



CRYSTALIN RESEARCH PVT. LTD.

Pharmaceutical Solid State Innovation R&D Laboratory

Technology Business Incubator Start-up Venture

About Crystalin Research Pvt Ltd

A Pharmaceutical Solid-State Innovation R&D Lab

Lab

Office at Banjara Hills, Hyderabad

Chemistry Lab at Technology Business Incubator, University of Hyderabad

Biology Lab at Life Science Incubator, IKP Knowledge Park, Hyderabad

Directors of Crystalin Research

Directors of Crystalin Research

Managing Director, Mr. Ravi Nangia, Chemical Engineer, Successfully running fine chemicals and perfumery manufacturing business

Director Operations, Ms. B. Mahalakshmi, Business & Administration of company

Director Technical, Dr. Ashwini Nangia, Chemistry Professor, Driver behind research innovation and technology transfer of drug products

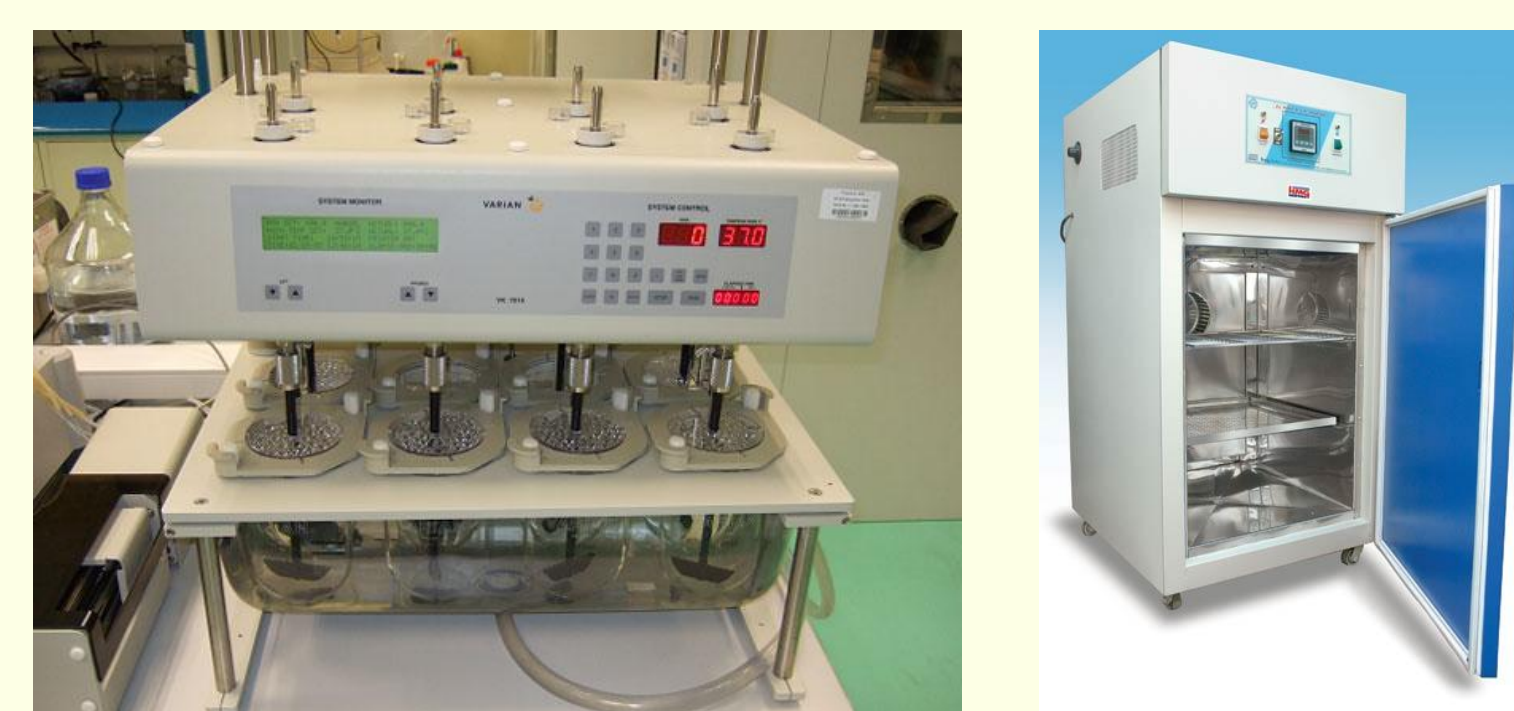
Characterization of Cocrystals

X-Ray Diffraction: SC-XRD and PXRD

