MEET US AT

CRS Controlled Release Society

BOOTH #213
JULY 24-28, 2023
LAS VEGAS, NV

BIODURO-SUNDIA

Developability of New Chemical Entities

Agenda

01 Hit to Lead Timelines

02 Developability Considerations

03 Solid State Properties
BCS and DCS

04 Rapid Formulation Screening

05 Case Studies

Timeline of Drug Discovery and Development

Drug Discovery	Pre-clinical research	Clinical trial	FDA approval
Process of drug discovery and development	Potential benefit and mechanism of action, dosage, effectiveness of drug	Dosage escalation, single ascending and multiple-dose study	TBD

Toward FDA Approval

Early Drug Discovery

- Target Identification & Validation
- Hit Discovery
- Assay Development & Screening
- High Throughput Screening
- Hit to Lead
- Lead Optimization

Preclinical Studies

- In Vivo, In Vitro & Ex Vivo Assays
- ADME
- Proof of Concept
- Drug Delivery
- Formulation Optimization & Bioavailability
- Dose Range Finding
- IND-enabling Studies
- IND Application

Clinical Development

- Phase I – Healthy Volunteer Study
- Phase II and Phase III – Studies in Patient Population
- Dose Escalation, Singe Ascending & Multiple Dose Studies
- Safety & Efficacy
- Pharmacokinetic Analysis
- Bioanalytical Method Development and Validation

FDA Review

- NDA / ANDA / BLA Application
- FDA Approval
- Drug Registration

Post-Marketing Monitoring

- FDA Adverse Event Reporting System (FAERS)

Drug Developability

- Likelihood a drug candidate to become:
  -Manufacturable
  -Safe and efficacious drug (sponsors and regulatory agencies)

- Likelihood a drug candidate to go smoothly through:
  -Chemistry, manufacturing and control (CMC) process
  -Reasonable cost
  -Reasonable timeline

- Assessment of developability:
  -Rapid and high-throughput screening
  -Consume small amounts of testing materials

Source: WeijieZhang, et al., Antibody Therapeutics, 2023, Vol. 6, No. 1 13–29

Developability: Solid State Properties

solubility and stability

- Polymorphism
- Solvate
- Salt formation

- Molecular design
- ‘‘drug-like’’ Properties
- Phase appropriate characterization strategies
- Salt and crystal form screening and selection

Salt and Crystal Form Screening and Selection processes

Tier 1

Crystallinity (visual, microscopy)

Crystallization from different solvents

Aqueous solubility including microscopic examination of suspended solid

Tier 2

Evaluation of crystalline form (powder X-ray diffraction, hot-stage microscopy)

- Thermal properties (DSC, TG)
- Hygroscopicity

Tier 3

Humidity/temperature-dependent changes in crystal form (powder X-ray, DSG, TG, VT-XRD, etc.)

Tier 4

Bioavailability (optional)

- Stress stability
- Scale-up consideration

Final Form

Tier 1

Physical characterization of the unionized form

In situ salt screening to rank order solubility of potential salts

Tier 2

In vitro testing:

- Diluting the solution of the most soluble salt solution into Simulated Gastric Fluid (SGF) and Simulated Intestinal Fluid (SIF) to determine if the compound precipitates and in what form it precipitates
- Intrinsic dissolution rates of the unionized form in SGF and SIF

Tier 3

Animal PK studies:

- Comparing the bioavailability of the solution of the most soluble salt with the suspension of the unionized form
- If the hydrochloride salt is very insoluble of the compound is acid labile, test whether bypassing the stomach can improve bioavailability (intra-duodenal dosing or enteric coating)

Tier 4

Preparation and characterization of top 2-3 salts:

- Crystal form screening and characterization, chemical stability, processability

Tier 5

Bioavailability confirmation if needed:

- Suspension/capsule of the solid at projected clinical doses and toxicological doses

Final Salt and Crystal Form

Source: L.F. Huang, W.-Q. Tong / Advanced Drug Delivery Reviews 56 (2004) 321–334

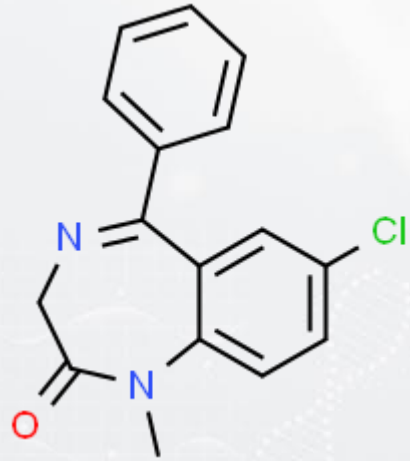
The Rule of Five (Lipinski)

poor absorption or drug permeability is more likely

- > 5 H-bond donors (-OH)
- > 10 H-bond acceptors (-O)
- > 500 Mw
- > 5 calculated Log P

- The Relationship between *in vivo* drug dissolution and the solution or intestinal wall concentration
- The Relationship between *in vivo* dissolution and *in vitro* dissolution

- Estimate solubility and permeability in drug discovery and development
- Simple algorithm to select for compounds most likely to be orally active



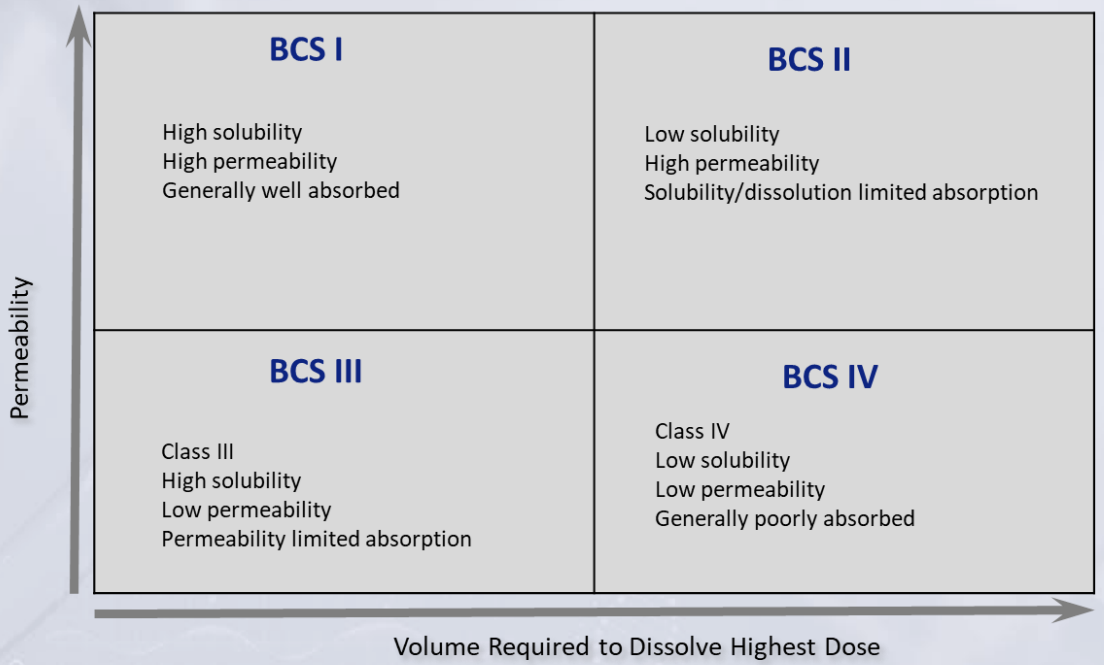
Challenges with Oral Bioavailability of NCEs

>90% Poorly Bioavailable

- > 70% poor aqueous solubility (BCS II)
- > 20% poor permeability (BCS III/IV)

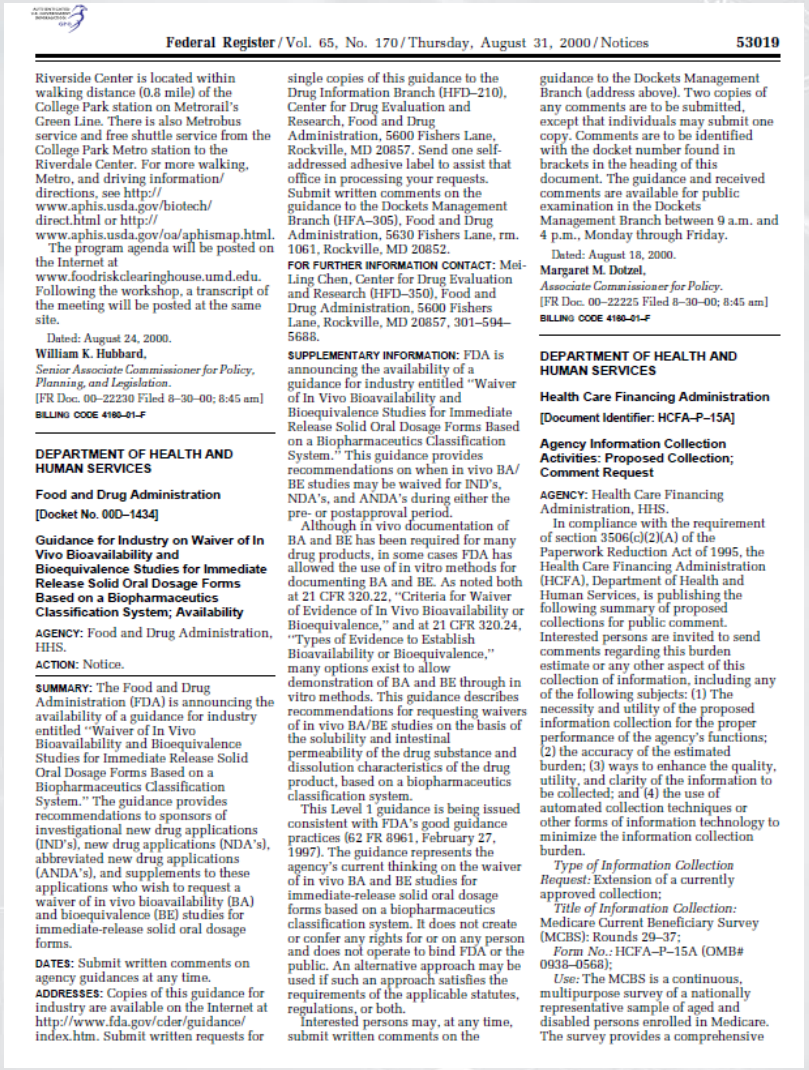
"***high solubility***" BCS classification:

