HEALTH

Solubility Enhancement:
Accelerate Development with Efficient Excipient-Led Approaches

Lubrizol Life Science Health

Controlled Release Society Annual Meeting

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July 12, 2022

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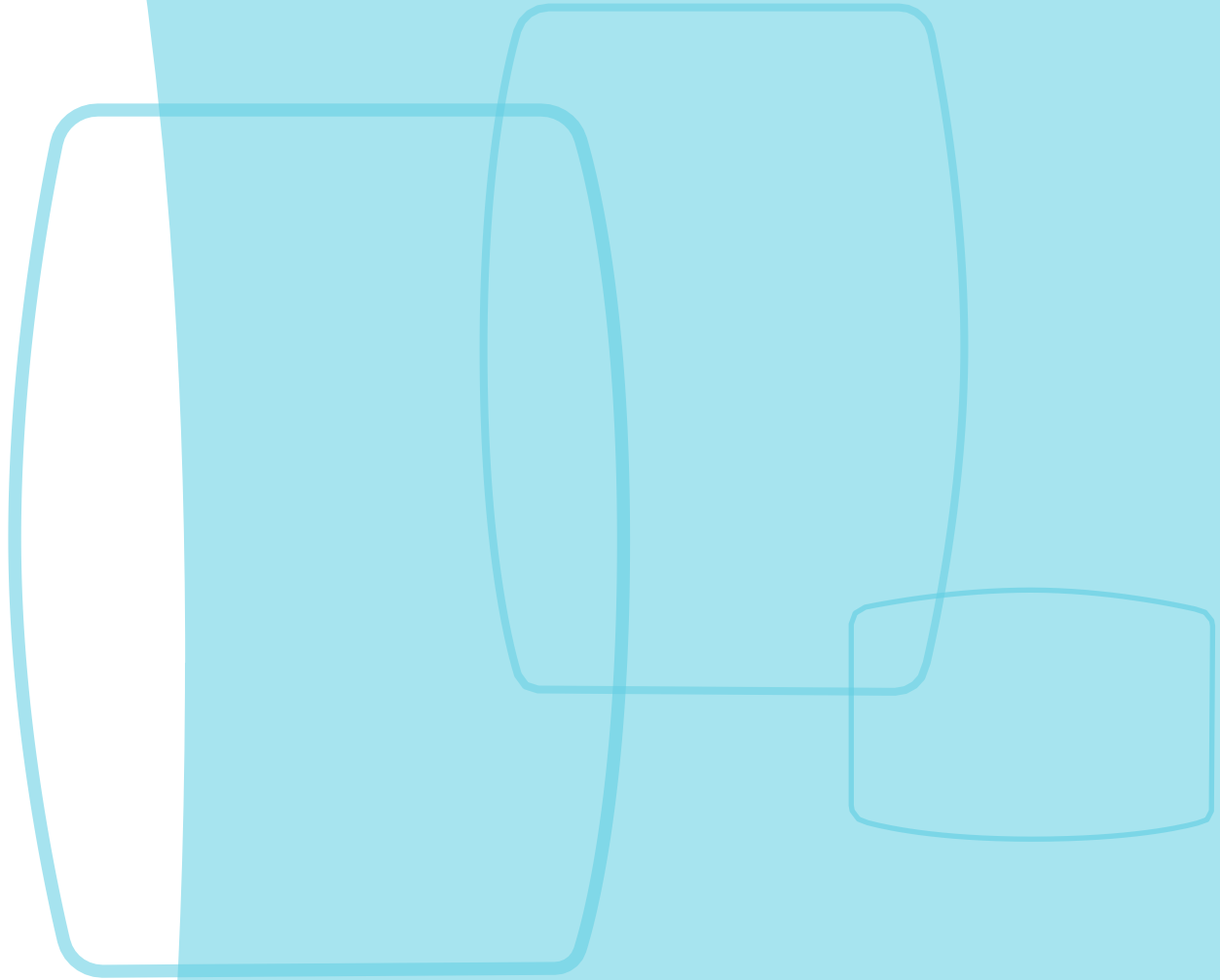

LLS | HEALTH

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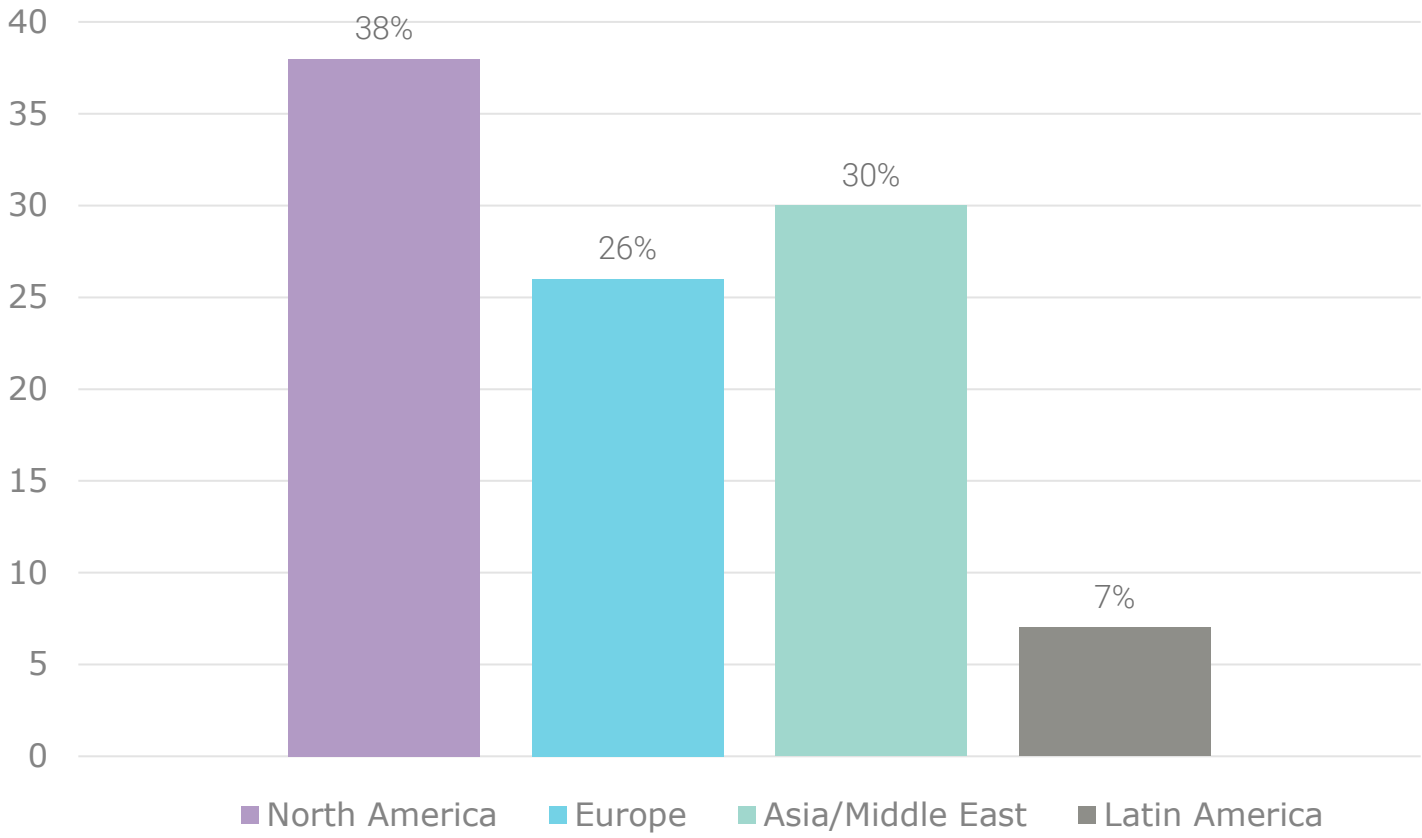
Lubrizol Life Science Health (LLS Health)

The Health business of Lubrizol Life Science serves the medical device and pharmaceutical industries.



2020 Lubrizol Global Revenue

$6+ Billion

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LUBRIZOL LIFE SCIENCE

LLS Health Global Footprint

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Pharma Segment Overview

Excipients

Multifunctional excipients which enable differentiated, patient-centric products

- Extended-release
- Solubility enhancement
- Permanent suspension
- Muco-adhesion
- Taste-masking

CDMO

A leading pharmaceutical contract development & manufacturing organization

- Insoluble APIs
- Sterile/aseptic products
- Long-acting implants & intravaginal rings

Nutraceuticals

Development & production of value-added nutraceutical ingredients

- Functional foods
- Dietary supplements
- Microencapsulation

Service offerings along the value chain provides simplification of supply chain
Built for sustainability - A Berkshire Hathaway Company

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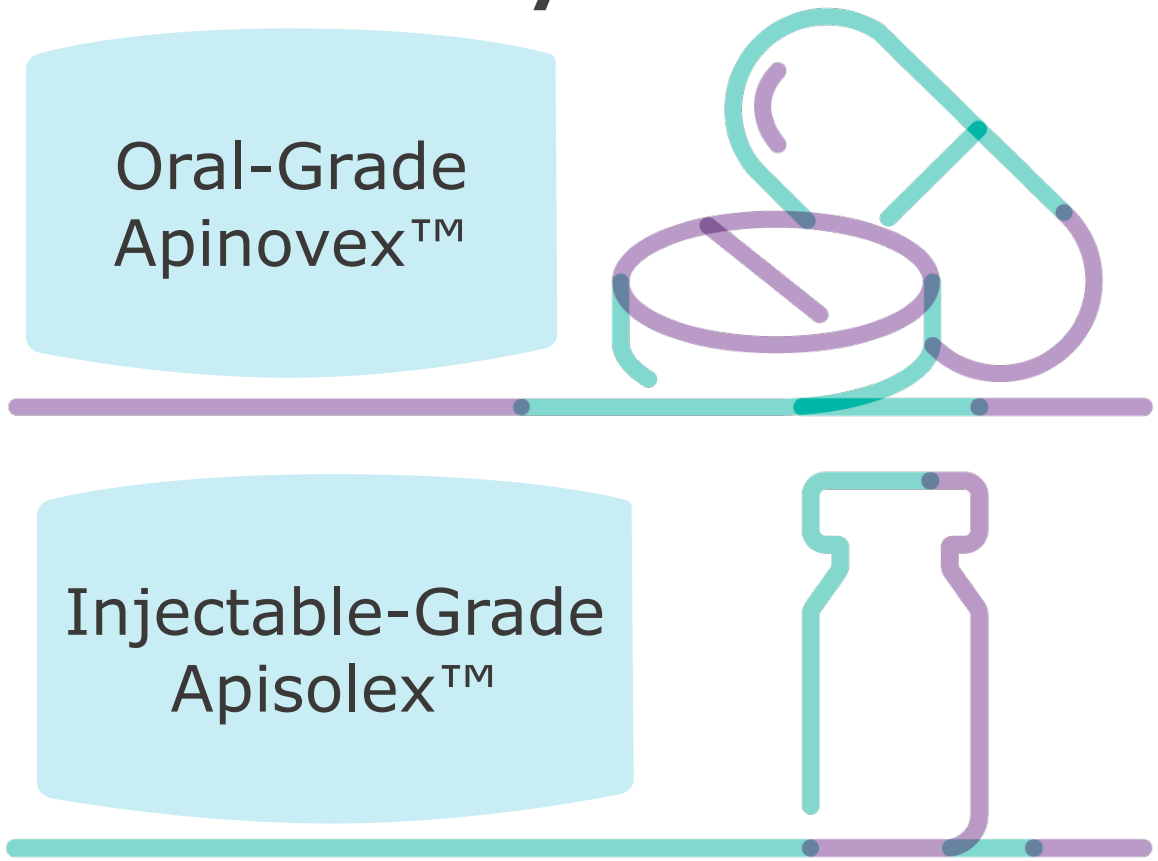
Why Choose Lubrizol Life Science Health?