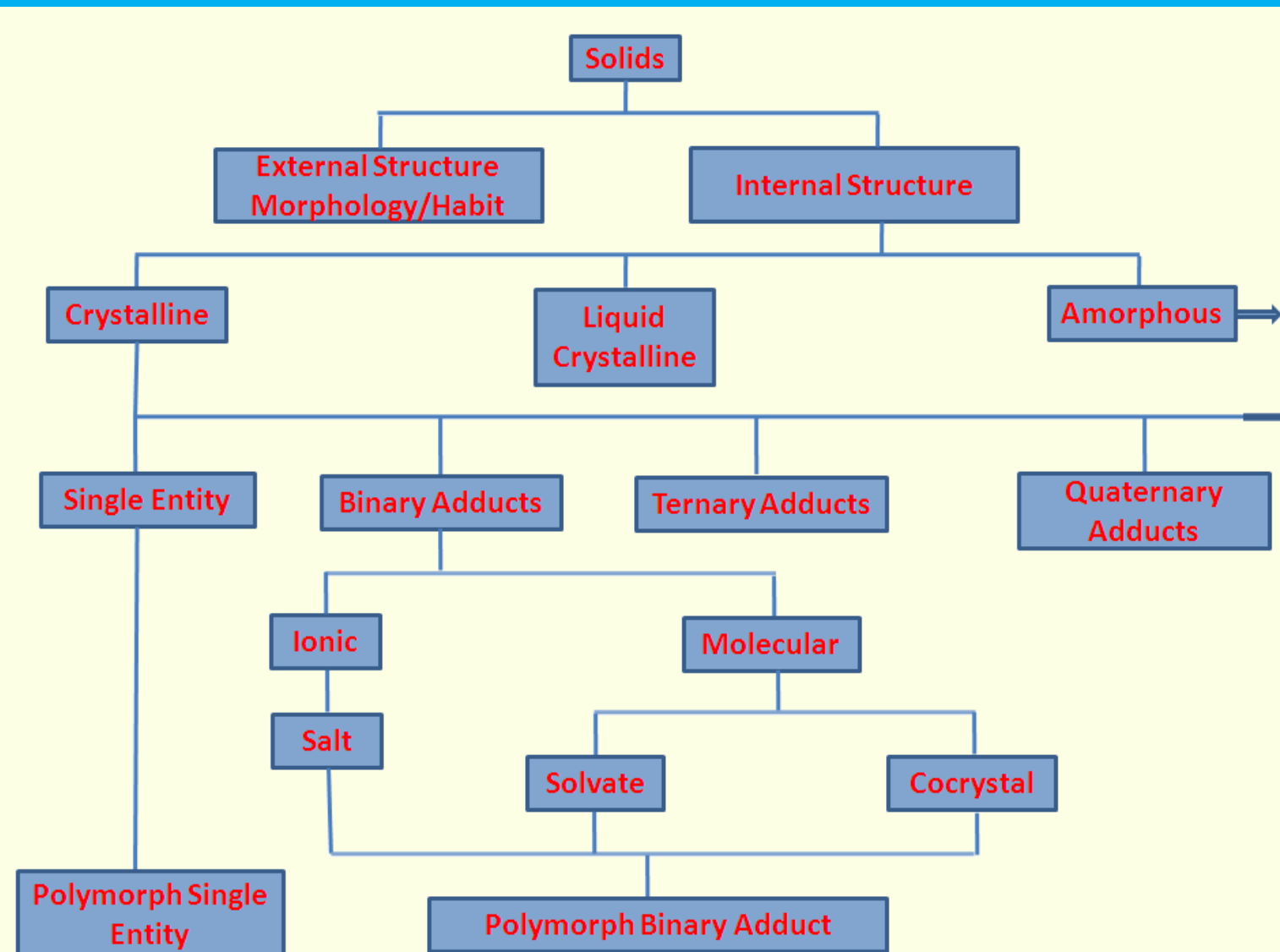
Spectroscopy: IR, Raman, NIR, NMR

Thermal: DSC, TGA, HSM

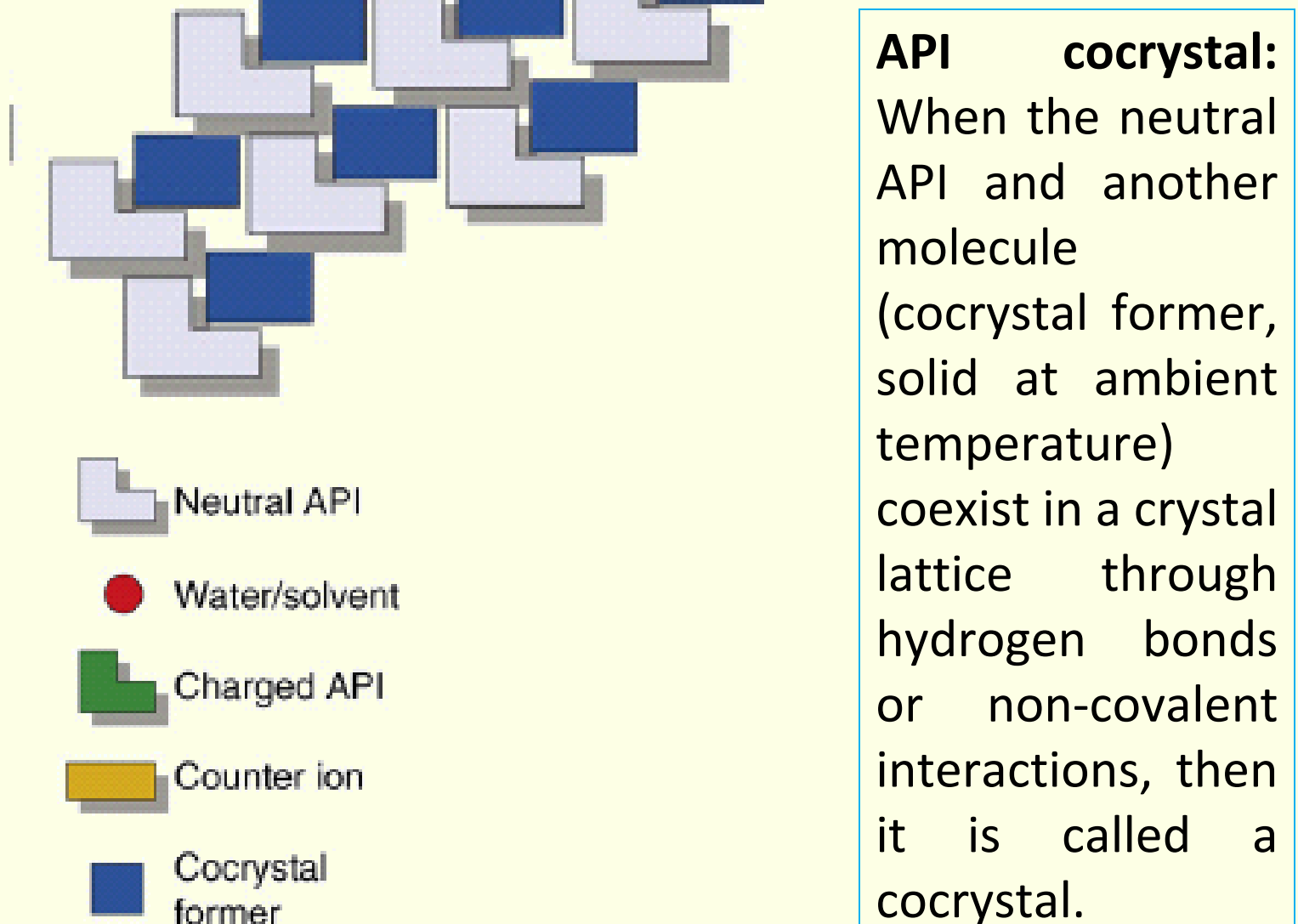
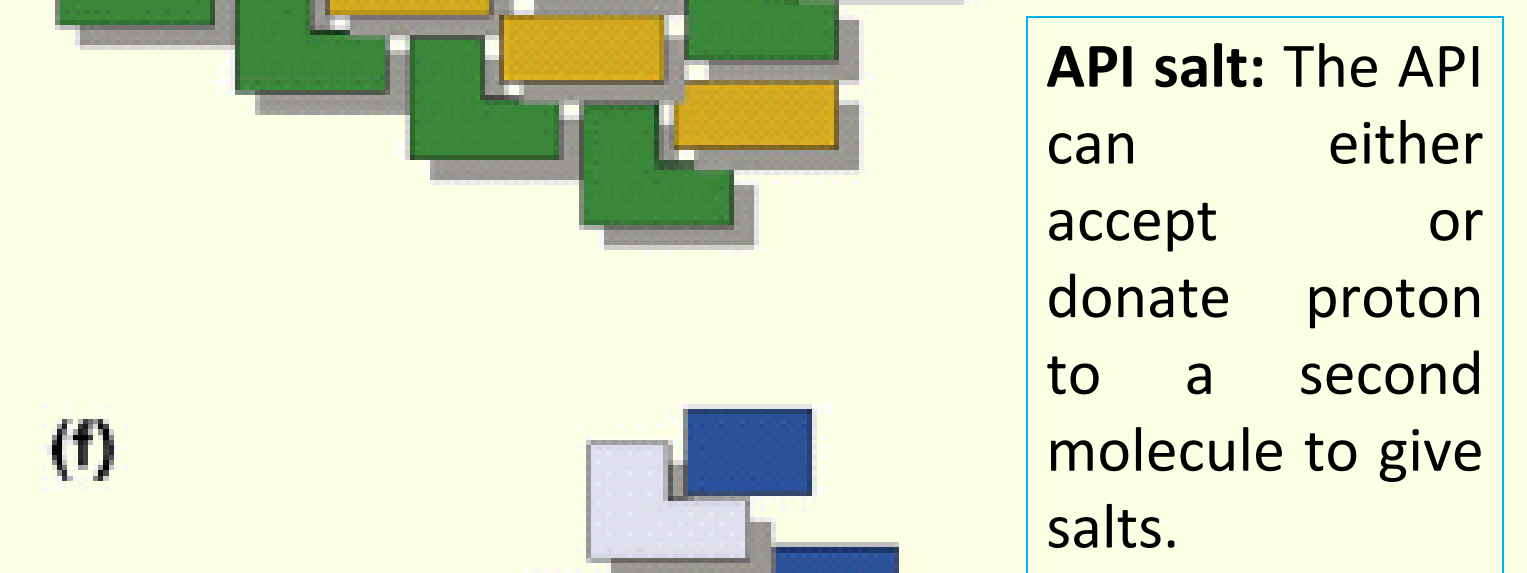
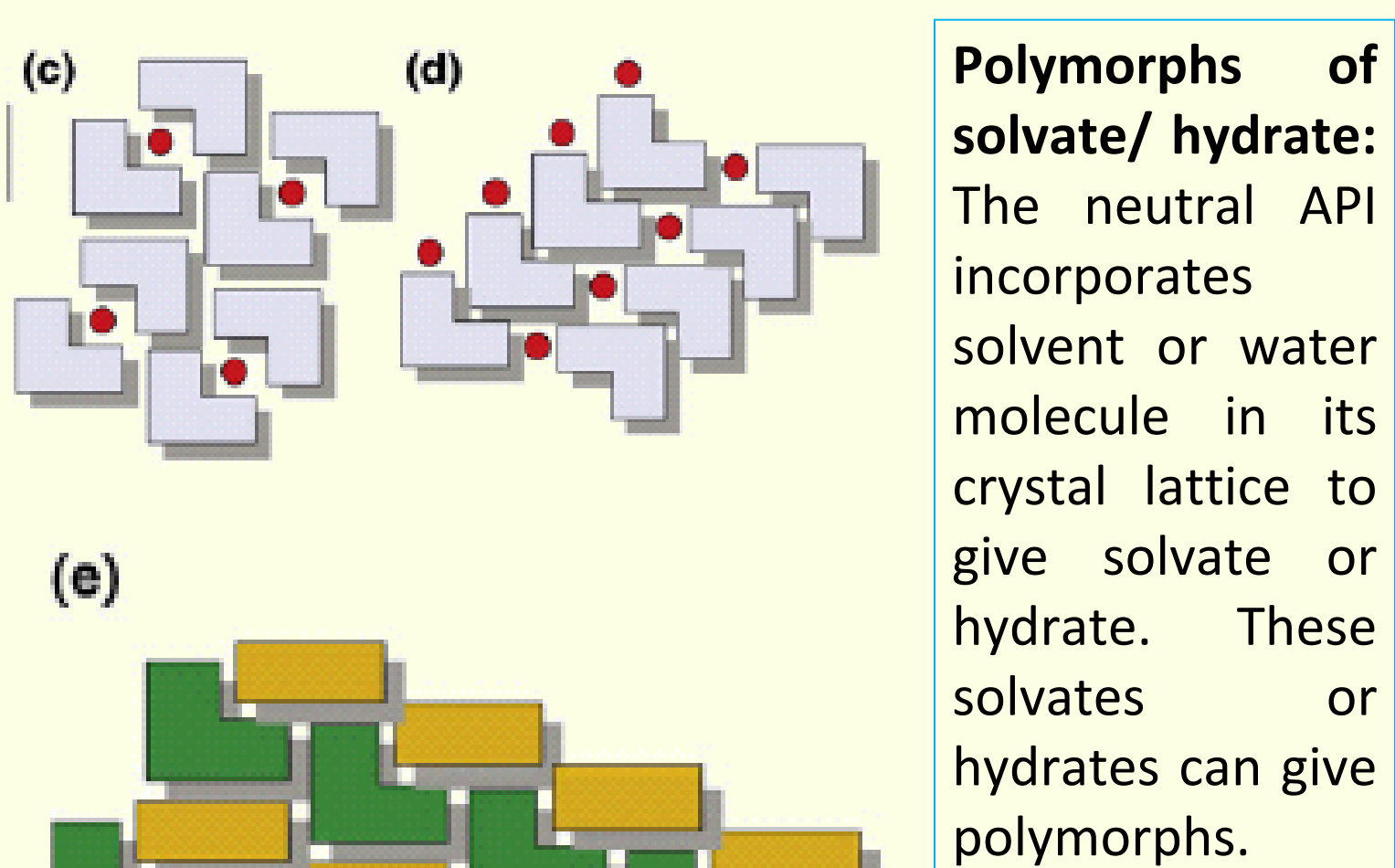
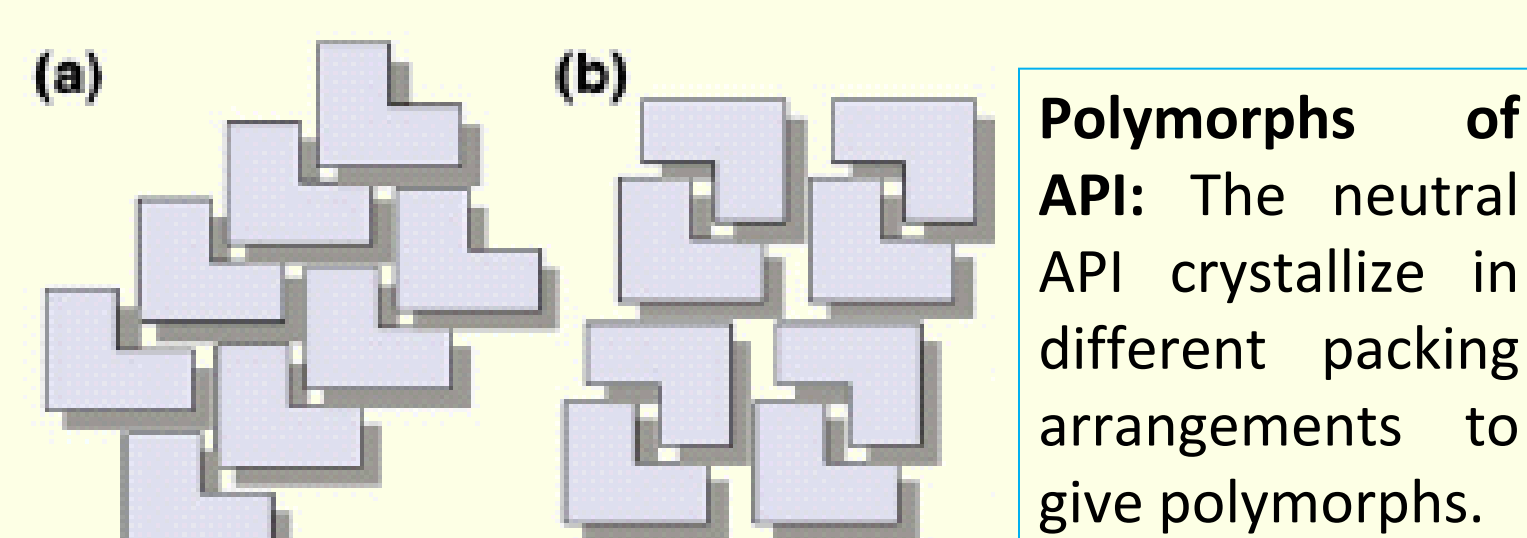
PC properties: Solubility and Stability