Highest **human dose** strength must be soluble in **250 ml** from **pH 1 to pH 7.5**



Source: Gordon L. Amidon, Pharmaceutical Research, 12:413-420(1995)

From BSC to BA/BE Waiver



Federal Register / Vol. 65, No. 170 / Thursday, August 31, 2000 / Notices 53019

Riverside Center is located within walking distance (0.8 mile) of the College Park station on Metrorail's Green Line. There is also Metrobus service and free shuttle service from the College Park Metro station to the Riverdale Center. For more walking, Metro, and driving information/ directions, see http:// www.aphis.usda.gov/biotech/ direct.html or http:// www.aphis.usda.gov/oa/aphismap.html.

The program agenda will be posted on the Internet at www.foodriskclearinghouse.umd.edu. Following the workshop, a transcript of the meeting will be posted at the same site.

Dated: August 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–22230 Filed 8–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1434]

Guidance for Industry on Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." The guidance provides recommendations to sponsors of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements to these applications who wish to request a waiver of in vivo bioavailability (BA) and bioequivalence (BE) studies for immediate-release solid oral dosage forms.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/ index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5688.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." This guidance provides recommendations on when in vivo BA/ BE studies may be waived for IND's, NDA's, and ANDA's during either the pre- or postapproval period.

Although in vivo documentation of BA and BE has been required for many drug products, in some cases FDA has allowed the use of in vitro methods for documenting BA and BE. As noted both at 21 CFR 320.22, "Criteria for Waiver of Evidence of In Vivo Bioavailability or Bioequivalence," and at 21 CFR 320.24, "Types of Evidence to Establish Bioavailability or Bioequivalence," many options exist to allow demonstration of BA and BE through in vitro methods. This guidance describes recommendations for requesting waivers of in vivo BA/BE studies on the basis of the solubility and intestinal permeability of the drug substance and dissolution characteristics of the drug product, based on a biopharmaceutics classification system.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on the waiver of in vivo BA and BE studies for immediate-release solid oral dosage forms based on a biopharmaceutics classification system. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–22225 Filed 8–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P–15A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

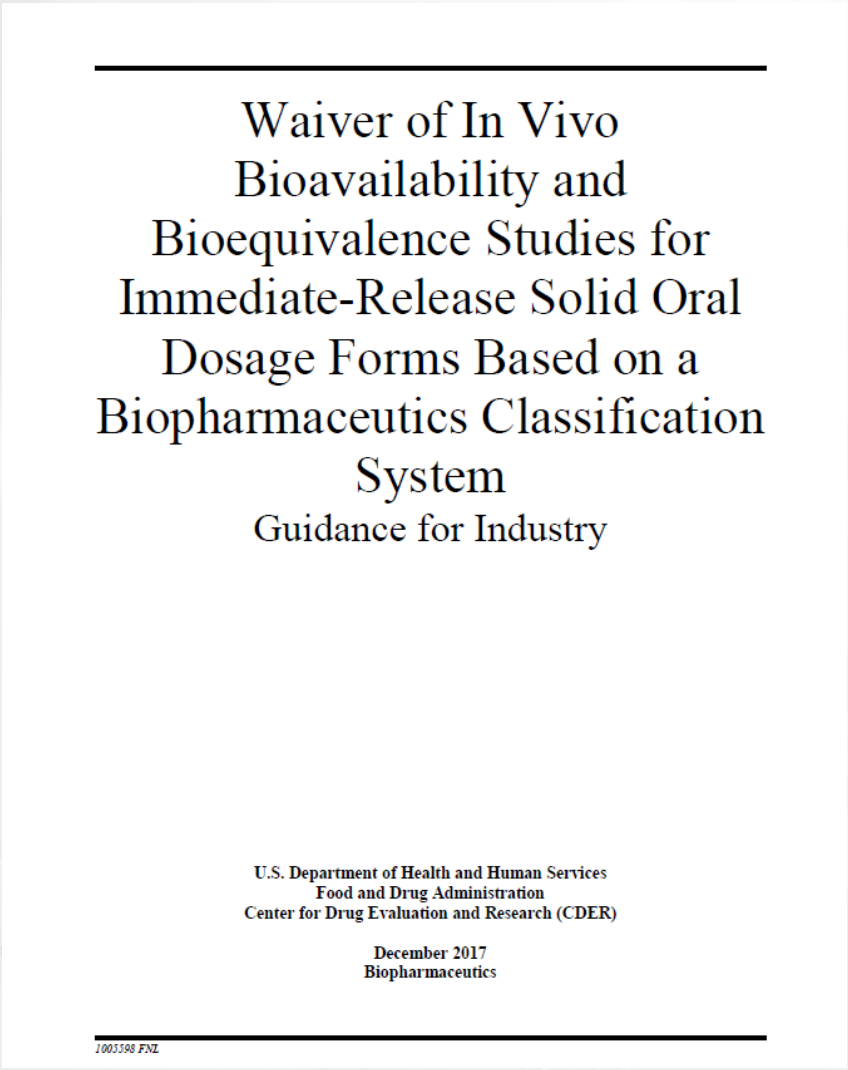
In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Medicare Current Beneficiary Survey (MCBS): Rounds 29–37;

Form No.: HCFA–P–15A (OMB# 0938–0568);

Use: The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive



Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2017
Biopharmaceutics

1005598 FNL

Source: Lipinski, C.A., Lombardo, F., Dominy, B.W., Feeney, P.J., 1997. Adv. Drug Deliv. Rev. 23, 3-25.