- Safe and effective excipient supply for **over 40 years**
  - Carbopol® polymers
  - Noveon® AA-1 polycarbophil
  - Pemulen™ TR-2 emulsifiers
  - Pathway™ TPU excipients
- Trusted CDMO services for **over 20 years**
  - Decades of collective experience in **nanomilling**

Novel Solubility-Enhancing Polymers



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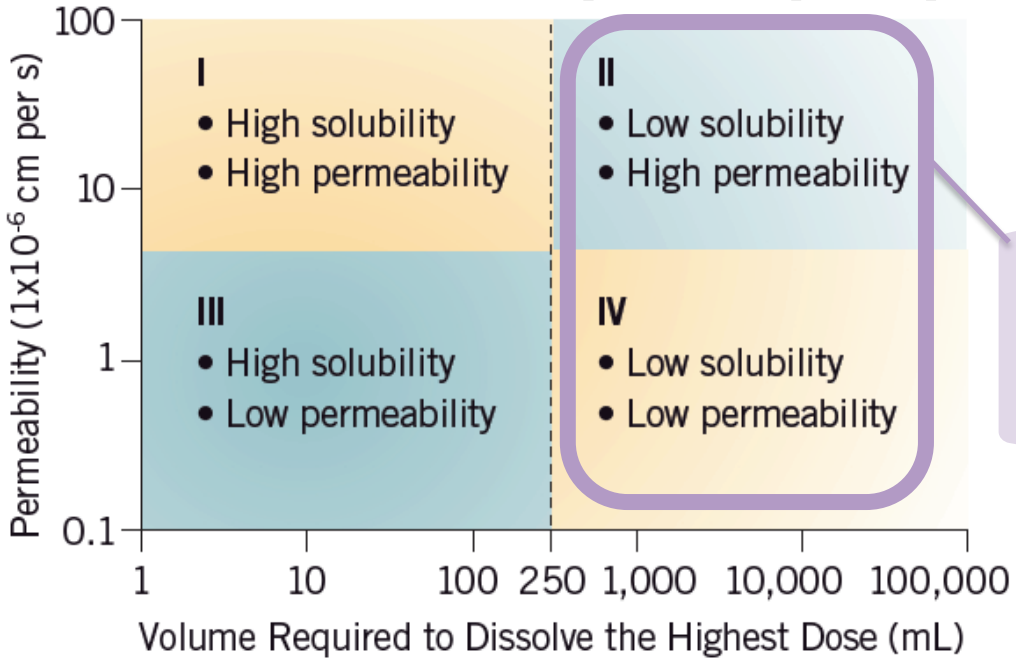
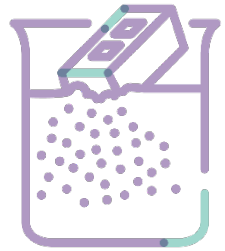
Poorly Water-Soluble APIs

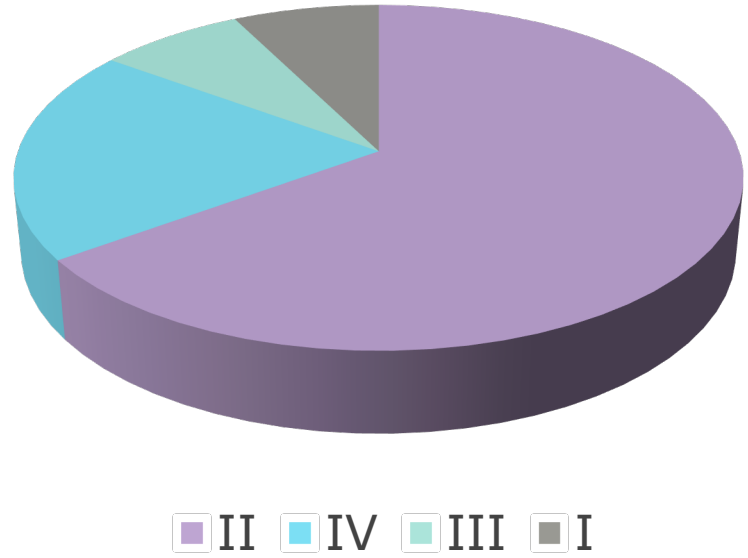
Biopharmaceutical Classification System (BCS)





Up to 90% of New Drugs

Projects at Lubrizol by BCS Class



Poor water solubility is a **common and growing challenge** in drug formulation

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Techniques to Address Low Water Solubility & Bioavailability

- **API Physical Modification**
  - **Nanomilling**
  - Micronization
  - Co-Crystals
  - **Amorphous Solutions and Dispersions**
- **API Chemical Modification**
  - pH Modification
  - Salt Formation
  - PEGylation
- **Encapsulation Techniques**
  - **Micelles**
  - Liposomes
  - Solid-Lipid Nanoparticles
  - Polymer Encapsulation
- **Inclusion Complexes**
  - β-cyclodextrins
  - Serum albumin

All techniques **rely on excipients** to interact with drugs or stabilize formulations

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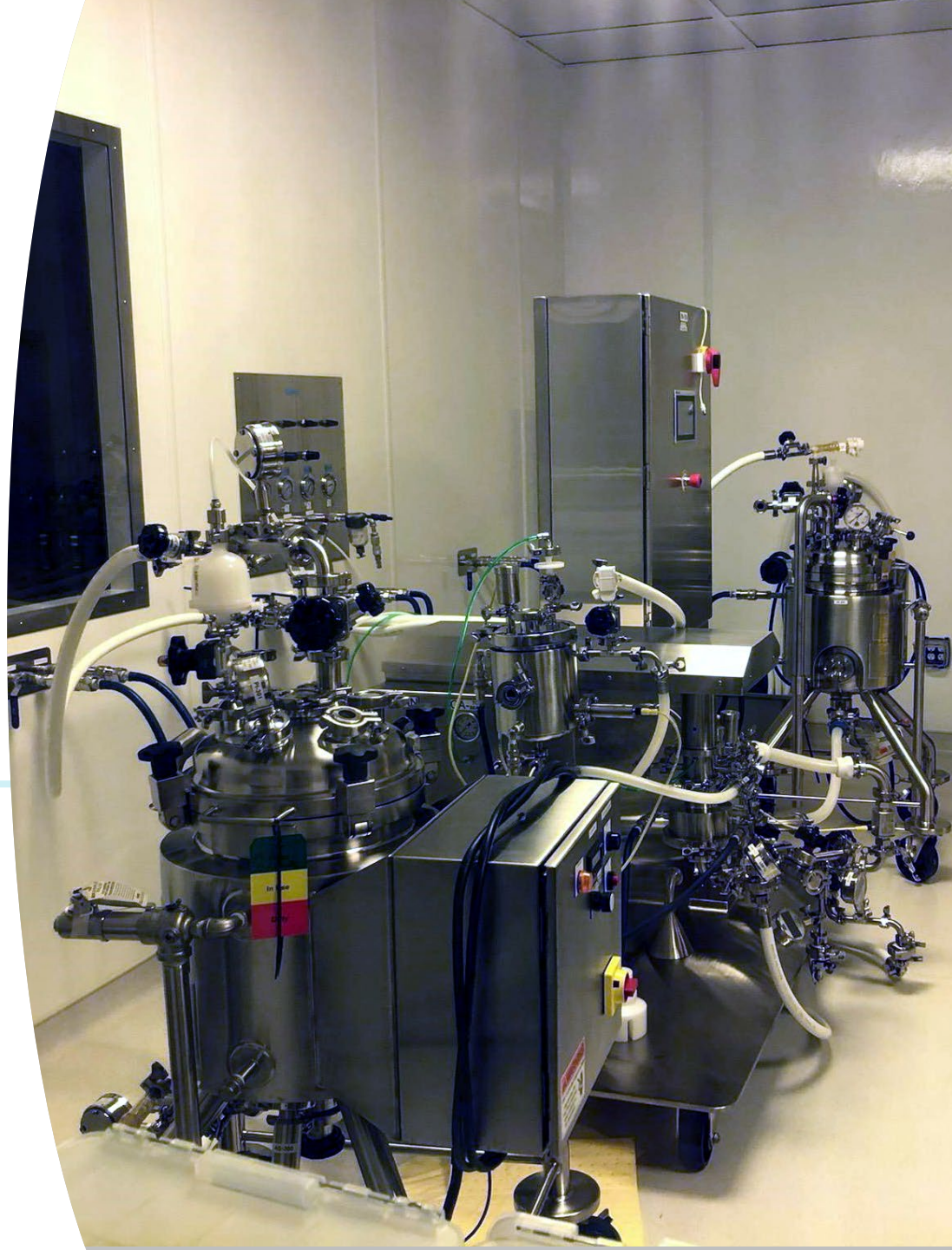
Nanomilling Services from Lubrizol

- LLS Health is the *only* for-hire CDMO offering aseptic nanomilling
- We have **decades of experience** developing nanosuspensions
- We utilize both commercially-available mills and our proprietary SteriMill™ Technology
- SteriMill™ Technology is **efficient, scalable, and highly reproducible at scale**



