



# Apinovex™ and Apisolex™ Polymers: New Tools for Solubility and Bioavailability Enhancement

Lubrizol Life Science Health

July 24, 2023

# Solubility-Enhancing Excipients from Lubrizol

- **Improved solubility and release** for BCS Class II and IV APIs
- **High, stable drug loading**
- **Simple, scalable** formulation techniques
- **Efficient, patient-friendly** dosage forms
- **IP protection** for NCEs and 505(b)(2) products



# 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

Oral-Grade  
Apinovex™

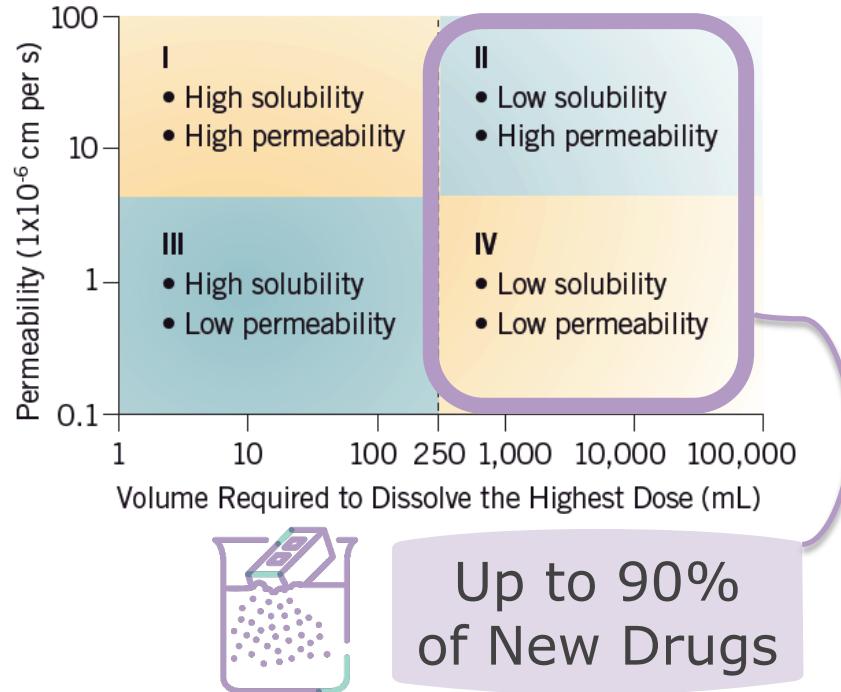


Injectable-Grade  
Apisolex™



# Shortcomings of Traditional Solubility Enhancers

## Biopharmaceutical Classification System (BCS)



**Low Efficiency/  
Poor Dosing**

**Undesired Side  
Effects**

**Complex  
Manufacturing  
Process**

There is no one-size-fits-all excipient!  
**New tools are needed to serve the growing pipeline of challenging APIs**

# Key Considerations for Novel Technologies

## Formulation Objectives



## Patient-Centric Objectives



## Business Objectives



**Does it Work?**

**Is it Safe/  
Patient-Friendly?**

**Does it Enable  
IP Protection?**

# Apinovex™ Polymer for Oral Solubility Enhancement



High molecular weight polyacrylic acid chemistry  
**designed for spray-dried amorphous solid dispersions**

## Does it Work?

Enables up to 80% drug loading  
Easy to process via spray-drying

## Is it Patient-Friendly?

Safe for oral use\*  
Enables smaller tablet size

## Does it Enable IP?

Patented technology for ASDs  
Opportunities for formulation IP

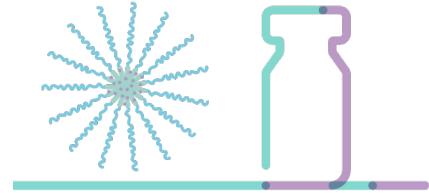
\* For detailed safety/tox data, contact  
[nick.difranco@lubrizol.com](mailto:nick.difranco@lubrizol.com)

# Apinovex™ Polymers: Looking Forward

- **Samples are readily available**
- Actively **seeking partnerships/ collaborations** with industry and academia
- **New Case Study Data – Q3**
  - Additional APIs with varied physicochemical properties
  - Multimedia and biorelevant dissolution testing
- **Additional Safety/Tox Data – early Q3**
  - Complete histopathology from 28-day study
  - Initiate a chronic *in vivo* study



# Apisolex™ Polymer for Injectable Solubility Enhancement



Polyamino acid-based multiblock copolymers  
**designed for efficient micellar encapsulation**

## Does it Work?

Enables up to 50,000-fold increase in solubility  
Simple formulation process

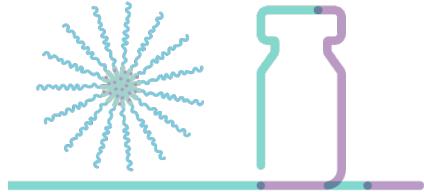
## Is it Patient-Friendly?