Approaches to Improve Oral Bioavailability

Aqueous solubility and/or dissolution rate enhancement

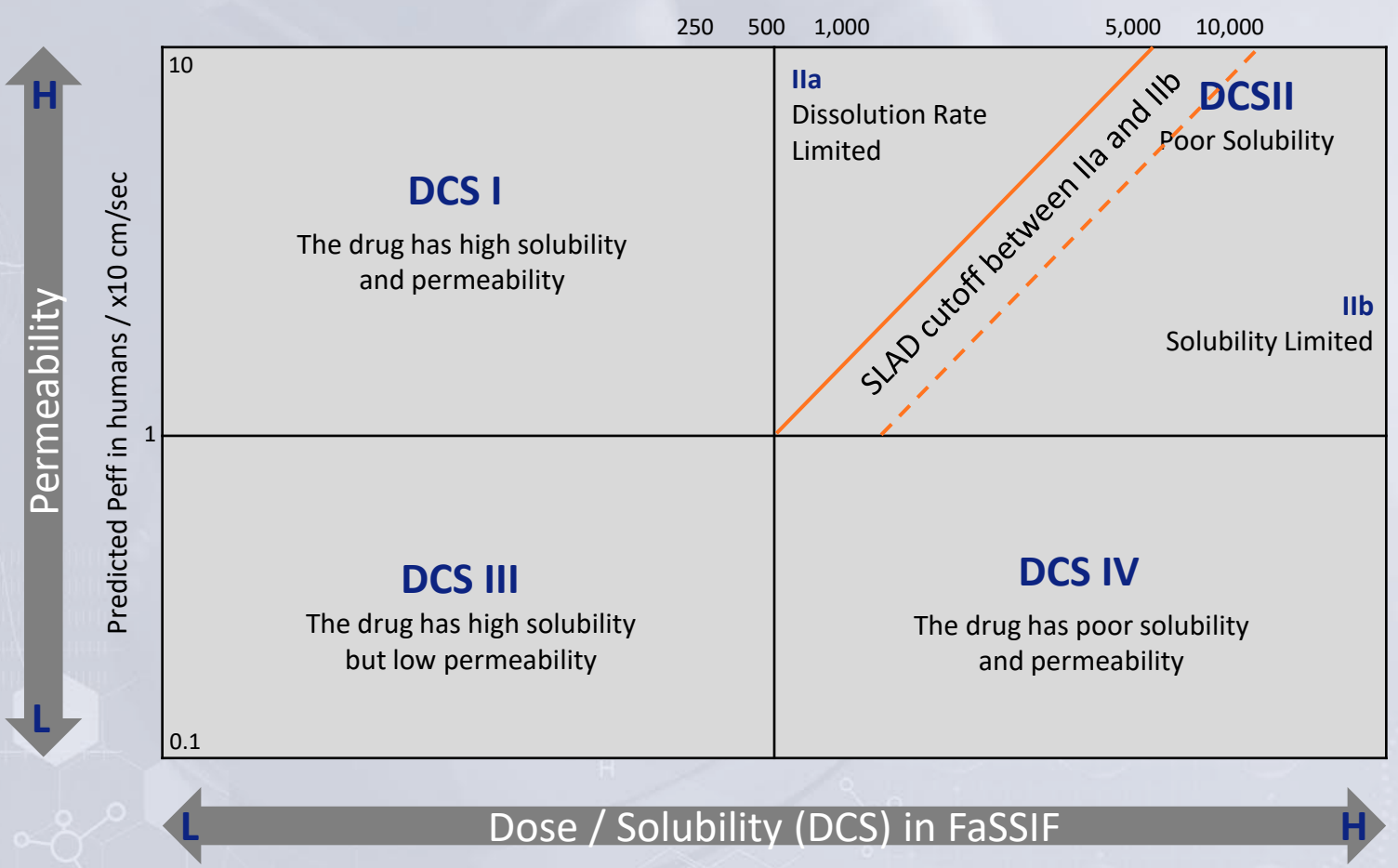
Chemical modifications

- Salts
- Co-crystals
- Prodrugs

Physical modifications

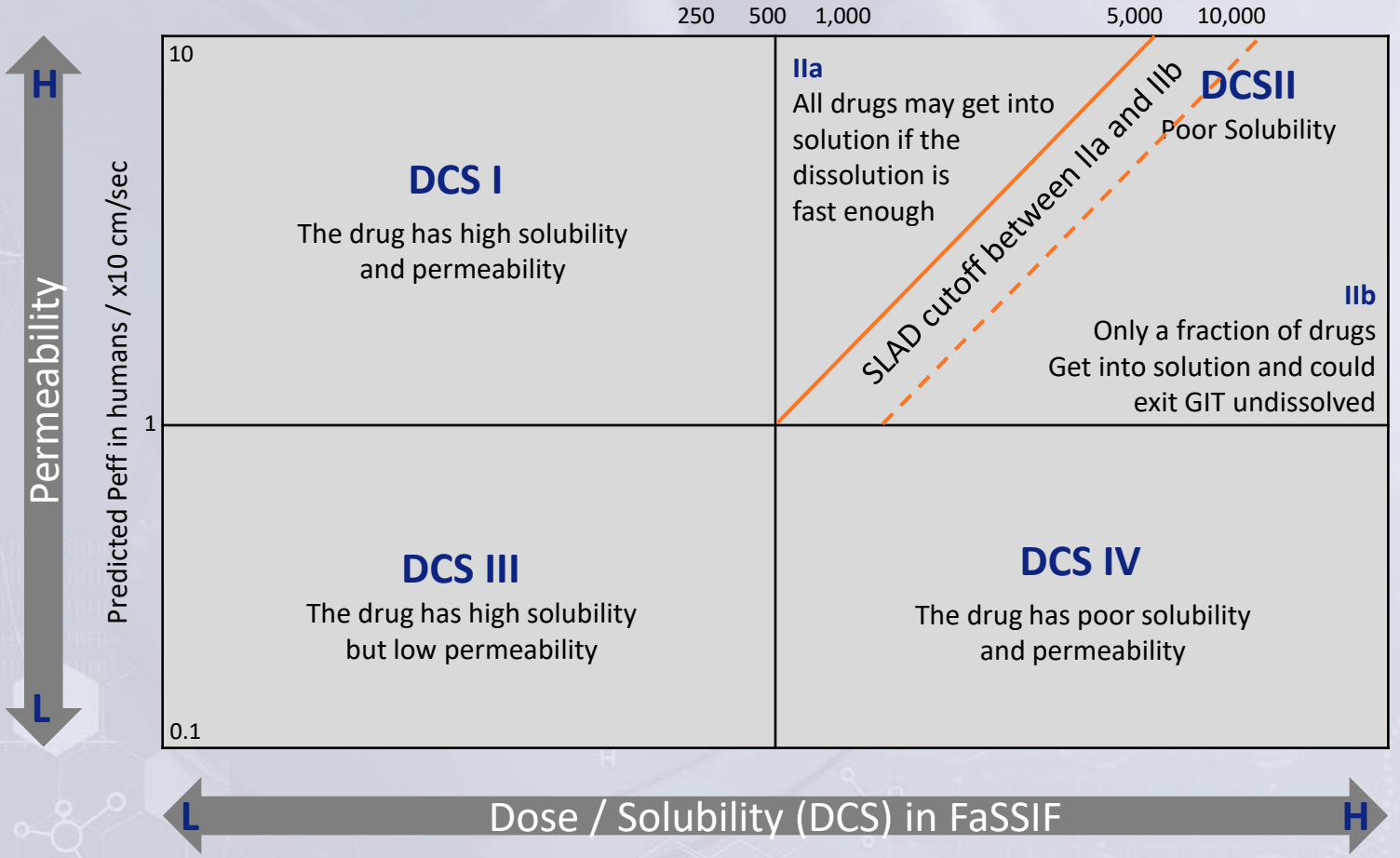
- Complexation
- Nanocrystals
- Amorphous solid dispersion (SDD and HME)

Developability Classification System (DCS) (1/3)



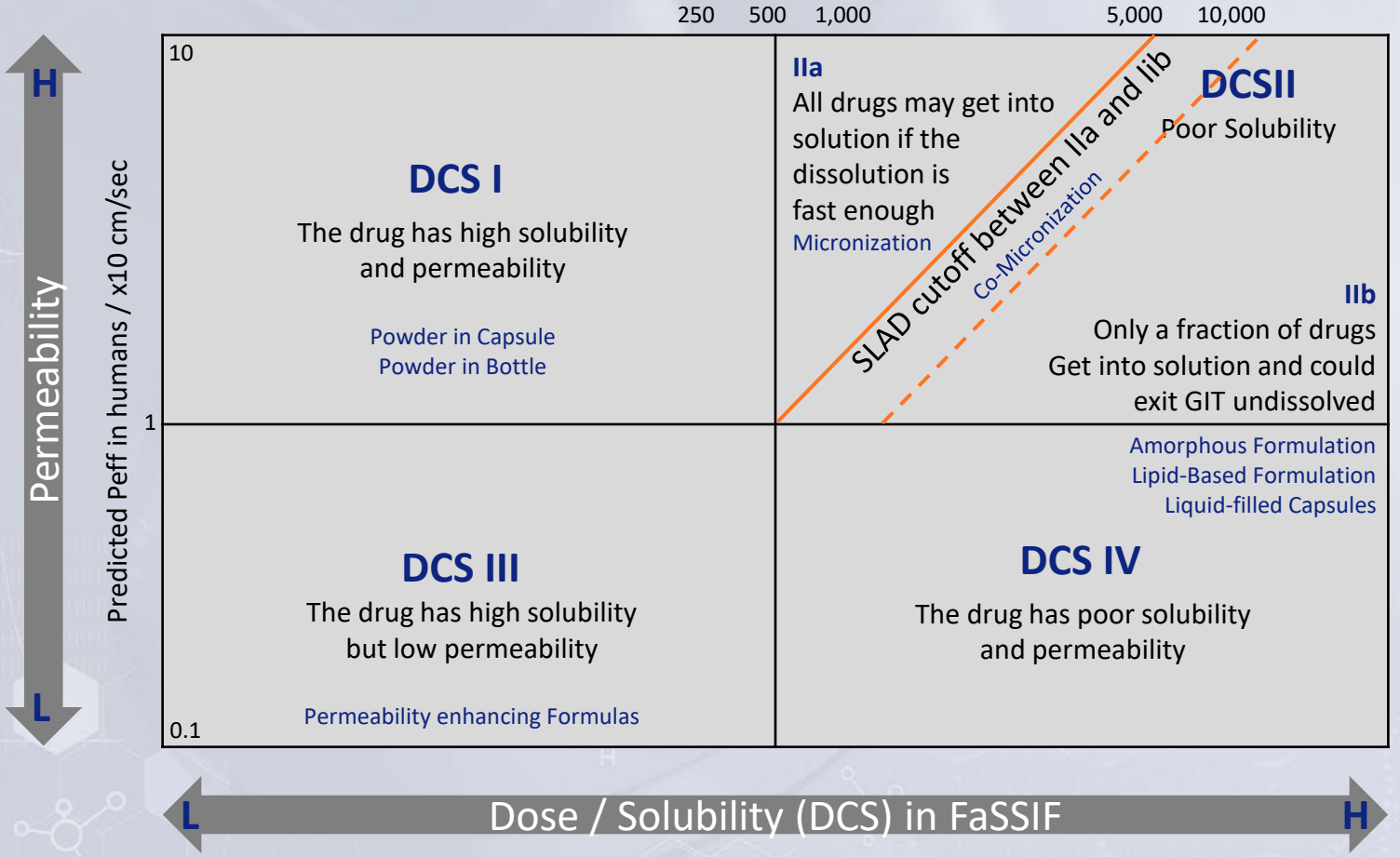
Source: J. Butler and J Dressman, J. Pharm Sci., Dec. 2010

Developability Classification System (DCS) (2/3)