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Apinovex™ Polymer

Oral Amorphous Solid Dispersions via Spray Drying

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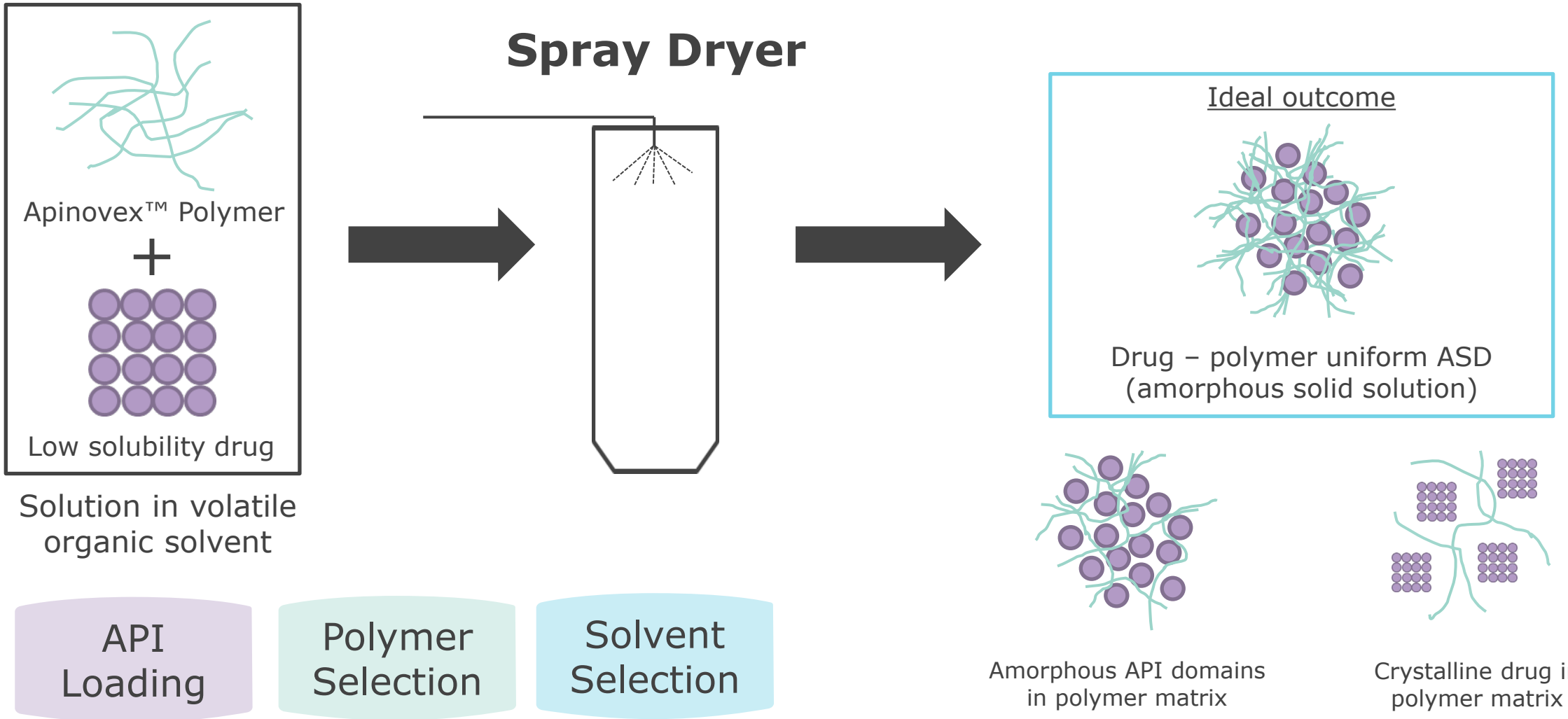
Spray Drying for Amorphous Solid Dispersions



API Loading

Polymer Selection

Solvent Selection

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Examples of FDA Approved Spray-Dried ASDs

Trade Name	API(s)	Company	Year of FDA Approval
Trikafta® Oral Tablet	Elexacaftor/Ivacaftor/ Tezacaftor	Vertex	2019
Symdeko® Oral Tablet	Tezacaftor/Ivacaftor	Vertex	2019
Erleada® Oral Tablet	Apalutamide	Janssen	2018
Zepatier® Oral Tablet	Elbasvir/Grazoprevir	Merck	2016
Zortress® Oral Tablet	Everolimus	Novartis	2010
Prograf® Oral Capsule	Tacrolimus	Astellas	1994

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Apinovex™ Polymer Value Proposition

- **Improved solubility and release** for BCS Class II and IV APIs
- **High, stable drug loading** (up to 80%)
- **Easy to process** via spray-drying
- **Offers IP protection** and 505(b)(2) potential

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Apinovex™ Polymer Properties

High molecular weight polyacrylic acid chemistry **designed for spray-drying**

Property		Apinovex™ polymer		
		LV	MV	HV
Tg (°C) – first heat cycle		128	126	126
Tg (°C) – second heat cycle		130	129	129
Solubility*	Ethanol (15% w/w)	S	S	S
	Isopropanol (10% w/w)	S	S	PS
	Dichloromethane/ Ethanol 1/1 (10% w/w)	S	S	PS
	Ethanol/Acetone 1/1 (10% w/w)	S	NT	NT

S – soluble; PS – partially soluble; NT – not tested
LV – low viscosity; MV- medium viscosity; HV – high viscosity

High Tg for stabilizing amorphous solid dispersions
Compatible with **common pharmaceutical solvents**

*Not soluble at 1% in Acetone, Dichloromethane, and Tetrahydrofuran.

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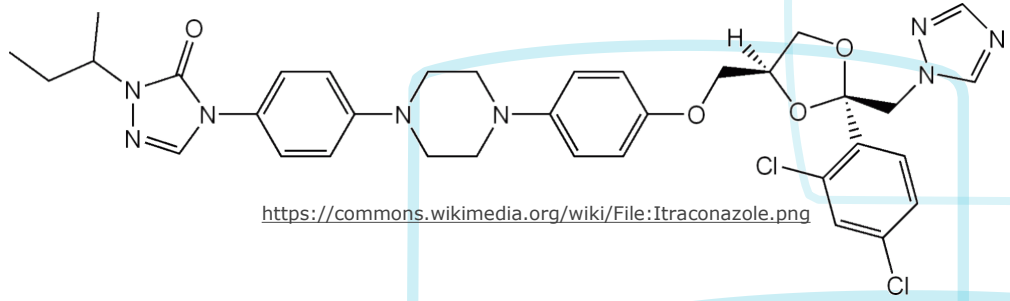
Apinovex™ Case Study: Spray-Dried Itraconazole ASD

- **API: Itraconazole**
  - Poorly solubility, low bioavailability
  - Difficult to formulate
  - First approval: 1992 (Sporanox®)

- **Excipients Evaluated**
  - Apinovex™ Polymer (Lubrizol)
  - Soluplus® (BASF)*
  - Affinisol® HPMC HME 15LV (Dow)**

- **Formulations Evaluated**
  - Physical mixtures (PMs)
  - Spray-dried amorphous solid dispersions (ASDs)



https://commons.wikimedia.org/wiki/File:Itraconazole.png

Parameter	Itraconazole
Water Solubility (g/L)	0.0096
BCS Classification	2
LogP	5.66
Reported concentration in ASD (literature)	40%

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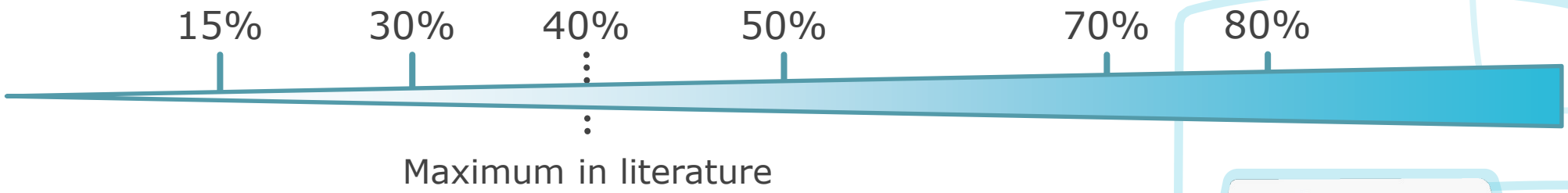
*Soluplus®, BASF, polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer
**Affinisol® HPMC HME 15LV, Dow, hydroxypropyl methyl cellulose

Apinovex™ Case Study: Spray-Dried Itraconazole ASD

- **Itraconazole Loading**



- **Spray Drying Process**
  - Equipment: Buchi B-290
  - Solvents: ethanol, ethanol/dichloromethane
- **Characterization**
  - Appearance
  - Phase identification/transitions
    - X-ray powder diffraction (XRPD)
    - Differential Scanning Calorimetry (DSC)
  - Assay & dissolution (powder, non-sink conditions)
  - Accelerated stability (selected formulations; 6 MO 40°C/75% RH)

Spray dryer image courtesy of Buchi.

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Apinovex™ Case Study: XRPD Results

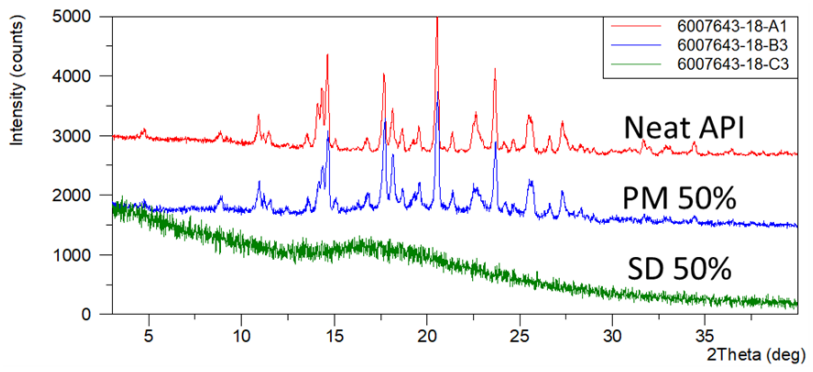
Formulations

Neat Itraconazole
API alone

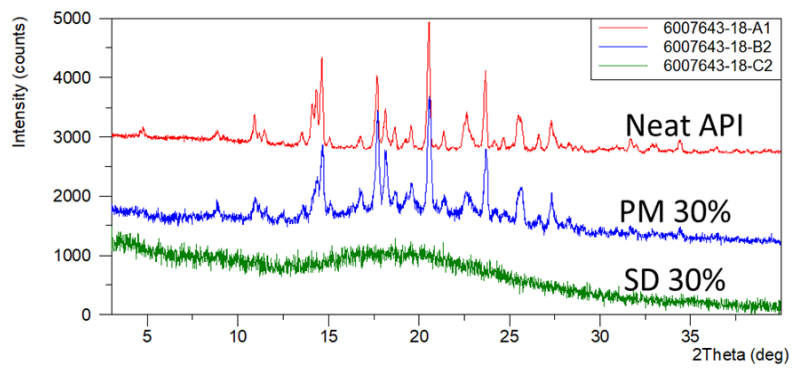
Physical Mixture (PM)
API + Apinovex

Spray-Dried (SD)
API + Apinovex

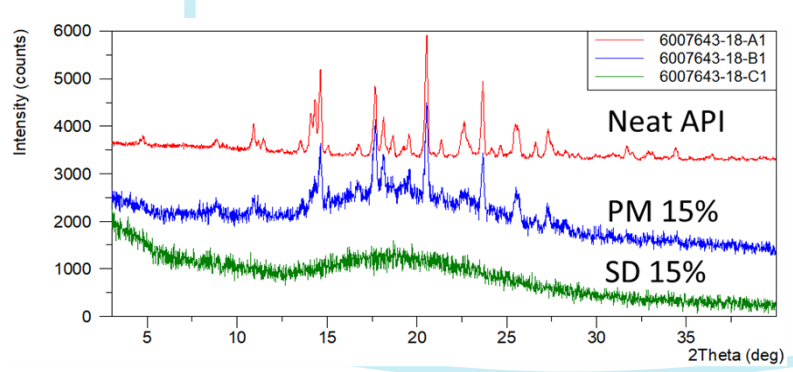
50% API Loading



30% API Loading



15% API Loading



Amorphous character was successfully achieved via spray drying API/Apinovex™ polymer