Solid State Categories



Schematic diagram to show the classification of chemical compounds in different solid state categories



Importance of Solid State Drug forms

Polymorphism is of fundamental importance in pharmaceutical industry because of physical property control, intellectual property, drug life cycle measurement and commercial issues

Discovery of a new polymorph of a drug with undesirable properties, such as low solubility, at a late stage can result in a market crisis and require re-development of drug form

The thermodynamically stable polymorph of a drug is usually the least soluble whereas metastable polymorphs can have 2-3 times higher solubility

Stabilizing a fast dissolving metastable polymorph of a drug can be challenging

Hydrates and Solvates are generally not preferred because of stability issues and possible toxicity of the solvent (except EtOH)

Amorphous and/ or **Salt** formulations are the preferred approaches to improve solubility

Salt formation is the first choice method for drug molecules containing ionizable functional groups such as COOH, NH₂, Pyridine, SO₃H etc.

Pharmaceutical Co-crystallization can offer tremendous control over physico-chemical properties

Drug molecules with non-ionizable functional groups, e.g. CONH₂, OH, chiral drugs prone to racemization in strongly acid/base conditions, and unstable drug molecules

Advantages of Pharmaceutical Cocrystals

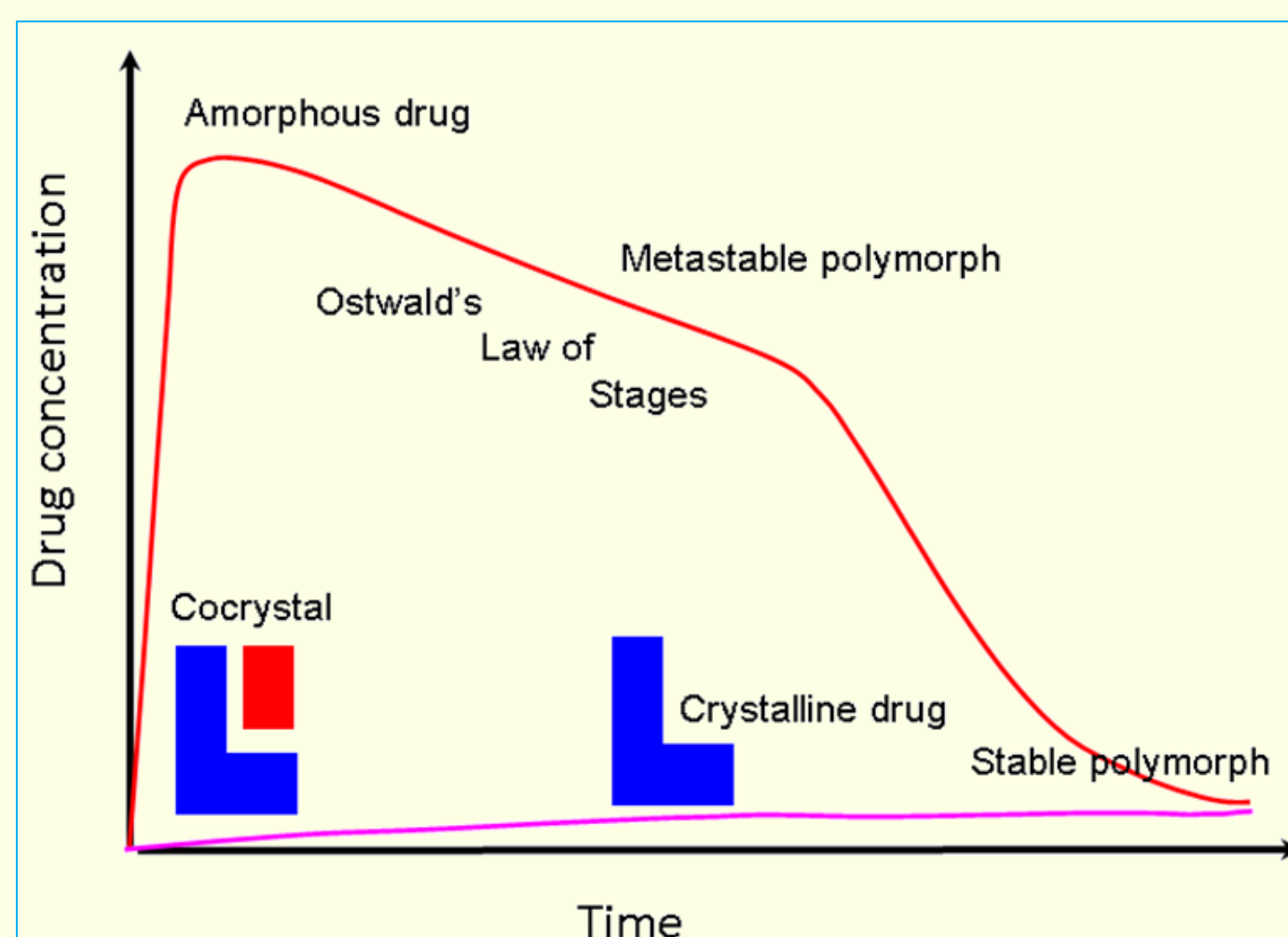
Numbers of pharmaceutically acceptable cocrformers is far greater than salt formers

