

Soluble and stable cocrystals and salts of APIs with GRAS coformers, fast dissolution polymorphs

Phase behavior

Kinetic & thermodynamic forms, anhydrous and hydrate/ solvate, amorphous and crystalline phases

Computations

Crystal structures of new molecules, lattice energy, density, stability and morphology of polymorphs

Patent advice

Interpretation of polymorphs and cocrystals for patent fling, Drug efficacy enhancement

## The decade of patent cliffs

Starting with Atorvastatin in Dec. 2011 (global sales \$12 bn), many blockbuster drugs will go off patent in the current decade. Over \$100 bn sales of branded drugs will see market erosion until 2015, a decline that will continue beyond 2020.

The number of new drugs being launched by innovator companies is declining. FDA approved 10 drugs annually in the last 5 years while this number was 35 in 2004 and 30 around 2000.

A possible business strategy in this era of declining small molecule drugs and global economic crisis facing the pharmaceutical industry is low-risk approaches such as drug-repositioning, differentiated drug products, and combination therapies for new drug targets.

The strength of the Indian pharmaceutical industry lies in exploiting the present situation by innovating improved generics at low cost. The approval of drug cocrystals through 505(b)(2) route of FDA and filing/ grant of several cocrystal patents in US, EU and WO since 2000 are positive indicators. Successful Para IV challenges offer market exclusivity to generics companies for innovator molecules. Crystalin Research provides strategic and innovative solid form discovery services to successfully navigate the stormy pharma climate.

## Instrumentation



X-ray diffractometers



IR-NIR-Raman workbench



Dissolution Tester and Spray Dryer



DSC and TGA

## Management Team

### Director Technical and Founder

Prof. Ashwini Nangia, PhD Yale University, 20 years experience in organic synthesis and solid state chemistry, Leader research group in pharmaceutical cocrystals, polymorphs, salts, drug form discovery and selection, Solubility Advantage of Amorphous Drugs and Pharmaceutical Cocrystals, Crystal Growth & Design, 2011.

### Director Operations

Ms. B. Mahalakshmi, BA Bombay University, 10 years experience in successful management of small-medium businesses and operations, administrative and financial responsibilities and liaise with businesses.

### Managing Director

Mr. Ravi Nangia, BTech IIT Kanpur, Successfully running a fine chemicals manufacturing unit for 40 years, entrepreneur and technology development and scale up of chemical processes.

## Research Laboratories



UOH Gachibowli & IKP Genome Valley