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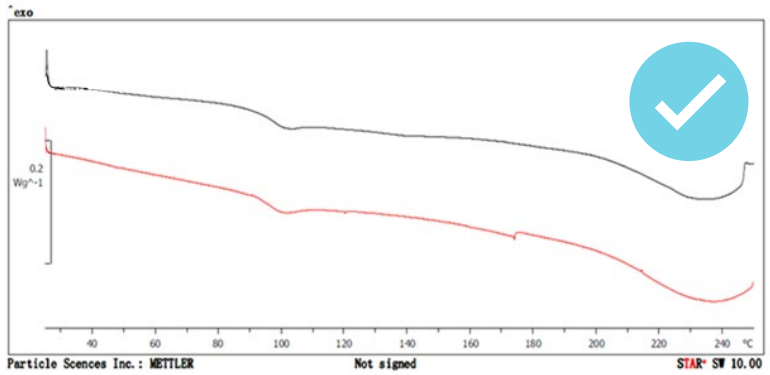
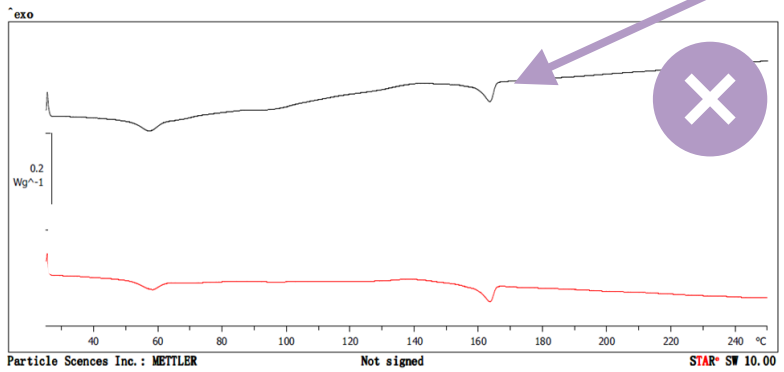
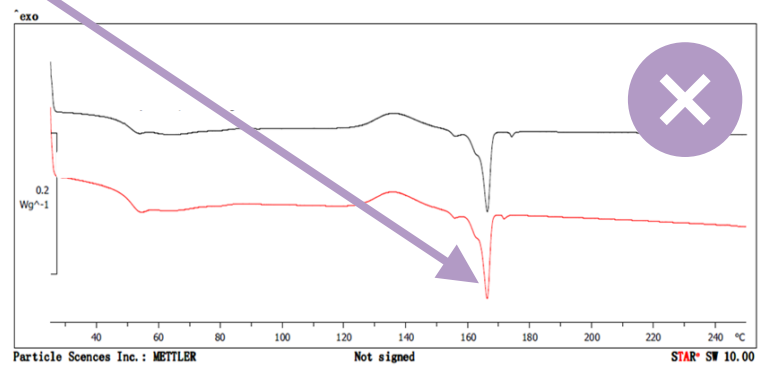
Apinovex™ Case Study: DSC Results

Apinovex Uniform, stable ASD	**Soluplus & Affinisol** Non-uniform ASDs with amorphous-amorphous phase separation	
80% API /Apinovex™ polymer	80% API / Soluplus	80% API / Affinisol
		

Apinovex™ enabled a homogenous amorphous dispersion, even at 80% drug loading

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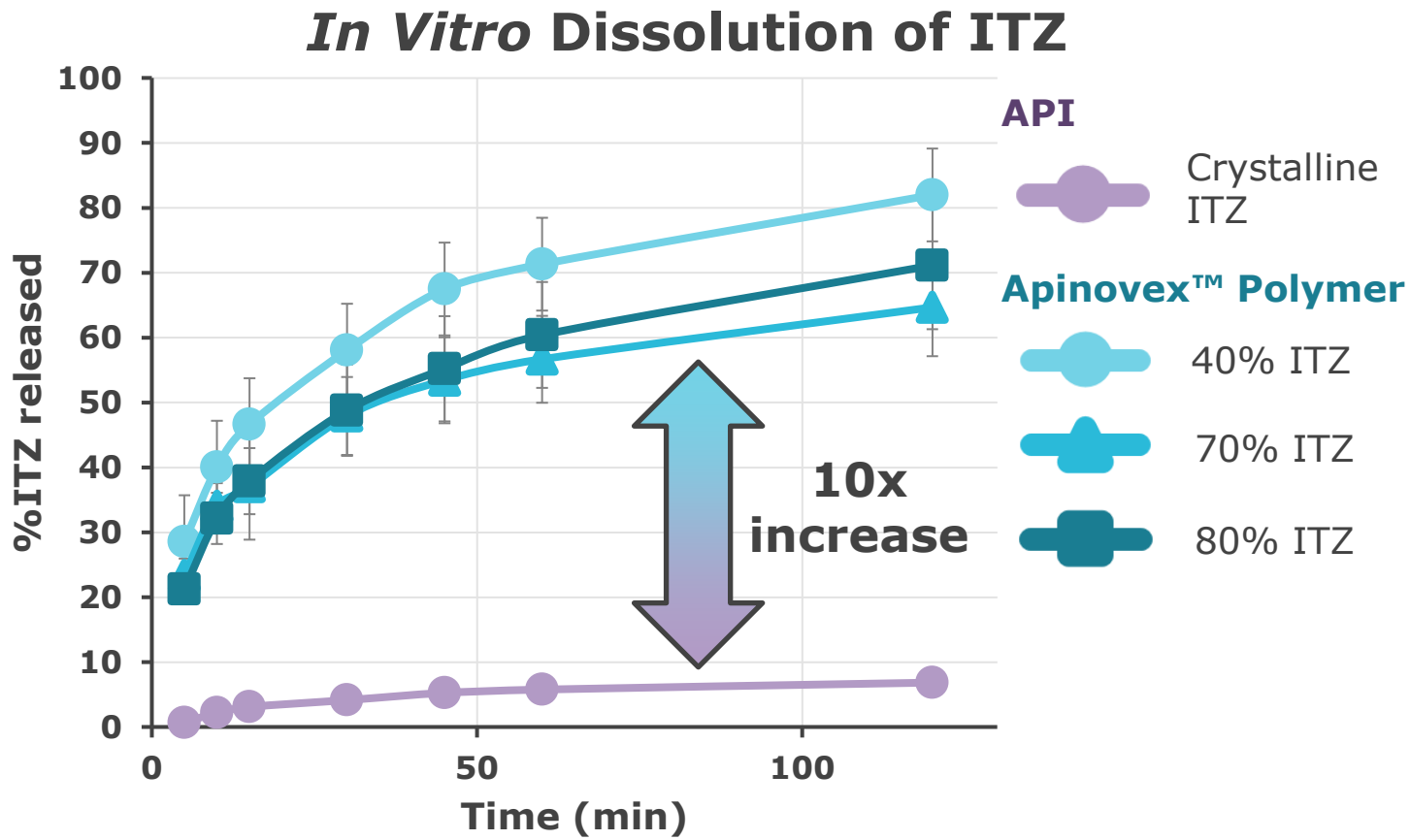
Apinovex™ Case Study: Drug Dissolution

- **Increased drug release 10x** relative to crystalline API



Apinovex™ enabled both **higher drug loading** (up to 80%) and **improved drug dissolution**

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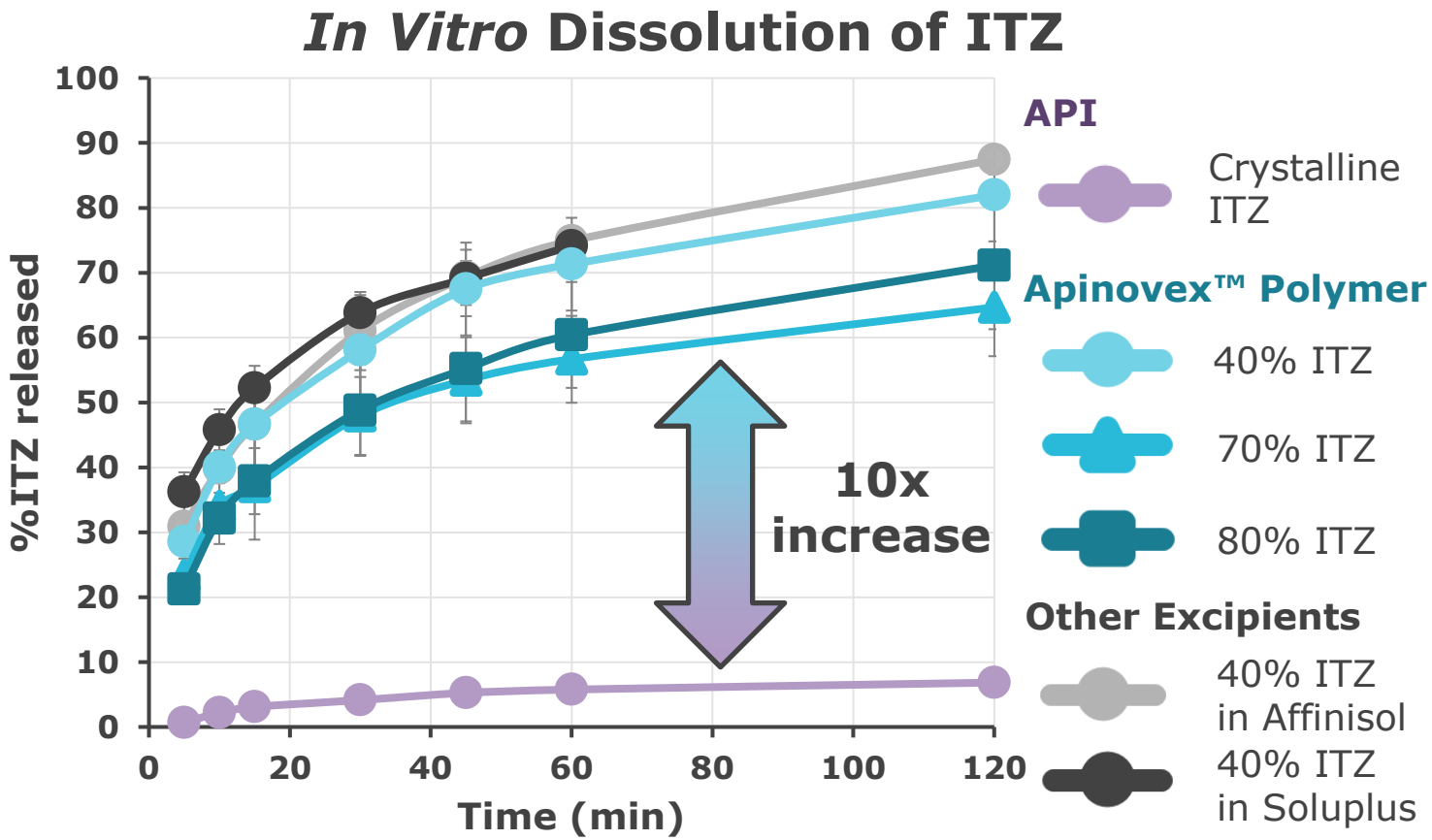
Apinovex™ Case Study: Drug Dissolution