Cocrystals are relatively more stable than metastable polymorphs and amorphous forms

Physicochemical properties can be modulated in a controlled way through cocrystals

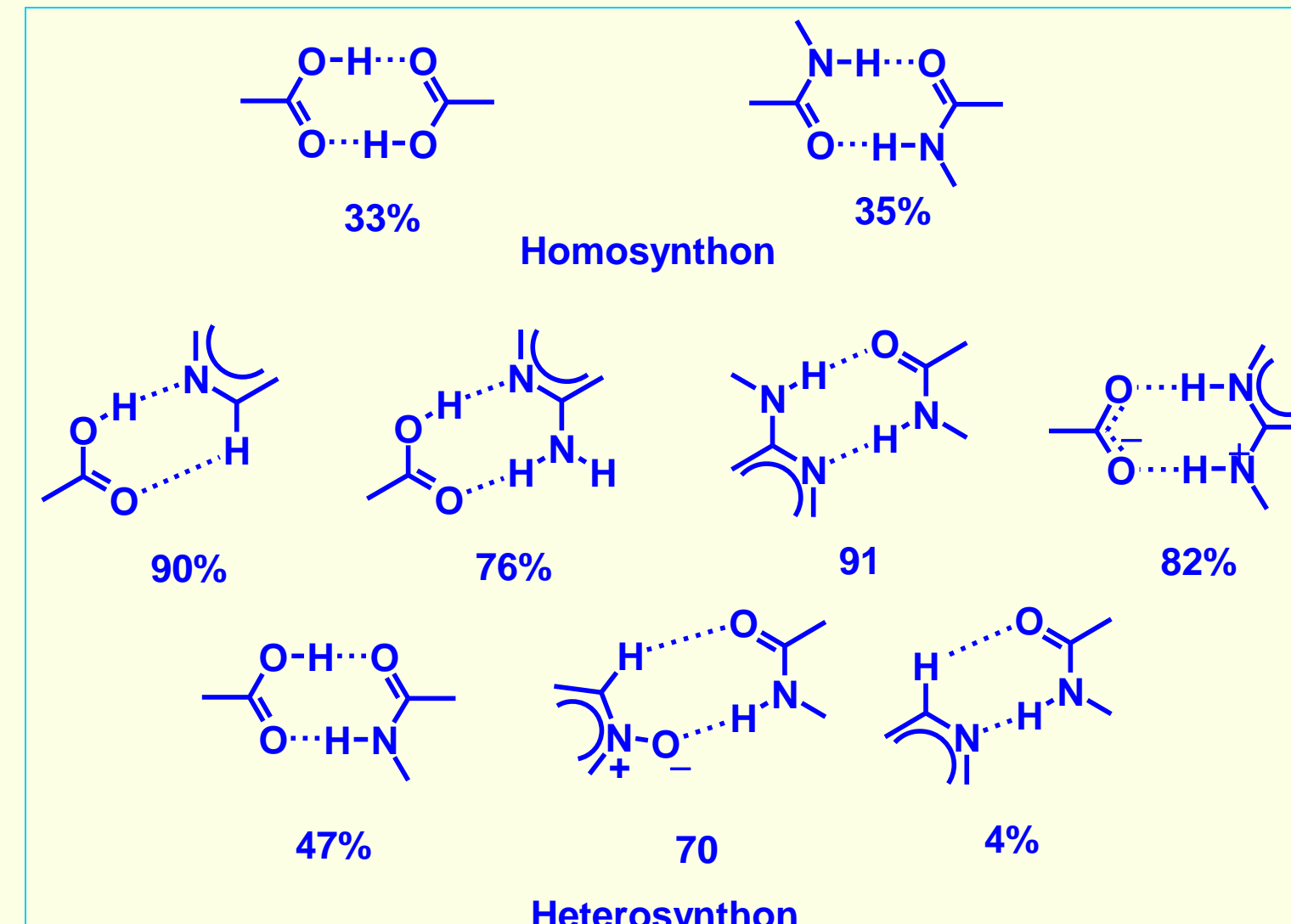
Tune the solubility of a particular drug between extremes, such as from low soluble to high soluble formulation

