



DCS classification of NCE Case study



Background

- US Biotech wanted to determine the DCS (Developability Classification System) designation for their small molecule



Project Scope

- GastroPlus® ADMET Predictor module estimated intestinal permeability as “high” based on the chemical structure.
- 24h solubility in 500mL intestinal buffer less than the expected therapeutic dose; solubility classified as “low”.
- Solubility also measured at 3h (a timeframe more relevant for drug absorption) and found to be >10 fold higher.
- Using this more physiologically relevant timepoint the molecule was classified as DCS IIA
- High permeability/low solubility with dissolution-limited absorption



Outcome

- As long as dissolution is rapid, absorption will be good, and desired plasma concentrations can be
- Quotient demonstrated that sophisticated solubilization technologies would not be necessary
- Simpler formulation strategy recommended - particle size reduction (micronization) and addition of
- Quotient developed and manufactured a powder-in-capsule formulation for the FIH clinical program