- **Increased drug release 10x** relative to crystalline API
- Achieved **2x drug loading** of commercial excipients
- **Maintained drug release**, even at higher loadings than commercial benchmarks



Apinovex™ enabled both **higher drug loading** (up to 80%) and **improved drug dissolution**

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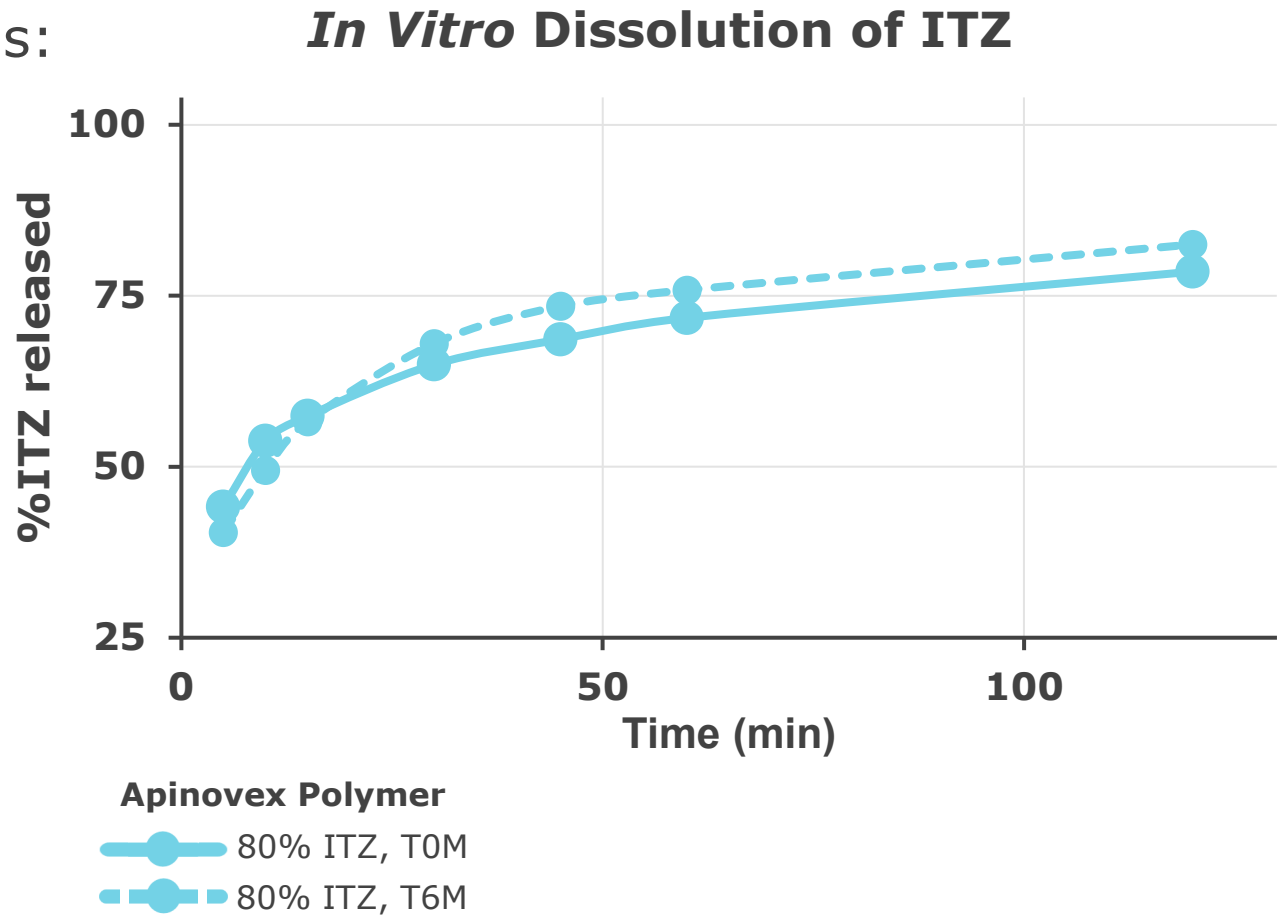
Apinovex™ Case Study: Accelerated Stability

- ASDs stored at accelerated conditions: **40°C/75%RH; 6 months**
- **80% ITZ in Apinovex**
  - Amorphous character confirmed with DSC & XRPD
  - No significant change in dissolution rate



Apinovex™ ASD **maintained properties** after 6 months in accelerated stability

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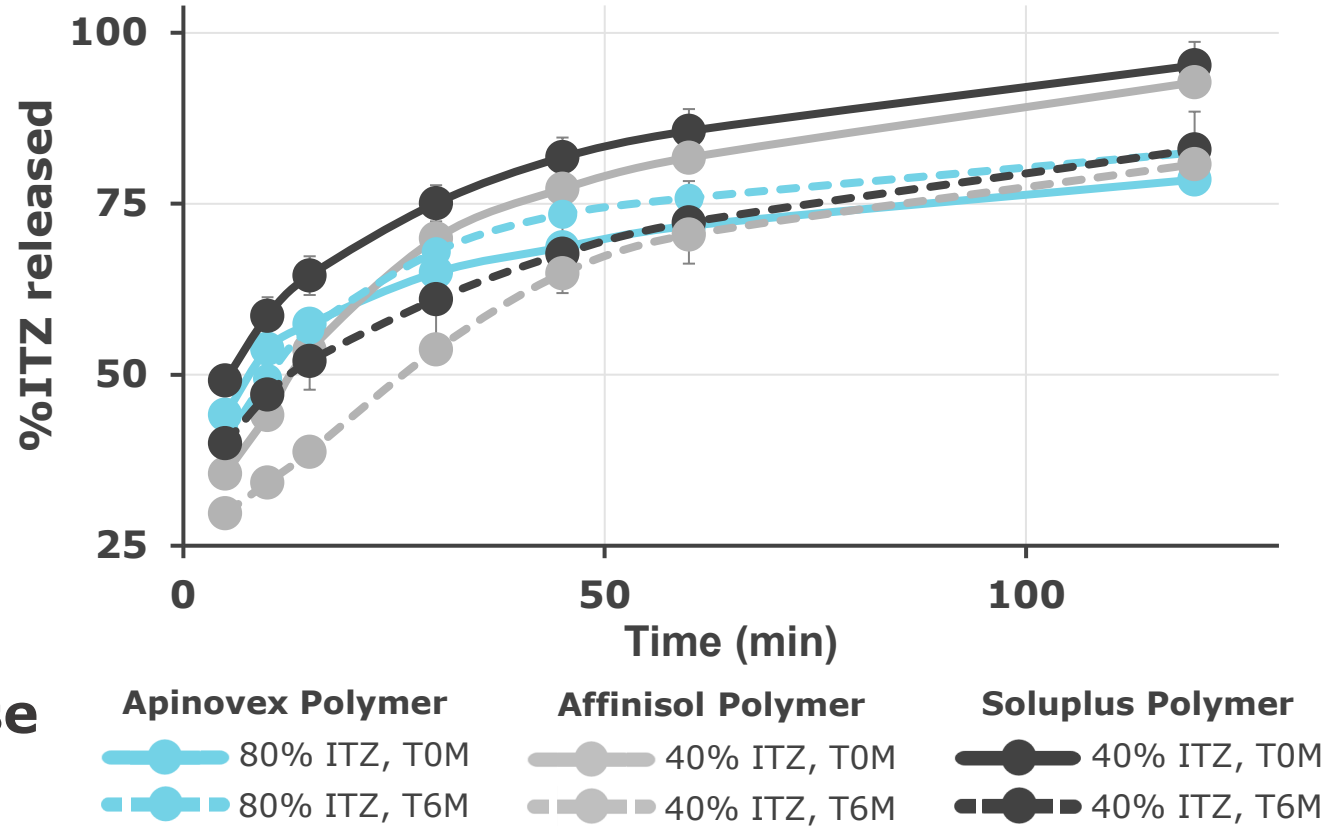
Apinovex™ Case Study: Accelerated Stability

- ASDs stored at accelerated conditions: **40°C/75%RH; 6 months**
- **80% ITZ in Apinovex**
  - Amorphous character confirmed with DSC & XRPD
  - No significant change in dissolution rate
- **40% ITZ in Affinisol/Soluplus**
  - Amorphous character confirmed with DSC & XRPD
  - Dissolution data show a **decrease** of drug release at 6 months

***In Vitro* Dissolution of ITZ**



Apinovex™ ASD **maintained properties** after 6 months in accelerated stability

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Apinovex™ Polymers Safety and Toxicology

- High molecular weight polyacrylic acid chemistry similar to well-established **Carbopol® polymers**
  - Consistent residual monomer and impurity levels
- Low residual Class 3 solvent levels **meeting USP <467> limits**
- Similar chemistry has precedence in long term human ophthalmic exposure
- Large scale **IPEC-GMP** manufacturing of Apinovex™ polymer conducted successfully
- **Type IV Drug Master File** planned