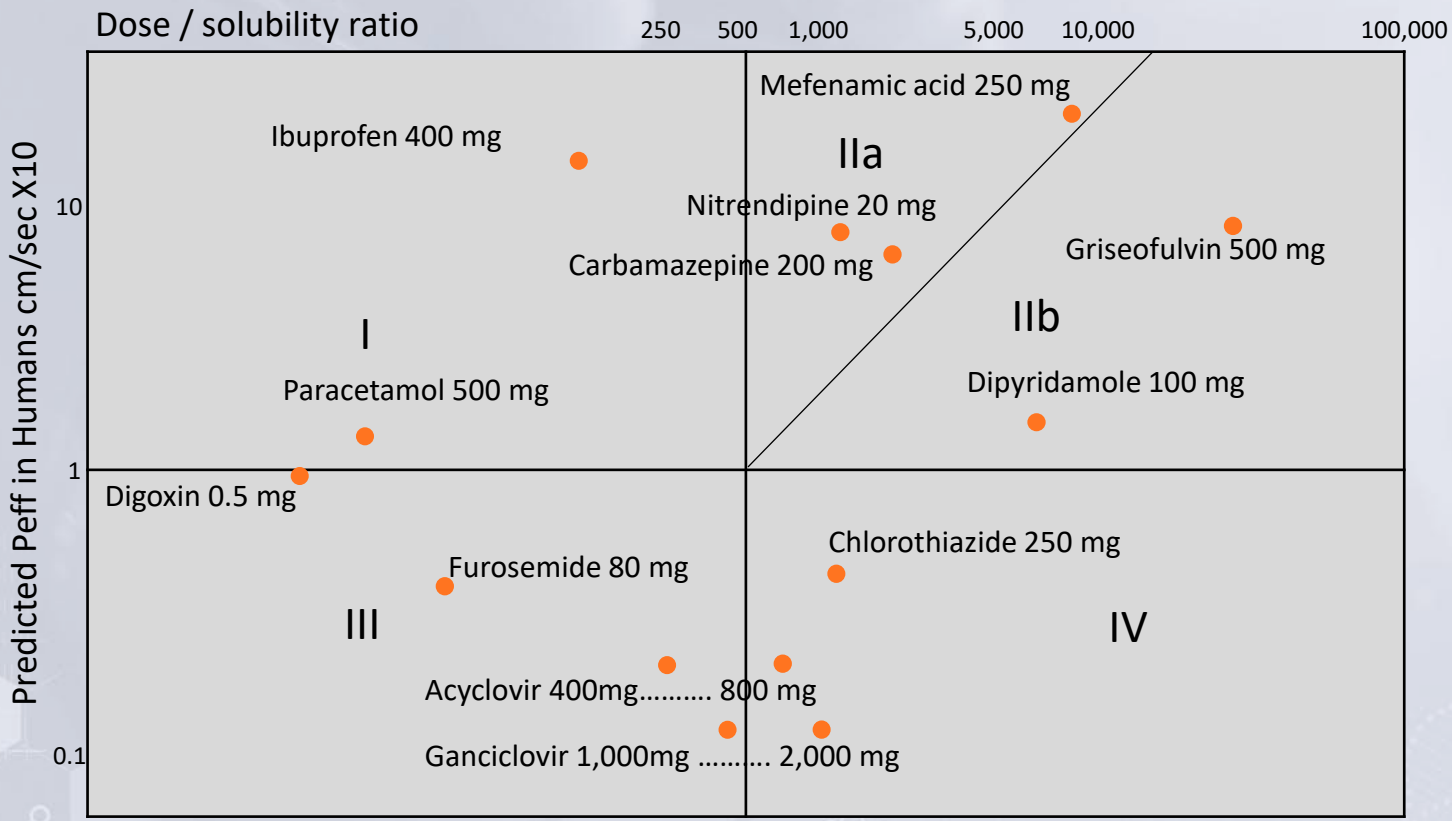
Source: J. Butler and J Dressman, J. Pharm Sci., Dec. 2010

Developability Classification System (DCS) (3/3)



Source: J. Butler and J Dressman, J. Pharm Sci., Dec. 2010

DCS Categorization of Selected Drugs



Source: J. Butler and J Dressman, J. Pharm Sci., Dec. 2010

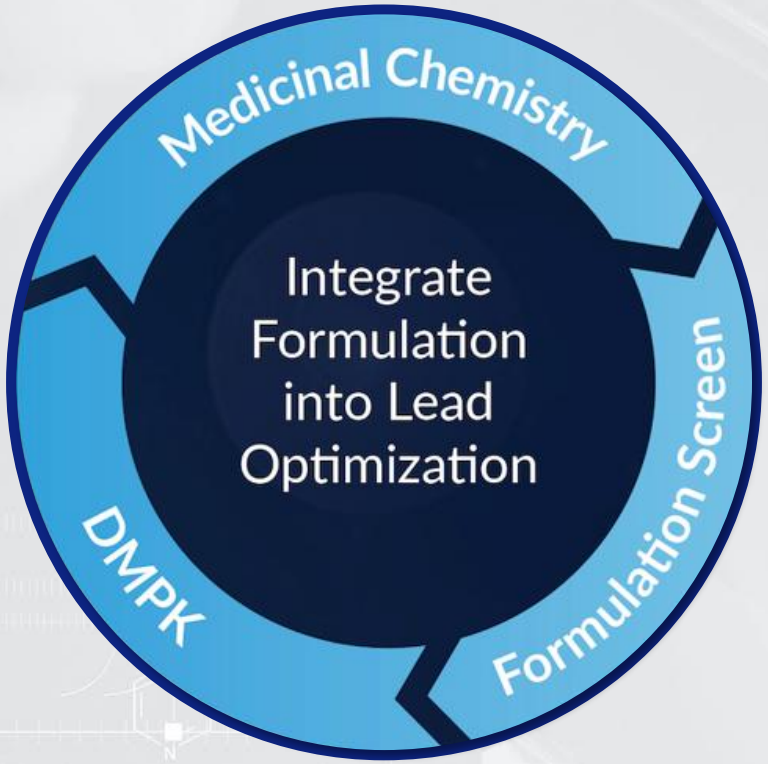
Formulator's Challenge

Discovery and preclinical stage IR and MR formulation development

- Scarce amounts of API available (100 to 200 mg)
- High cost of synthesis
- Tight timelines
- Fierce competition




Screening Bioavailability Enhancement Technologies



Amorphous Solid Dispersion Screening Studies:

- In Silico modeling before random mixing and matching (not QbA)
- Like dissolves like applies to all solubilization technologies (0 g API)
- Miniaturized Screening based on in silico predictions
- Amorphous Solid Dispersion (ASD)
- Two rounds of Animal PK studies
- Best Performing combination selected for Phase I development

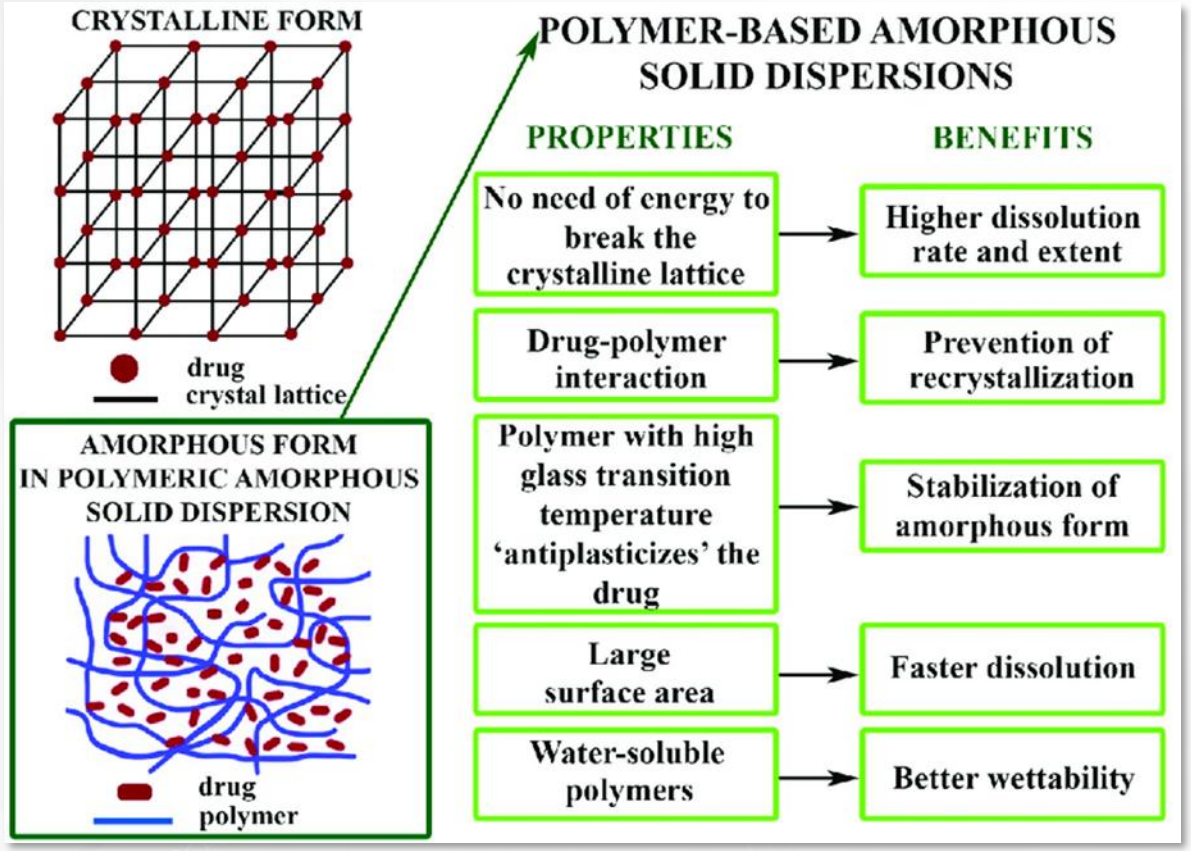
Additional Modules:

- Mesoporous Silica ASD
- Lipid Based Formulations and S(M)EDDS (DCS IIb)
- Nano-Suspension (DCS IIa)
- Micronization (DCS IIa)
- Modified Release

Amorphous Solid Dispersions

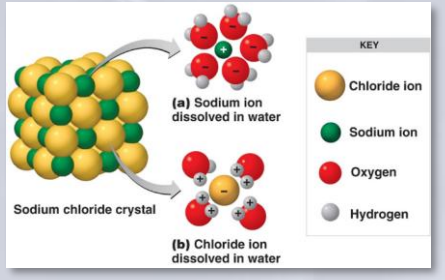
- High energy state of amorphous drug leads to high transient solubility.
- Presence of polymer sustains supersaturation.
- Inter-molecular interaction between the API and the polymer will significantly promote the dissolution of API within the polymer matrix.
- Thermodynamic solubility follows the concept of “like dissolves like”.