Systematically modify solid drug dosage for immediate release (IR) or extended release (ER)



Spring and Parachute concept to achieve high supersaturation of amorphous and cocrystal drugs

Designing Pharmaceutical Cocrystals



Crystal Engineering

Homosynthon: Hydrogen bond synthon among the same functional group
Heterosynthon: Hydrogen bond synthon between complementary functional groups

Screening for Various Solid State Forms



Slow evaporation from solvent, cooling crystallization, high temperature crystallization, solvent diffusion, anti solvent addition, crystallization using hetero-seed and cofomer/additive, solvent less methods of melting and sublimation etc.

Co-crystallization is accelerated by solvent drop grinding, neat grinding, ball mill grinding, ultrasonication, temperature etc.

Our Achievements



Milestones and Achievements

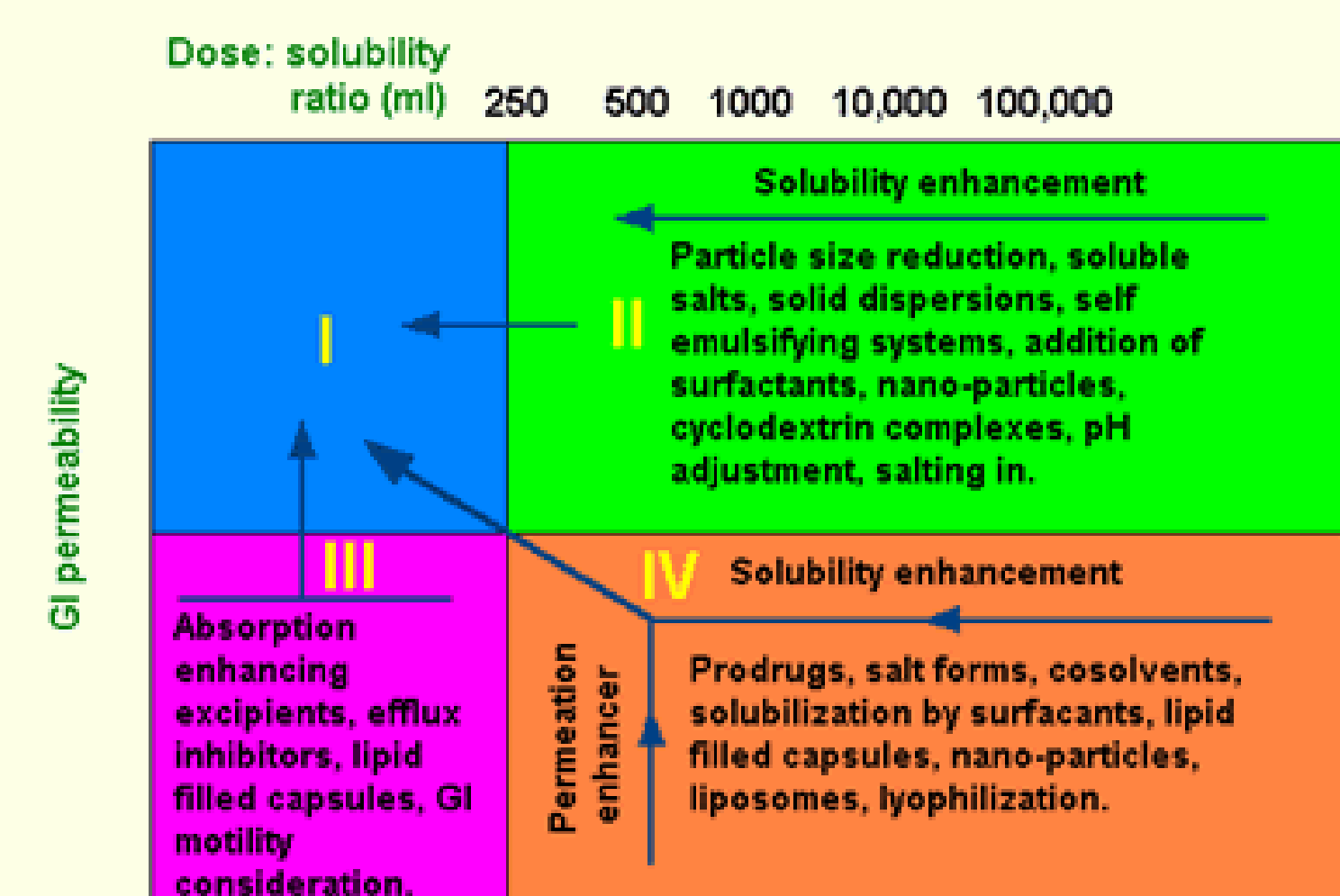
- Chalk2Salt Biz Plan, May 2010
- UK-India Biotech-Pharma, Sep. 2010
- Power of Ideas, Oct. 2010
- Lab at TBI UOH, Nov. 2010
- Member of MSME Cluster, Mar. 2011
- Registration of Co., Mar. 2011
- IKP Incubator, May 2011
- Lab at LSI IKP, Nov. 2011
- IKMC Poster Award, Nov. 2011
- Start Pre Clinical Trials, Jan. 2012