Safe for parenteral use\*  
Fast, easy reconstitution

## Does it Enable IP?

Strong composition of matter patents  
Opportunities for formulation IP

\* For detailed safety/tox data, contact  
[joey.glassco@lubrizol.com](mailto:joey.glassco@lubrizol.com)



## Apisolex™ Polymers: Looking Forward

- Scale up and GMP manufacturing – 3Q23
- Excipient Drug Master File (DMF) – 4Q23
- Safety & Toxicology - Future work to include:
  - Ames
  - in vitro cytogenicity
  - in vivo chromosomal damage
  - Six month repeat dose



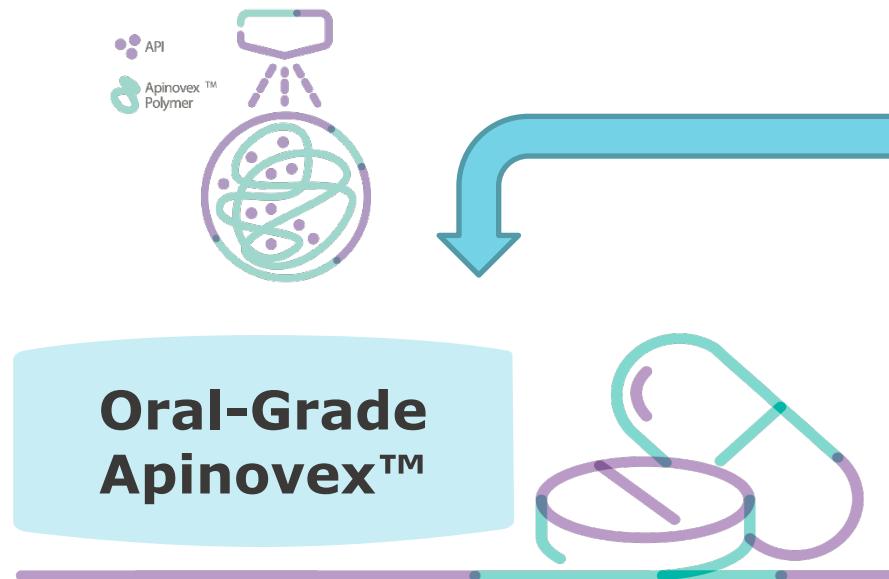
# Selecting the Right Partner

The ideal excipient/technology provider will have **deep experience in pharma** and provide:

- **Regulatory Support**
  - Understanding of global requirements
  - Safety/toxicity data for intended purpose
- **Quality and Manufacturing Assurance**
  - GMP manufacturing and documentation
  - Reproducible scale-up capability
  - Stability data
- **A Collaborative Mindset with Secure, Long-Term Supply**



# Solubility-Enhancing Excipients from LLS Health



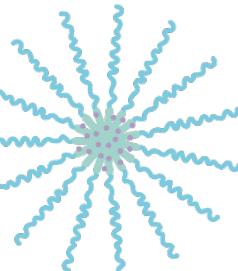
Stable amorphous solid dispersions with up to  
**80% drug loading**

Learn more at  
[apinovex.com](http://apinovex.com)

**Brick-Dust API**



**Injectable-Grade Apisolex™**



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

Learn more at  
[apisolex.com](http://apisolex.com)

# Thank you!

## Oral-Grade Apinovex™

**Nick DiFranco**

Global Market Manager

Oral Drug Delivery

[Nicholas.DiFranco@lubrizol.com](mailto:Nicholas.DiFranco@lubrizol.com)

Connect with me on LinkedIn!



[Apinovex.com](http://Apinovex.com)

## Injectable-Grade Apisolex™

**Joey Glassco**

Senior Global Market Manager

Parenteral Drug Delivery

[Joey.Glassco@lubrizol.com](mailto:Joey.Glassco@lubrizol.com)

Connect with me on LinkedIn!



[Apisolex.com](http://Apisolex.com)

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