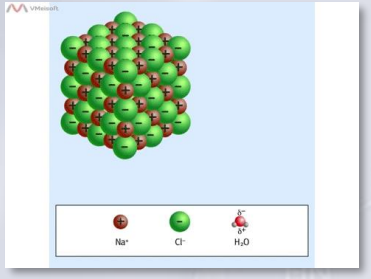
Dissolving the API in the carrier polymer matrix without melting the API. (solubilization regime):



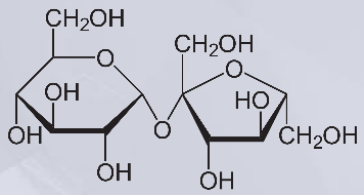
Like Dissolves Like: Reaching Tm is Not Necessary

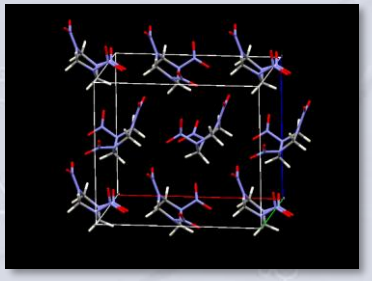
- Sodium chloride (NaCl) salt crystals are made up of face-centered cubic unit cells with a lattice energy of 787 kJ/mol and melting temperature of 801^{o}C.





- Sucrose crystal lattice has a monoclinic structure with a enthalpy of fusion of ~ 64 kJ/mol and melting temperature of 186 ^{o}C (decomposes upon melting).





Theoretical Assessments

- According to F-H theory, the Gibb's free energy of mixing of polymer-API blend can be expressed as:

$$\Delta G_{mix} = \Delta H_{mix} - T\Delta S_{mix}$$

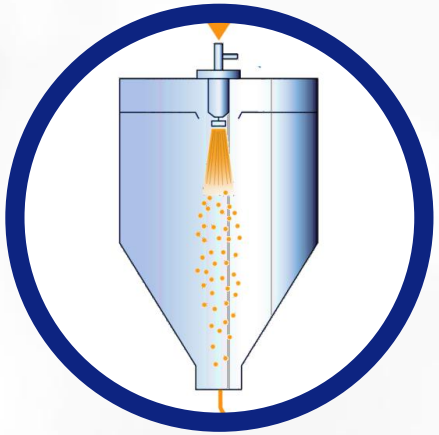
$$\Delta G_{mix} = RT(\varphi_{drug} \ln \varphi_{drug} + \frac{\varphi_{polym}}{m} \ln \varphi_{polym} + \chi_{drug-polym} \ln \varphi_{drug} \ln \varphi_{polym})$$

- Where m is the ratio of the molecular volume of polymer to drug and ϕ is volume fraction.
- For a drug and a polymer without specific interactions, the Flory–Huggins interaction parameter is determined from the solubility parameters of those two components:

$$\chi_{drug-polym} = \frac{V_{lattice}}{RT} (\delta_{drug} - \delta_{polymer})^2$$

- A small value of leads to a small magnitude of enthalpy of mixing and a more negative free energy, favoring the mixing.

Solution Engine 2.0: Solubility Enhancement



In Silico Modeling

- Computer software
- Hansen and Florey-Huggins
- Active material chemical structure
- Polymer type/chemistry
- Screen >20 polymers-API combinations
- No API required
- Timeline: <1 day

Miniaturized Screening

- Minimize number of experiments
- Based on In Silico Results
- 50 mg to 100 mg API required
- Up to 10 to 20 combinations screened at once
- ASD Dissolution ranking
- Timeline: < 2-3 weeks

Animal PK (in vivo validation)

- Two rounds of rodent PK study
- Final ASD formulation selection
- Animal PK provides more accurate product performance data compared with in vitro dissolution studies only.
- Timeline: < 5 days/round

Process Selection Optimization

- Spray drying vs hot melt extrusion
- Assay/non-sink, sink dissolution method development
- Small scale: 1 → 5 gm
- Scale up and clinical manufacturing
- >1 Kg → >100 Kg

Scalable Solubility Enhancement Capabilities

We offer scalable equipment for SDD and HME from Pre-clinical to Pilot Level

< 0.5 g
API

Discovery
(Candidate Selection, Early Tox, Early Preclinical)

- MicroEvap Processing – Pre-Clinical Solubilization
- Screen Excipients for HME, SDD

< 5 g
API

Amorphous Dispersion Feasibility
2-10g scale Dispersion

- Gram-scale Extrusion (Haake)
- Gram-scale SDD (Buchi B290)

< 10 kg
API

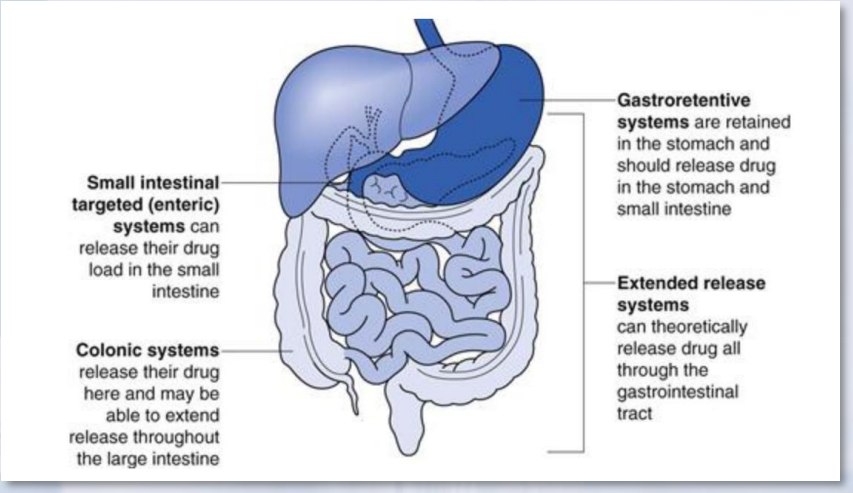
Amorphous Dispersion Development/Scale-Up
100g-kg scale Dispersion

- HME (Leistritz Nano 16mm or ZSE 18mm)
- SDD (Anhydro MS-35 and MS-150)

Modified Release Oral Delivery of NCEs

Stability, dose frequency and site of absorption

- Stomach and upper GI acidic conditions
  May cause denaturing and/or degradation
  Peptides, Proteins, PPIs
- Short residence time in stomach
- Most absorption is achieved in intestinal tract
- Delivery of active to the site of action (colonic delivery)
- Dose Regiment (e.g. QD dose vs QID or more)
- Tailor C_{max} and T_{max}



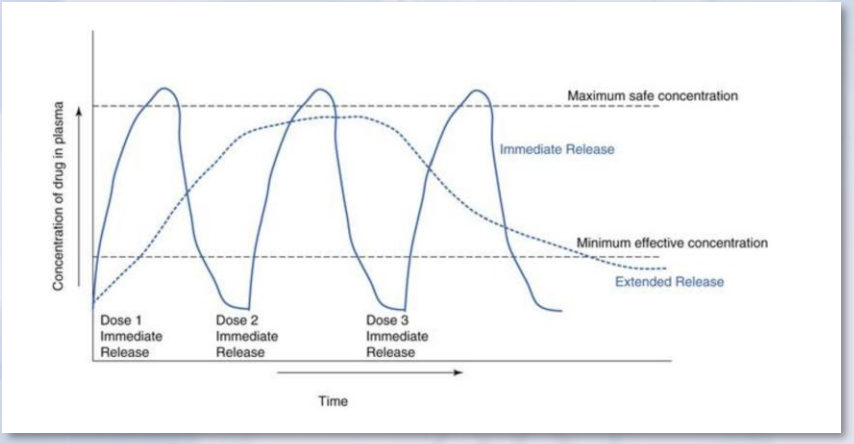
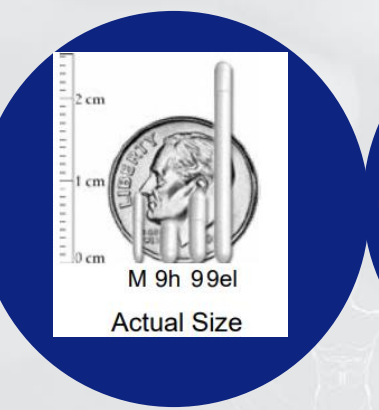
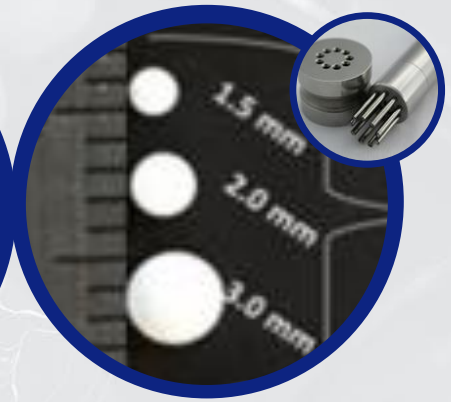