Test	Results
Acute oral toxicity	Not acutely toxic (LD50 > 5000 mg/kg)
Mutagenicity in bacteria (AMES)	Non-mutagenic

Second phase *in vivo* TOX studies underway

Apinovex™ polymers are **GMP validated** and expected to be **safe for oral use**

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Apisolex™ Polymer

Solubility-Enhancement for Injectable Formulations

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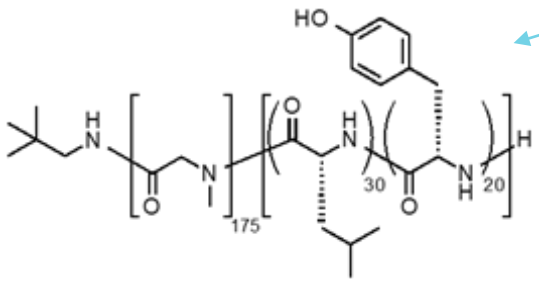
Apisolex™ Polymer Structure and Properties

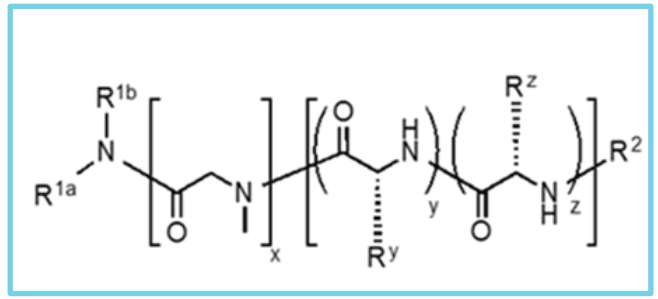
- Multiblock copolymers: poly(sarcosine) block and D,L-mixed poly(amino acid) block
- Sarcosine: non-toxic, non-immunogenic, biocompatible, & biodegradable alternative to PEG

- **Versatile synthesis**: possibility of generating unique structures based on API requirements
- **Highly efficient and streamlined** drug product manufacturing process
- **GMP manufacturing** in place
- **Robust IP protection** with long patent life remaining

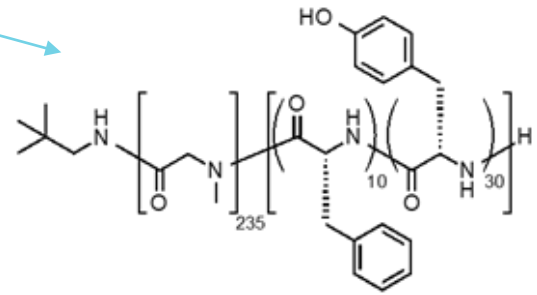
Apisolex™ LY



PSar175-P(dLeu30/Tyr20)



Apisolex™ FY



PSar235-P(dPhe10/Tyr30)

Created to solubilize hydrophobic APIs

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Polymer Micelle Technology

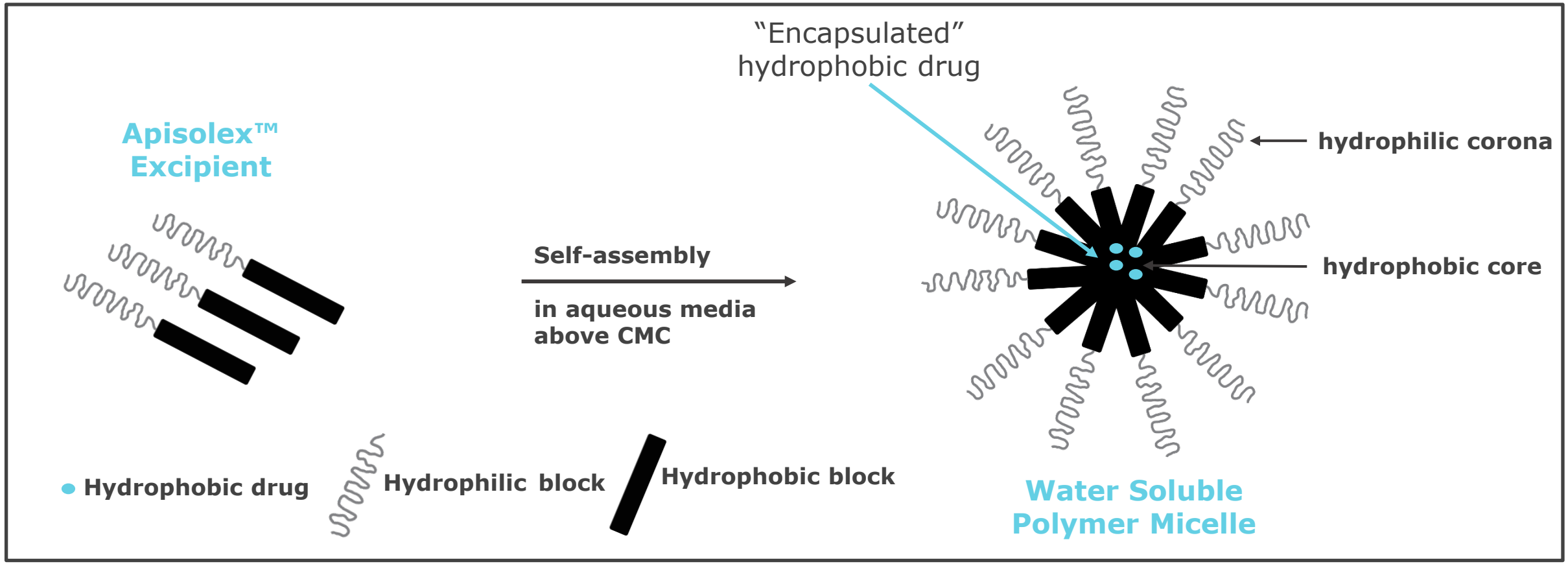

Figure adapted from Frontiers in Pharmacology 2014, 5:77

Sequesters the drug in the hydrophobic part of the micelle
to increase water solubility of APIs **by up to 50,000-fold**

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Examples of FDA Approved Injections Using Solubilizing Excipients

Trade Name	API(s)	Company	Excipient	Technique
Taxol®	Paclitaxel	BMS	Cremophor® EL	Micelle
Abraxane®	Paclitaxel	Celgene	Human albumin	Albumin-Bound
Genexol-PM®	Paclitaxel	Samyang	mPEG-PDLLA	Micelle
Veklury®	Remdesivir	Gilead	Betadex sulfobutyl ether sodium	Complexation
Kyprolis®	Carfilzomib	Amgen	Sulfobutylether beta-cyclodextrin	Complexation
Vfend™	Voriconazole	Pfizer	Sulfobutyl ether beta-cyclodextrin sodium	Complexation
Sporanox®	Itraconazole	Janssen	Hydroxypropyl-β-cyclodextrin	Complexation

Solubility remains an unmet market need for both new chemical entities and 505(b)(2) products

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Apisolex™ Polymer Value Proposition

- **Increases the solubility** of hydrophobic APIs **up to 50,000-fold**
- **High drug loading** (up to 40:100 API:excipient ratio)
- **Simple formulation techniques** with minimal API loss (recovery >90%)
- Stable, lyophilized drug product that **reconstitutes in saline in <30 seconds**
- **Offers IP protection** and 505(b)(2) potential

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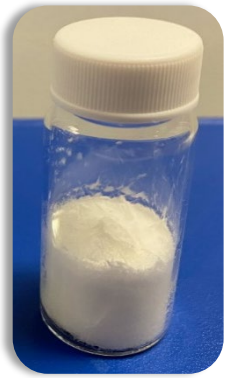
Formulation Techniques – tBuOH/Water Solution Mixing

+

Mixing/Homogenization

Lyophilization



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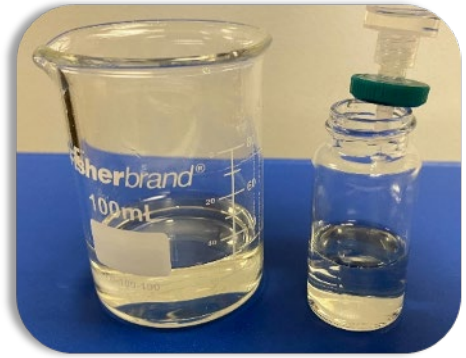
Formulation Techniques – High Shear Emulsion Processing

API solution in organic solvent

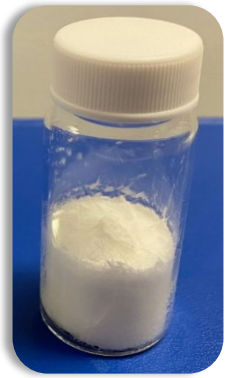
Polymer and cryoprotectant in water

Emulsification

- Diafiltration with trehalose solution (optional)
- Sterile filtration



Lyophilization



Final Drug Product

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Putting Apisolex Polymers to Test

- The solubilization properties of Apisolex polymer were evaluated in comparison with other excipients for a series of poorly water soluble active pharmaceutical ingredients

- The experiments were conducted by non-optimized, standard dispersion techniques (mixing/homogenization), followed by dilution or lyophilization and reconstitution

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Metrics for Success: Final Drug Product

Target API concentration after dilution or reconstitution of finished drug product:

- 500 µg/ml

Solubilization criteria:

- Turbidity (NMT 100 NTU)
- Particle diameter (NMT 150 nm)
- Drug recovery after filtration (NLT 80%)