Contact Information

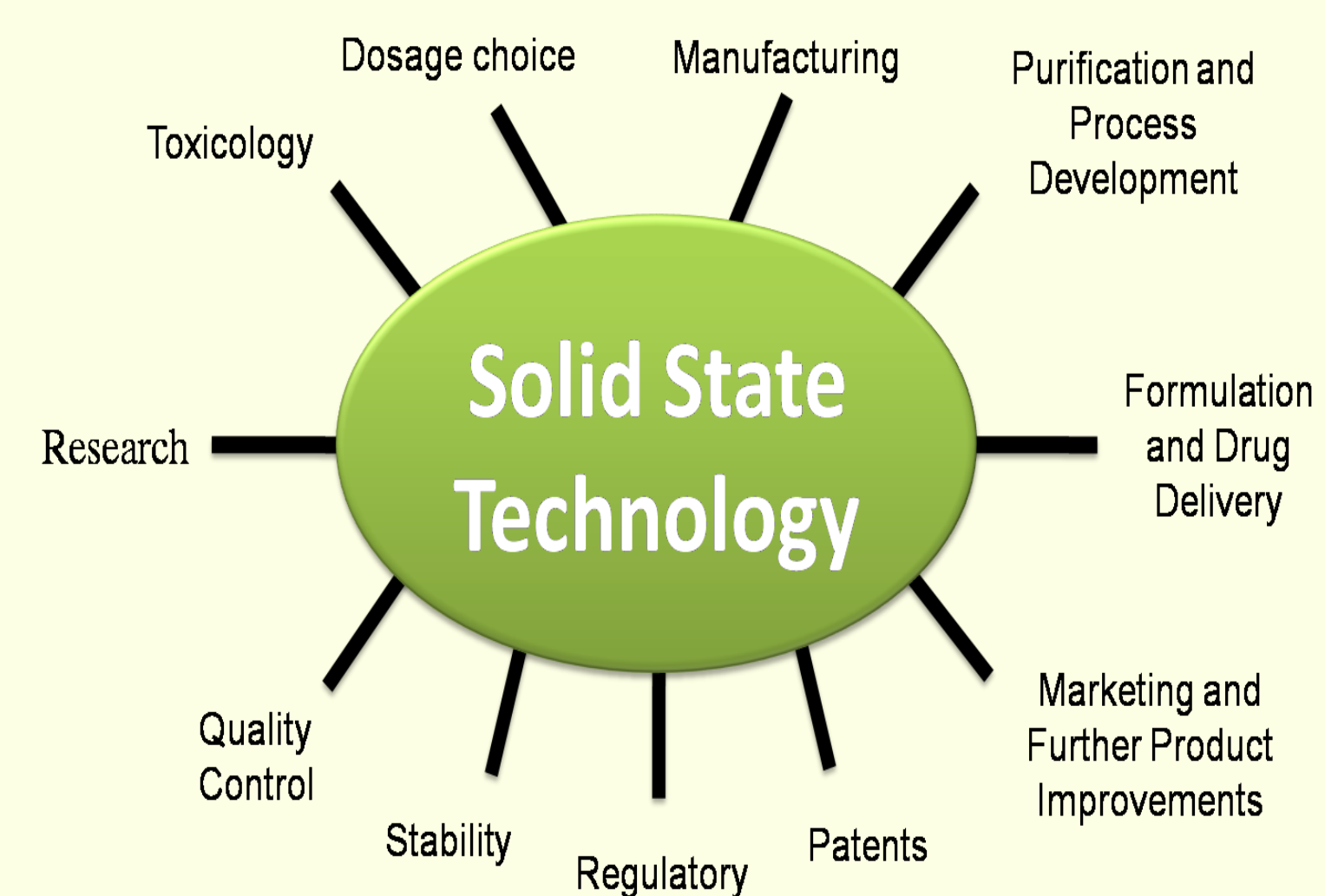
Plot 81 A/C, Unit D, MLA Colony, Banjara Hills, Hyderabad 500 034
director.crystalin@gmail.com
www.crystalin.org
B. Mahalakshmi 98496 59109
Ashwini Nangia 98481 55416

BCS Classification of Drugs

BCS class	Solubility	Permeability	% Drugs on market	% Drugs in pipeline
I	High	High	35	5-10
II	Low	High	30	60-70
III	High	Low	25	5-10
IV	Low	Low	10	10-20



Solid State Technology of Drugs



Role of solid-state chemistry in Pharmaceutical Research and Development

Where does solid state form discovery fit in Integrated Drug Discovery?