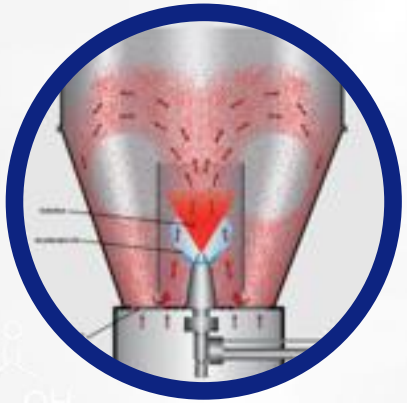
Image Source: Basic Medical Key

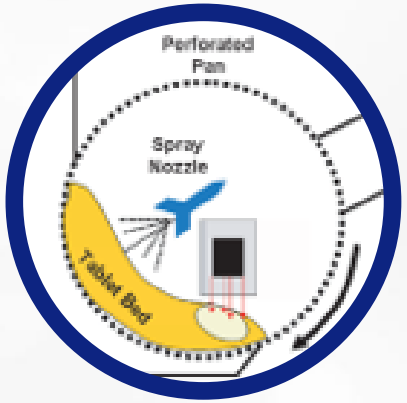
Solution Engine 2.0: Controlled Release

Develop Controlled prototypes for Clin Dev with 1 to 5 g of API









Miniaturized Screening

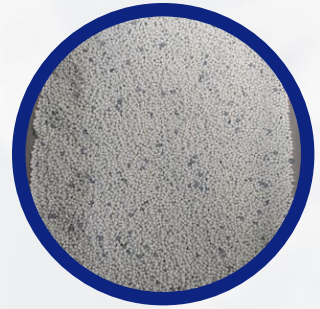
- Minimize API use
- Mini-tablets, Size 9 capsules
- Delayed, modified release
- 1-5 g API required
- Assay/Dissolution method development
- Timeline: < 10-12 weeks

Animal PK (In vivo validation)

- Two rounds of rodent PK study
- Animal PK provides more accurate product performance data compared with in vitro dissolution studies only
- Timeline: < 5 days/round

Process Selection, Optimization

- Tablet, capsule, mini-tablet, drug layering, extrusion spheronization
- Pan coating, fluid-bed coating
- Small scale: 1-5 gm
- Scale-up and clinical manufacturing
- > 1 Kg to > 100 Kg



Case Studies

ASD Case Study I

Accelerated Phase I drug development for poorly soluble drug

Program Overview

- New client needs a solubility enabling formulation for pre-clinical PK and toxicology studies that can be advanced to a solid oral dosage from for Phase 1 Clinical Studies.

Customer Risks/Challenges

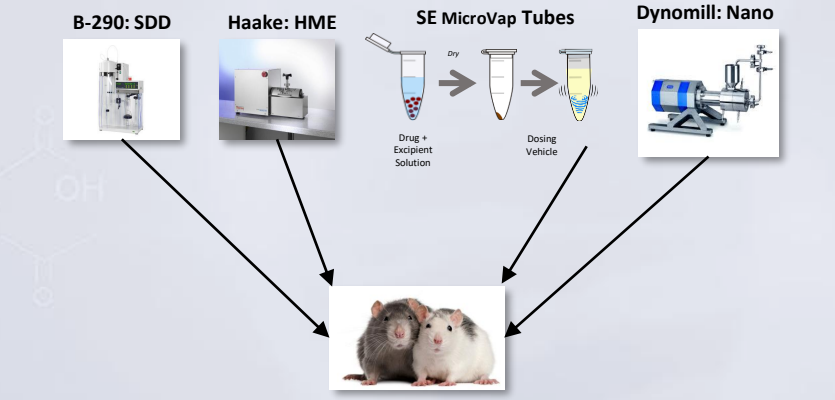
- Customer wanted BioDuro-Sundia to thoroughly evaluate SDD, HME and Nanosuspension formulation options.
- API solubility is very low in water and organic solvents
- API has a high melting point making it prone to crystallization from the amorphous form

BioDuro-Sundia Solutions

- BioDuro-Sundia Solution Engine was used to prepare several different SDD and HME formulations as well as a nanosuspension formulation. Animal PK studies were conducted at BioDuro-Sundia Shanghai DMPK site.

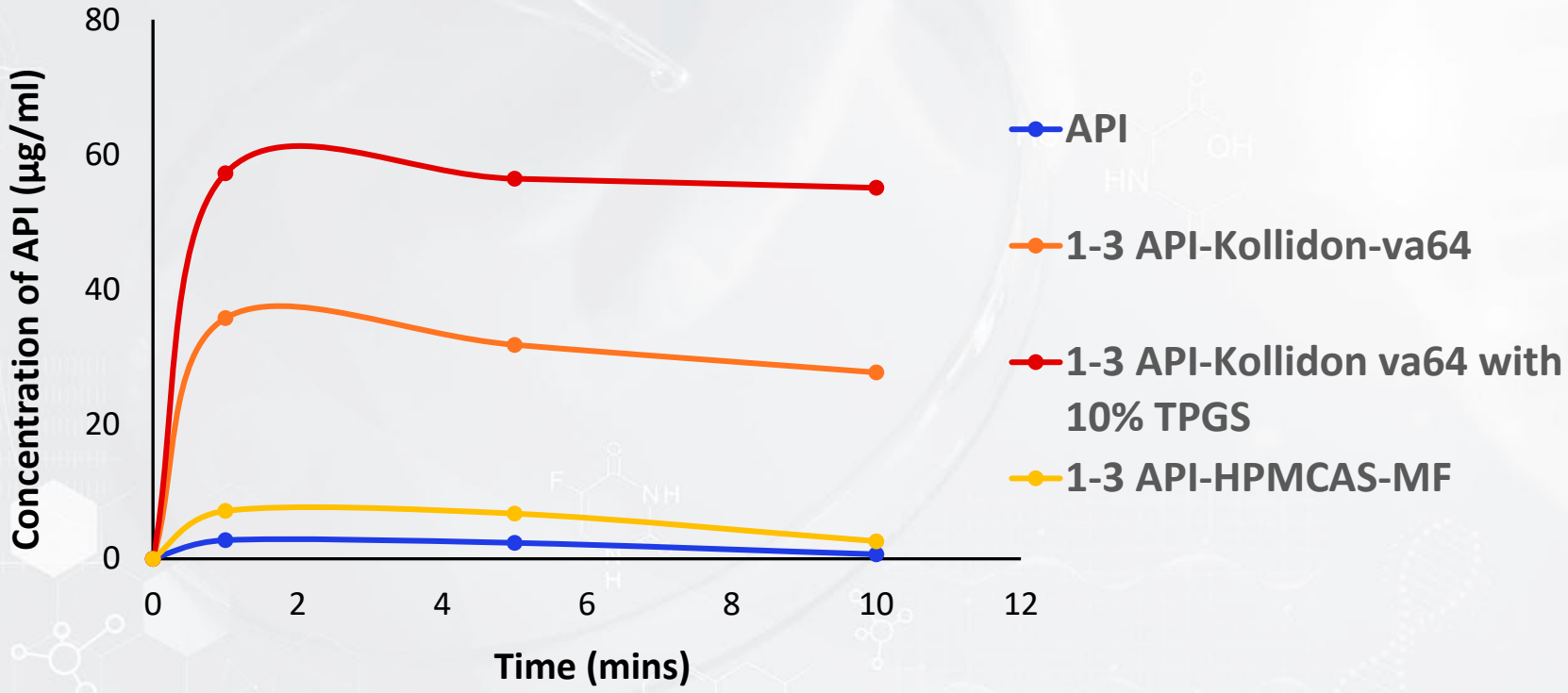
Successful Outcome

- Animal PK results led to selection of a SDD formulation for tox studies and Phase 1 Clinical Studies.
- Rank ordering correlation between in vitro and in vivo data
- A SDD tablet formulation was successfully developed and scaled up for manufacture of Phase 1 Clinical Supplies.



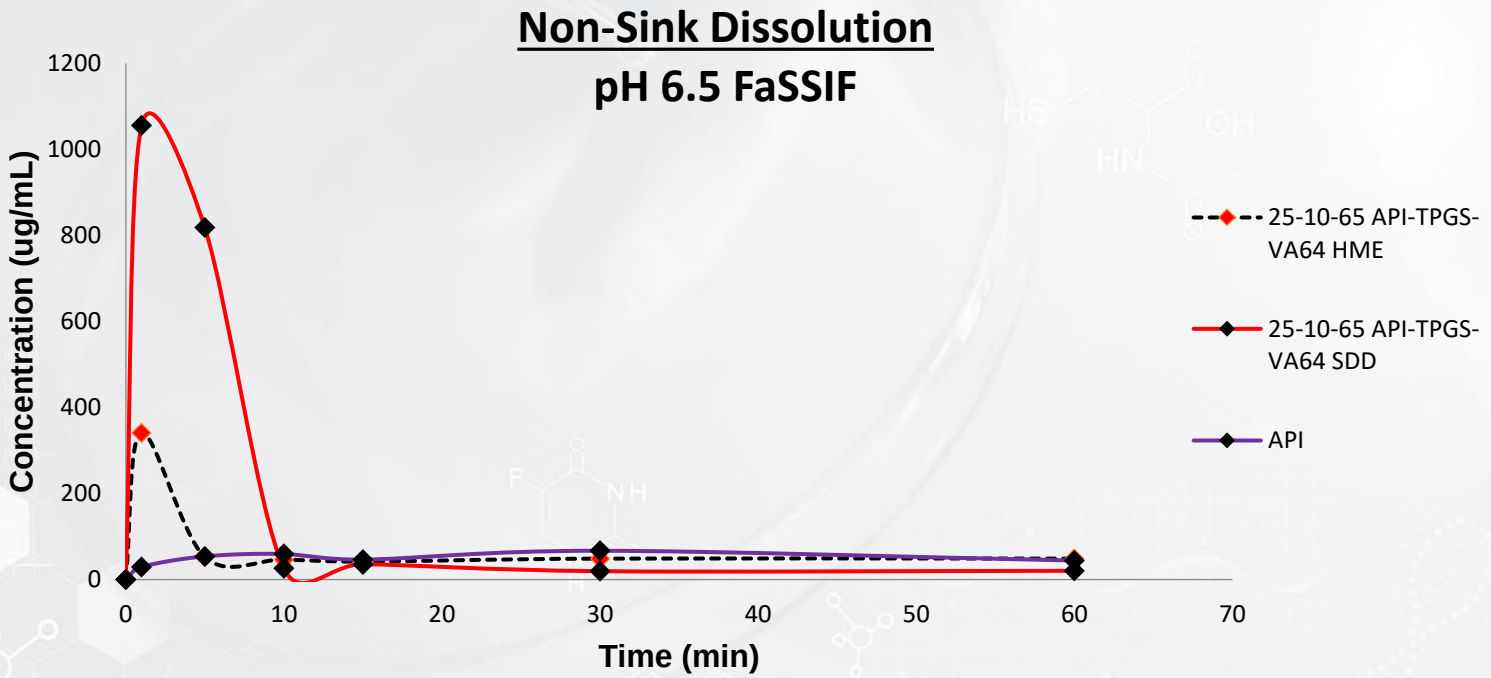
MicroEvap UV Dissolution Screening Results

