PARTICLE ENGINEERING
for High Concentration Suspensions

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There is a growing interest across the industry in developing technologies for subcutaneous delivery of high dose protein therapeutics. High concentration protein solutions are limited by viscosity and stability; both phenomena are driven by protein-protein interactions in solution. Three primary approaches have emerged to overcome the technical challenges associated with high dose delivery: viscosity reducing excipients, high volume delivery, and high concentration suspensions.

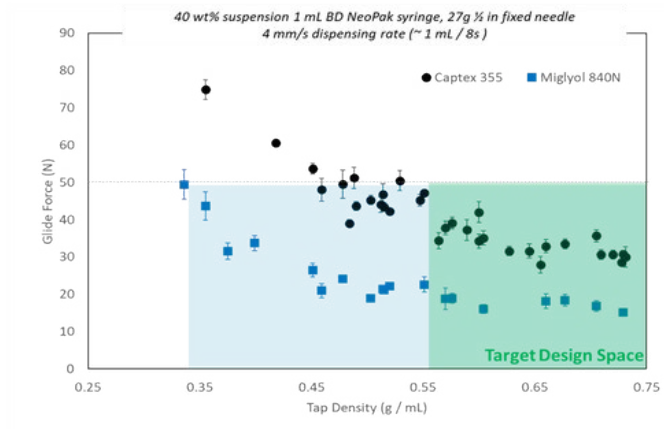
EXAMPLE TARGET PRODUCT PROFILE

- 300 – 600 mg dose
- Stable at 2-8° C, preferably 25° C for up to 2 years
- Injectable, subcutaneously
- 27 g ½" needle
- 2 mL in ≤ 20 seconds
- ≤ 50N maximum dispensing force
- Precedented excipients for parenteral administration
- Solid state particles
- Vehicle

SUMMARY IMPACT

- Tap density is an easily accessible empirical measurement that reflects particle porosity
- Particle porosity is a key attribute impacting suspension viscosity, and thus dispensing force
- Particle porosity depends on the intersection of formulation, process, and protein properties
- Particle size & size distribution within the relevant design space for administration via a 27g needle have minimal impact on dispensing force
- Particle morphology and surface roughness have minimal effect on dispensing force in comparison to porosity

EXAMPLE TARGET DESIGN SPACE



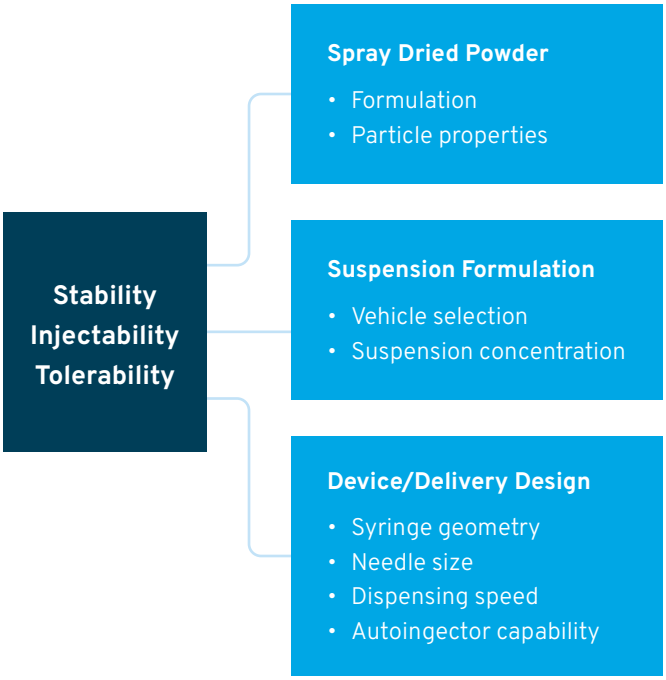
WHY DO WE NEED THEM?

- ✓ Improved patient experience
- ✓ Reduced healthcare costs
- ✓ Expanded accessibility
- ✓ Life-cycle management
- ✓ Biosimilars (IP)

Product Development Considerations for High Concentration Suspensions.

SUSPENSION STABILITY FORMULATION

- Vehicle optimization to minimize suspension viscosity while maintaining acceptable physical stability, colloidal stability, and protein stability
- Emphasis on pharmaceutical excipients with precedented use for parenteral administration
- Vehicle formulations designed to target desired dissolution profile (sustained release)



SPRAY DRIED POWDER

- Formulation screening aimed to maximize protein content in the solid state while maintaining in-process and storage stability requirements
- Particle engineering to optimize properties to minimize suspension viscosity and to support downstream processing
- Process design and to achieve acceptable in-process stability

STABILITY

- Achieving an acceptable stability profile is paramount in product development
- Stability considerations include physical stability of the solid-state particles, colloidal stability of the suspensions, and protein stability
- Solid state formulation and vehicle selection must be tailored to the specific stability profile for each molecule, and thus a singularly defined platform approach is unrealistic
- In-process stability must also be considered – excellent process engineering and spray dryer design enable in process stability for even the most sensitive molecules

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