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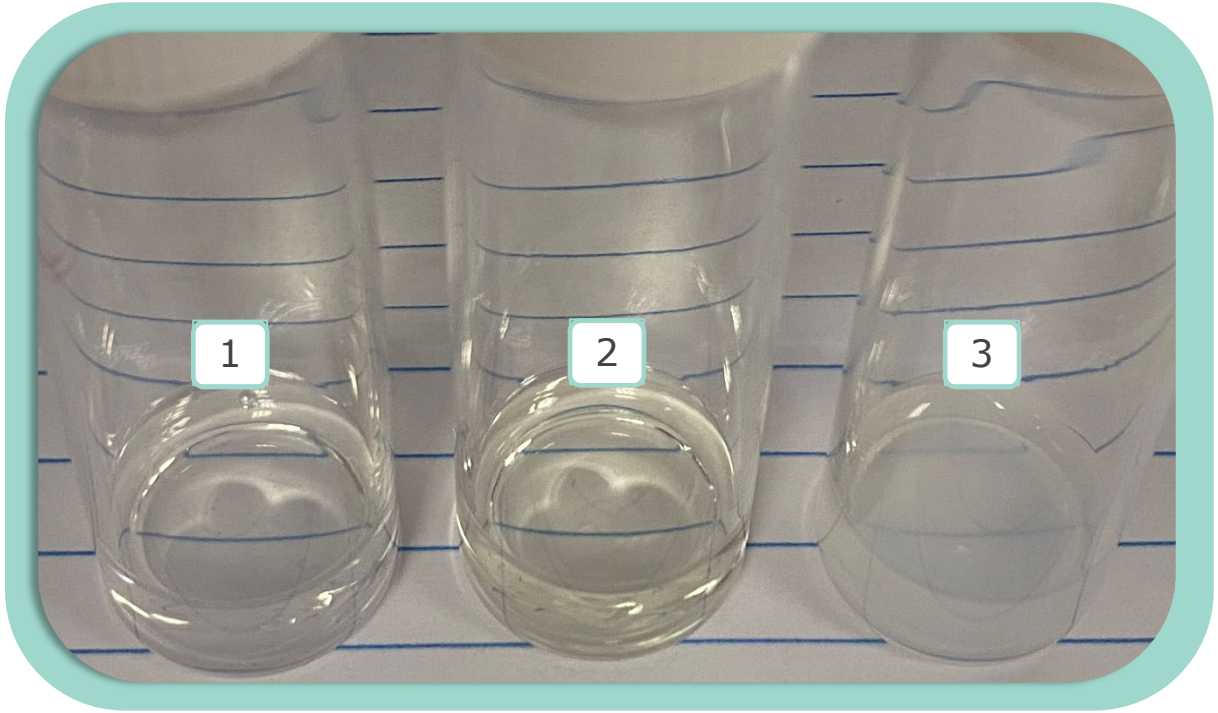
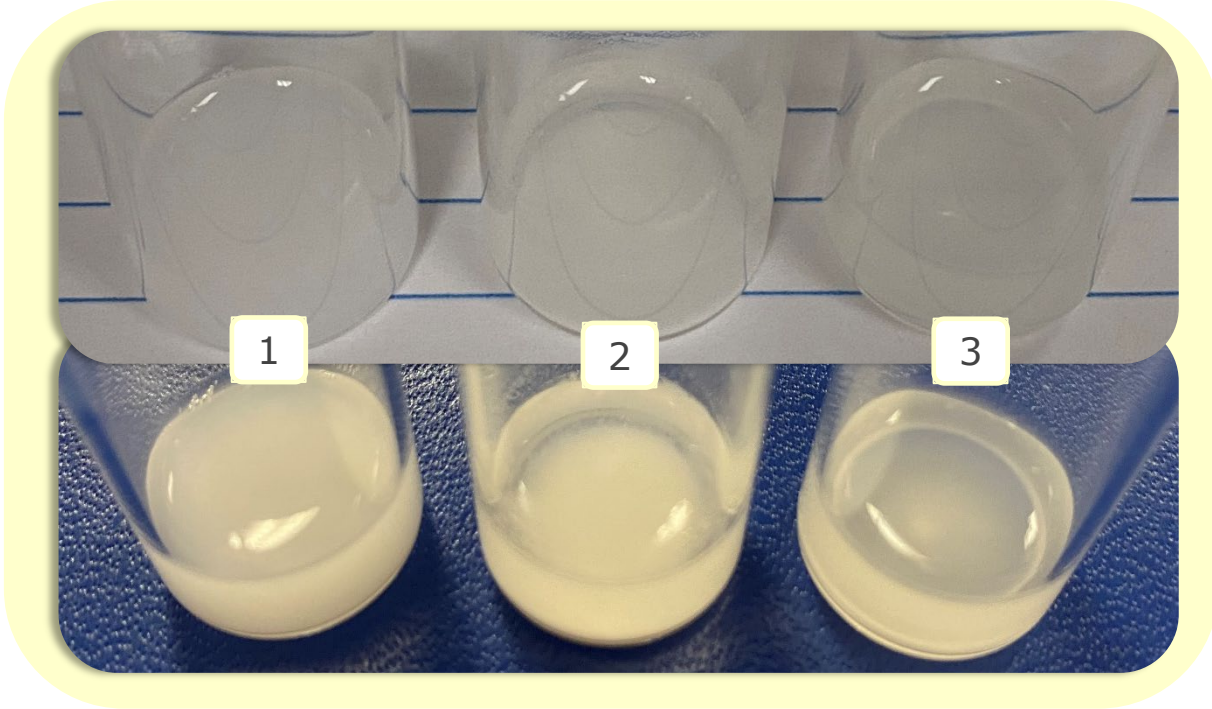
Examples of Results



Pass

(1) Clear and colorless solution
(2) Clear and colored solution
(3) Homogenous & slightly turbid (<100 NTU)



Does not Pass

(1) Homogenous but turbid (>100 NTU)
(2) Heterogenous suspension
(3) Precipitated/ insoluble drug

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Series A Results

API \ Excipient	Polysorbate 20	Polysorbate 80	Cremophor®[1]	Apisolex™
Amphotericin B	Fail	Fail	Fail	Pass
Cyclosporin A	Pass	Pass	Pass	Pass
Etoposide	Pass	Pass	Pass	Pass
Melphalan	Fail	Fail	Fail	Pass
Paclitaxel	Pass	Pass	Pass	Pass
BI-001[2]	Pass	Pass	Pass	Pass
BI-002[2]	Pass	Pass	Pass	Pass
BI-003[2]	Pass	Pass	Pass	Pass
BI-004[2]	Pass	Fail	Fail	Pass
BI-005[2]	Pass	Pass	Pass	Pass
Excipient : API Ratio	100 : 1			100 : (5 – 10)

Compared to solubilizers that utilize a dissolution and dilution technique, only Apisolex polymer enabled successful solubilization of all APIs evaluated and at a much lower ratio of excipient to API.

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[1] *Polyethoxylated castor oil (Kolliphor® ELP or Kolliphor EL, formerly known as Cremophor EL, is a registered trademark of BASF Corp)*

[2] *APIs for this study were provided by Boehringer Ingelheim Pharm. Inc.*

Series B Results

API \ Excipient	TPGS[1]	Captisol®[2]	PEG-PLGA[3]	Apisolex™
Amphotericin B	Fail	Fail	Fail	Pass
Cyclosporin A	Pass	Fail	Fail	Pass
Etoposide	Pass	Fail	Pass	Pass
Melphalan	Pass	Pass	Pass	Pass
Paclitaxel	Fail	Fail	Pass	Pass
BI-001[4]	Fail	Fail	Fail	Pass
BI-002[4]	Fail	Fail	Fail	Pass
BI-003[4]	Pass	Fail	Fail	Pass
BI-004[4]	Fail	Fail	Fail	Pass
BI-005[4]	Fail	Fail	Fail	Pass

Compared to solubilizers processed using the same lyophilization and reconstitution technique, only Apisolex polymer enabled successful solubilization of all APIs evaluated.

[1] *D-α-tocopheryl polyethylene glycol succinate*
[2] *Cyclodextrin (Captisol® SBE-AE-Beta-CD is a registered trademark of Ligand Pharmaceuticals Incorporated)*
[3] *Polyethylene glycol-poly lactic acid-co-glycolic acid*
[4] *APIs for this study were provided by Boehringer Ingelheim Pharm. Inc.*

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Series C Results

API	Solubility in Water (µg/ml)	Solubility in Formulation with Apisolex Polymer (µg/ml)	Solubility Increase with Apisolex Polymer (Fold)
BI-001[1]	20	2,000	100
BI-002[1]	8	2,000	250
BI-003[1]	0.4	20,000	50,000
BI-004[1]	1.2	10,000	8,333
BI-005[1]	4	5,000	1,250

Additional experiments conducted for experimental APIs BI-001 – BI-005 showed that Apisolex polymer increased the drug solubility up to 50,000-fold.

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[1] *APIs for this study were provided by Boehringer Ingelheim Pharm. Inc.*

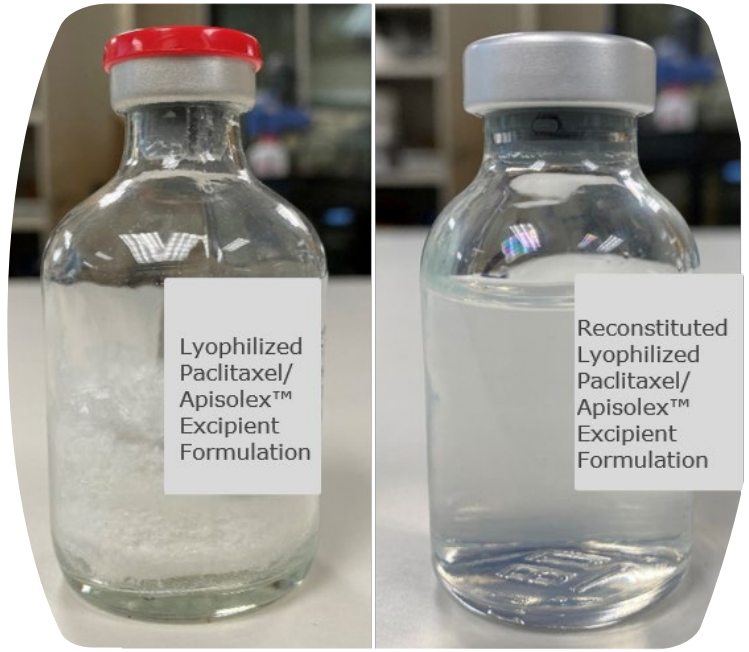
Paclitaxel Formulation

HEALTH

Paclitaxel Formulation Using Apisolex™ Excipient

- tBuOH/water solution mixing process provided drug product that is 13% by weight paclitaxel
- Greater than 90% efficient process
- Lyophilized drug product reconstitutes in less than 30 seconds in saline
- 12 months of stability under ambient conditions with no change in physiochemical properties

	Formulation Characteristics
API	Paclitaxel
Indication	Chemotherapeutic
Route of administration	IV
Dosage form	Nanosuspension
Ingredients	Paclitaxel Apisolex™ excipient Trehalose
Process	tBuOH/water solution mixing



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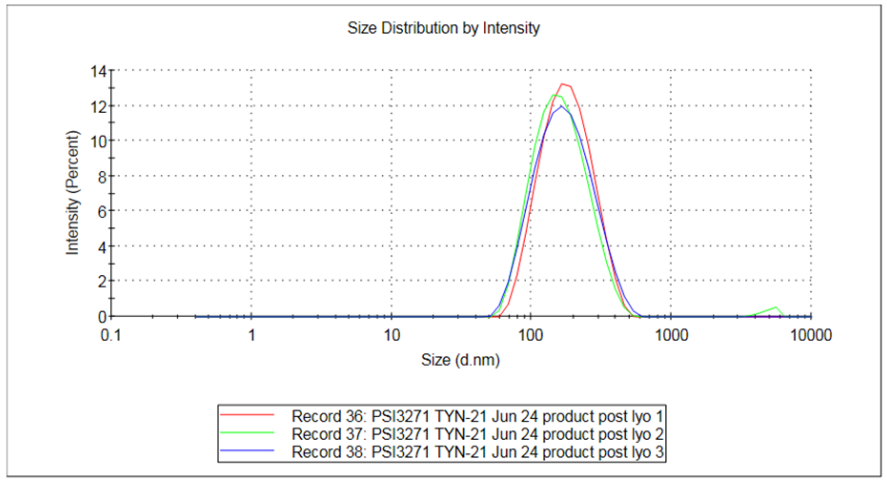
Paclitaxel/Apisolex™ Excipient – Formulation Characterization