- Example Data
  - Re-dispersed samples in aqueous buffer
  - 1:3 API: Kollidon VA64 with 10% TPGS gave the best results



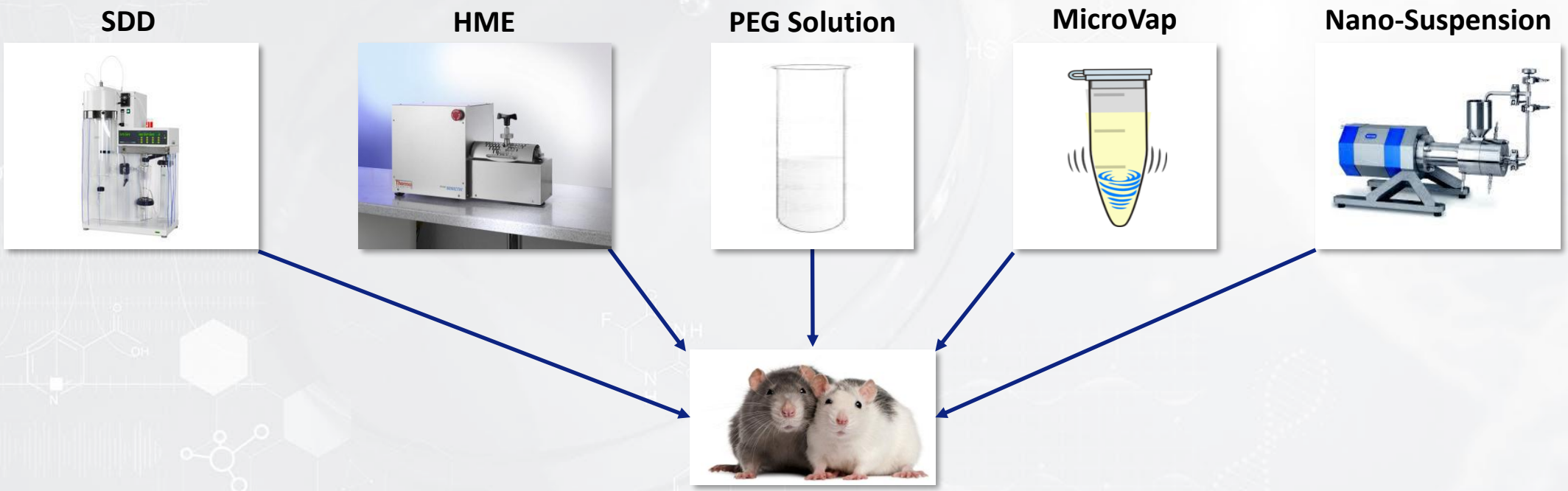
Non-Sink Dissolution Evaluation of HME and SDD

- Example Dissolution Profiles
  - Dissolution run under non-sink conditions in FASSIF media
  - Use results to select candidates for Mouse PK studies



Mouse PK Study

- Mouse PK results led to selection of SDD formulation for Pre-Clinical Tox and Phase 1 Tablet Development
- Mouse PK studies performed by BioDuro-Sundia Shanghai
  - Quick data turnaround



PK Results

Representative Results – Rat PK

Formulation	AUC (Male) (hr*ng/ml)	AUC (Female) (hr*ng/ml)
API in PEG400 (control)	13074	28187
API in 80% PEG/20% water	6318	8778
Nanosuspension	9969	10996
SDD (25:10:65, API-TPGS-Kollidon VA64)	**6975**	**7291**
HME (25:10:65, API-TPGS-Kollidon VA64)	4799	4095
Tubes (25:10:65, API-TPGS-Kollidon VA64)	**7237**	**7170**
Tubes (25:10:65, API:TPGS:HPMCAS M)	3763	3039

ASD Case Study II

CRS Montreal, Poster Presentation 2022: S. Rahimi and F. Asgarzadeh

Introduction

Amorphous solid dispersion (ASD) technology has been successfully utilized to enhance solubility and bioavailability of poorly soluble APIs. The proposed ASD screening platform provides the following benefits for new discovery NCEs:

- **Only 200 mg to screen ASD formulation and in-vivo PK studies**
- **In-silico solubility parameters modeling minimizes API use**
- **In-vitro and In-vivo Miniprep studies are completed in 8 to 10 weeks**

Method(s)

In-silico modeling of solubility parameters for compound X using the HSPiP and Gibbs free energy calculations allowed selection of miscible pairs with pharma grade polymers

Polymer and API organic solutions were combined in micro-centrifuge tubes based on the predicated miscibility levels and vacuum dried in a Savant™ SpeedVac™ to produce ASD thin films

Kinetic solubilities were measured using UV on the reconstituted solution centrifuged supernatant PK study was performed on ICR-CD1 mice (30mg/Kg)

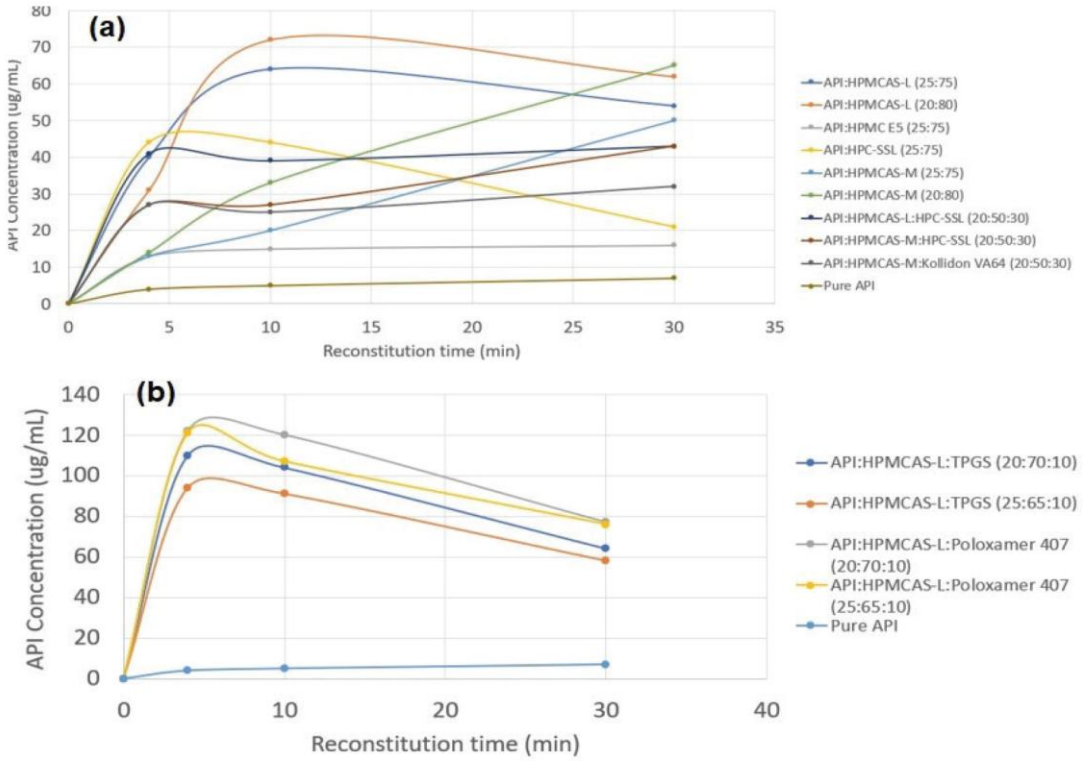


Figure 1: High throughput solubility enhancement screening of Compound X ASDs

ASD Case Study II

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RESULT(S)

API in HPMCAS-L systems provided the highest API supersaturation concentration. Adding Vitamin E-TPGS and Poloxamer 407 further improved the saturation solubility of API and bioavailability in mice

CONCLUSION(S)

Using this Solution Engine 2.0 platform, a representative compound (x) was formulated into an enabled ASD form with bioavailability improvement up to 12x compared to pure API utilizing only milligram quantities of API.