Particle size distribution of post–lyophilization reconstituted Paclitaxel/Apisolex™ formulation

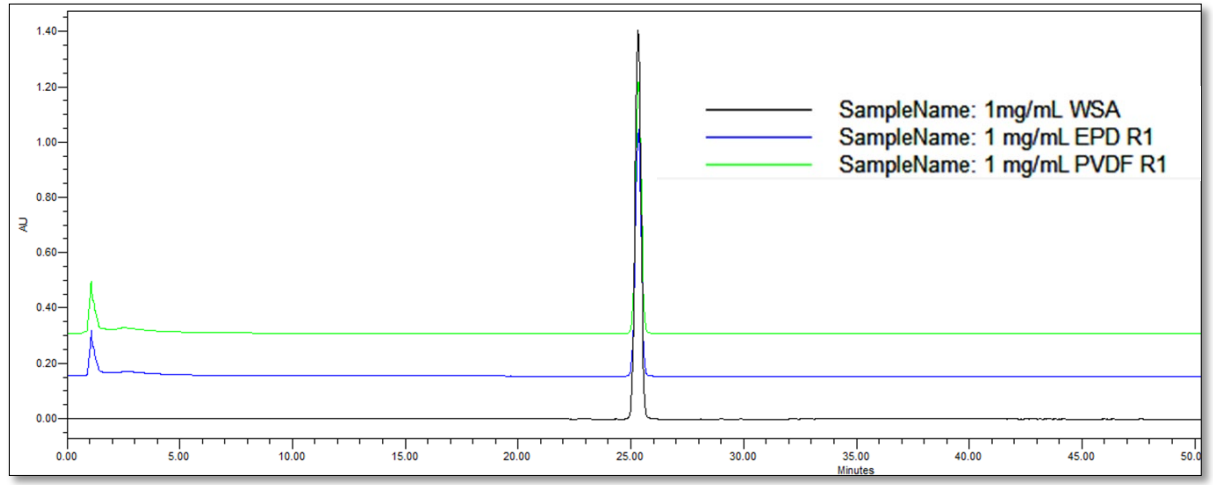
Results

		Size (d.nm):	% Intensity:	St Dev (d.n...
Z-Average (d.nm): 151.0	Peak 1:	185.0	100.0	85.96
PdI: 0.207	Peak 2:	0.000	0.0	0.000
Intercept: 0.969	Peak 3:	0.000	0.0	0.000

Result quality : Good



Paclitaxel Assay Results



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Paclitaxel/Apisolex™ Excipient – Formulation Systemic Toxicity

Cytotoxicity

- Cells lines (A549/Human Lung Carcinoma and MCF7/Human Breast Adenocarcinoma).
- Test substances
  - Saline control;
  - Apisolex™ control at 50nM;
  - Paclitaxel at 50nM;
  - Paclitaxel (13% active)/ Apisolex™ formulation at 50nM
- Results: viability counts were comparable between the following two pairs
  - Saline control vs. Apisolex™
  - 50nM Paclitaxel vs. 50nM Paclitaxel/Apisolex™ formulation

Tolerability

- Species: rat
- Test article administration was performed by fast bolus IV infusion at 2 or 50 mg/kg, on Day 1, 8 and 15. The animals were sacrificed on Day 22.
- Results from the of 2 mg/kg dose group were comparable to control group; treatment-related effects were detected in the 50 mg/kg group

Apisolex™ excipient inactive in formulations and supports oncology drug development

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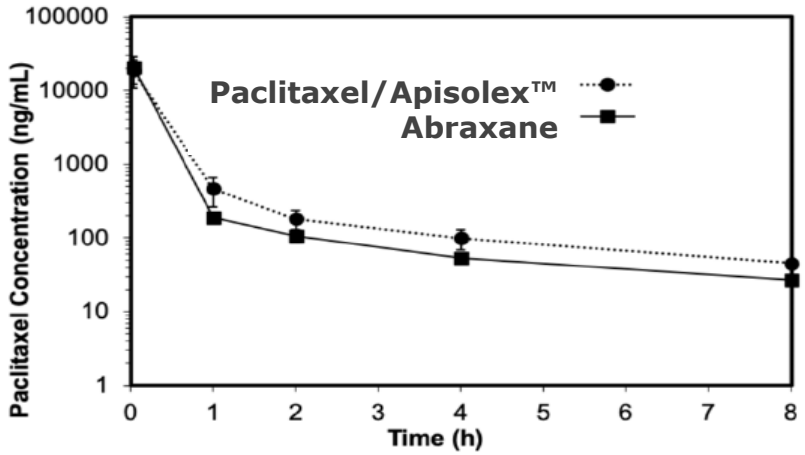
Paclitaxel/Apisolex™ Excipient – Formulation Pharmacokinetic

Administration

- Male and female rats (Sprague Dawley)
- A single IV dose equivalent to 5.0 mg/kg paclitaxel
  - Abraxane
  - Paclitaxel/Apisolex™ formulation

Results



Test article	AUC (ng*h/mL)	T1/2 (h)	Cl (mL/min/kg)
Abraxane	4,648 ± 1,306	3.1 ± 0.6	18.4 ± 5.3
Paclitaxel/Apisolex™	5,873 ± 2,103	3.2 ± 0.4	15.3 ± 4.6

Formulation bioequivalent to Abraxane in rats

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Safety and Toxicology

	Test	Results
Systemic toxicity	Tolerability (rats and mice)	Test article was well tolerated by rats and mice at doses as high as 1,500 mg/kg
	32-Day IV Injection Toxicity with 28-day recovery (rats)	No treatment-related effects were detected
Pharmacokinetics	[^{14}C] labelled Apisolex IV dose in male and female rats	Can be distributed to distant organs but does not accumulate Tissue: plasma AUC_{0-t} ratios <1.0

Safe for Parenteral Use
(conclusion based on animal testing and pre-IND packages)

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Apisolex™ Polymer Path Forward

- Scale up and GMP manufacturing 2022
- Excipient Drug Master File (DMF) 2023
- Safety & Toxicology - Future work to include AMES, *in vitro* cytogenecity, *in vivo* chromosomal damage, and six month repeat dose

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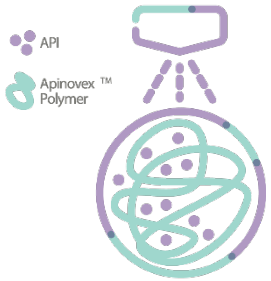
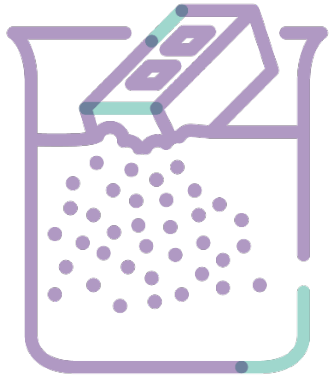
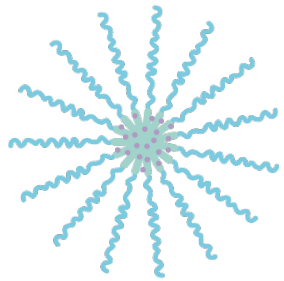
Solubility-Enhancing Excipients from LLS Health



Brick-Dust API





Oral-Grade Apinovex™

Stable amorphous solid dispersions with up to **80% drug loading**

Learn more at apinovex.com

Injectable-Grade Apisolex™

Increases the solubility of hydrophobic APIs up to **50,000-fold**

Learn more at apisolex.com

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Lubrizol's Excipient Value Proposition

Through our **multifunctional** excipient offerings, we enable our partners to create:

- **Patient and consumer centric** medicines for easier administration
- Highly **efficient, stable** products with reproducible performance
- **Safe, mucoadhesive** formulations with improved efficacy

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Excipient Snapshot

- Inventors of pharma grade carbomers and polycarbophils
- One of the world's largest manufacturers of pharma grade carbomers, polycarbophils, and thermoplastic polyurethanes
- Manufacturing pharmaceutical excipients for more than 40 years
- Safe for use in a variety of dosage forms

Oral Treatments

- Oral Solid Dose
- Oral Solutions & Suspensions (Liquids)
- Amorphous Solid Dispersions

Topical Delivery

- Gels
- Emulsions (Creams)

Oral Care

- Toothpaste
- Mouthwash
- Denture Adhesive
- Denture Cleaner
- Whitening Products

Ophthalmics

- Eye Drops (Solutions & Suspensions)
- Gels

Drug-Eluting Devices

- Subcutaneous implants
- Vaginal Rings
- Combo Products

Injectables

- Bolus injections
- IV infusion

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Excipient Brands

Carbopol® Polymers

- High molecular weight acrylic acid polymers
- Processed in either ethyl acetate or a cosolvent mixture of ethyl acetate + cyclohexane
- Suitable for use in oral and topical applications

Noveon® Polycarbo-phil

- High molecular weight acrylic acid polymer
- Processed in ethyl acetate
- Excellent mucoadhesive properties
- Suitable for use in oral and topical applications

Pemulen™ Polymers

- High molecular weight acrylic acid copolymers
- Processed in cosolvent mixture of ethyl acetate + cyclohexane
- Form stable oil-in-water emulsions
- Suitable for use in topical applications

Pathway™ TPU

- Thermoplastic polyurethane polymers
- Non-bioabsorbable with flexible chemistry
- Suitable for use in implantable drug delivery systems and drug/device combination products

Apinovex™ Polymers

- High molecular weight linear acrylic acid copolymer
- Processed in ethyl acetate
- Enables spray-dried amorphous solid dispersions with high drug loading (up to 80%)
- Suitable for oral applications

Apisolex™ Polymers

- Poly-amino acid-based multi-block copolymer
- Nano-encapsulates hydrophobic APIs to increase solubility up to 50K times
- High drug loading (up to 40%)
- Suitable for IV infusions and bolus injections

Manufactured under IPEC-PQG GMP guidelines
and have established Drug Master Files (DMFs)

Thank you!

Oral-Grade Apinovex™

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