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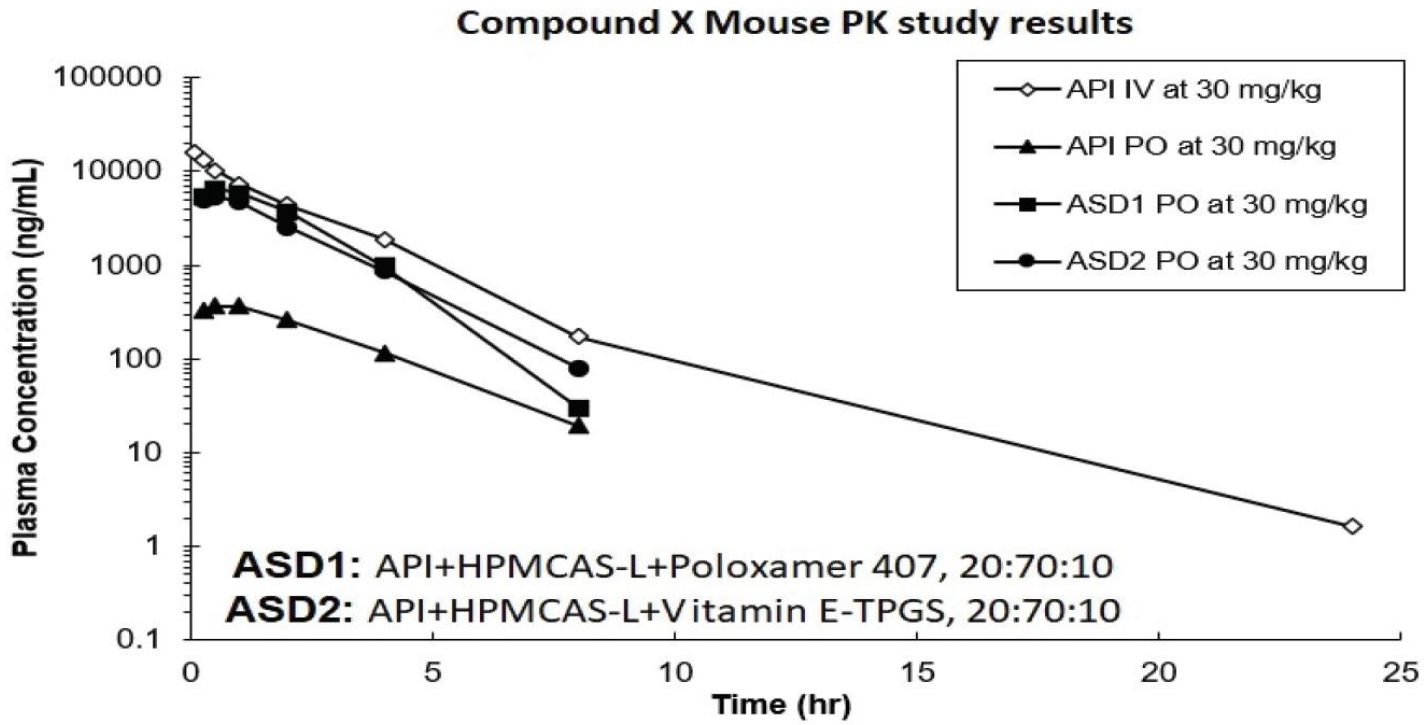


Figure 2: Mouse PK study results (plasma concentrations) for 2 lead ASD prototypes compared to API dosed PO and in IV

Modified Release

Modified Release Formulation Development: MR Case Study

Sustained Release Development

- Processes:
  - Compress Active and Placebo Mini tablets
  - Bulk up with Placebo
  - Apply SR Coating

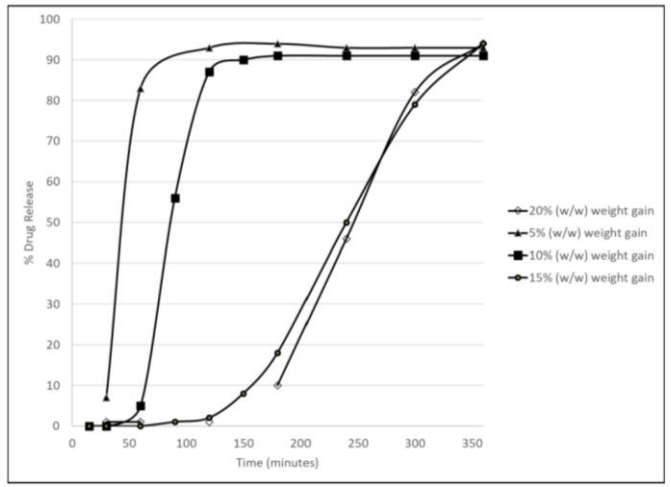


Figure1. Effect of different weight gain of Surelease on dry weight basis (w/w)

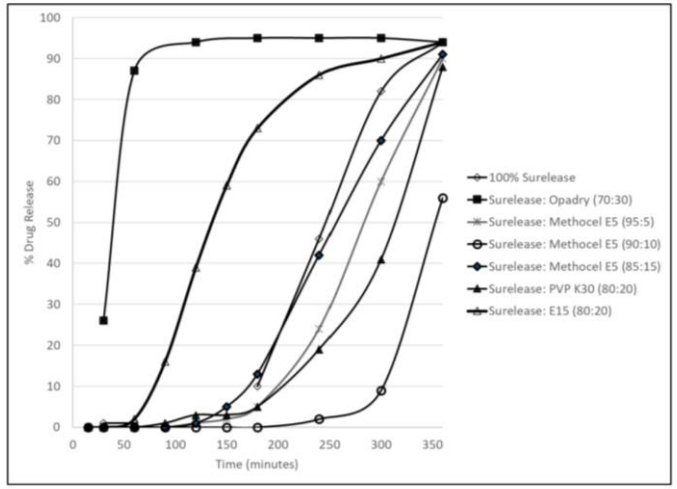


Figure 2. Effect of different levels of different pore formers at 20% weight gain

Welcome to BioDuro-Sundia

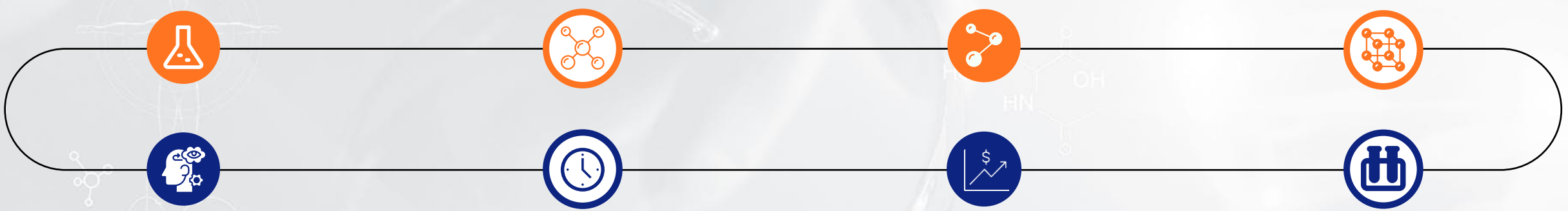
Proven Ability to Accelerate Timelines & Generate Return on Investments

Trusted Partner
27+ Years Experience in CRDMO,
Pioneer in ASD Services

Integrated CRDMO
Screen, Hit, Lead, Candidate,
IND, API, Drug Product

Global Presence
10 Strategic Sites
US & China

Expertise
3,000+ Employees
2,300+ Active Projects



Flexibility & Scale
Custom Requirements,
Small to Large Clients

Quick Turnaround
Fast-track Therapeutics to Clinic,
Go/NoGo Decisions

Value Creation
Reduce Cost & Risk,
Meet Deadlines,
Extend Runway,
Achieve Milestones

Proprietary Platforms
Free and Clear to Clients
Fragment Library,
Bioavailability (10-200x),
Pharmacology Models

Moving You Forward

End-to-end Solutions: Integrated Services to Navigate your BEST Path to Market

Discovery → **Development (DS + DP)** → **Manufacturing (DS* + DP)**

Discovery → **Pre-Clinical** → **Clinical** → **Commercial**

Target Identification	Target Validation	Lead Generation	Lead Optimization	Preclinical Development	Phase I	Phase II a/b	Phase III	Commercial

Three Business Units: Collaborative and Flexible!

Discovery

- Hit Generation
- Lead Optimization
- Candidate Selection

Chemistry, DMPK, Discovery Biology, Oncology, Pharmacology, Biologics

Drug Substance

- Scaleup g → Kg
- RSMs, Intermediates & API
- IND Filing (FDA, NMPA and others)

Process R&D, Scale-up Synthesis, Manufacturing

Drug Product

- Solubility Enhancement
- Oral Solid Dosage Forms (OSD)
- Clinical & Commercial

Pre-Formulation, Formulation R&D, Manufacturing

** Drug Substance services support Pre-Clinical and Clinical up to Phase II*

Global CMC Solutions: cGMP Manufacturing

- Solutions for Poorly Soluble and Complex Drug Products
- Scalable Manufacturing
- Equipment & Process (mg → Kg)

- On-time delivery of CTM
- Flexible Resources
- Single-site Integrated CMS Functions

Manufacturing

- Hot Melt Extrusion
- Spray Dried Dispersion
- Roller Compaction
- Wet Granulation
- Pan Coating and Wurster Coating Granulation (wet, dry, high shear)
- Fluid Bed Drying
- Milling, Blending, Compression
- Encapsulation
- Spray Granulation

Dosage Forms & Process Technologies

- Tablets
  - Immediate release tablets
  - Coated Tablets
  - Matrix Tablets
- Capsules
  - Blend in capsules
  - Tablets in capsules
  - Liquid in capsules
  - API in a capsule (Xcelodose®)
  - Pellets in capsule
- Beads, Pellets, Granules
  - Coated pellets/beads
  - Controlled release beads
- Oral liquids
  - Liquids
  - Suspensions
  - Lipid-based delivery systems
- Topicals
  - Creams
  - Gels
  - Ointments
- Patches

BIODURO-SUNDIA

Thanks for your attention!

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