Release testing strategies for dissolution for larger sample sizes

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USP <711>

Stage 1: 6 tablets

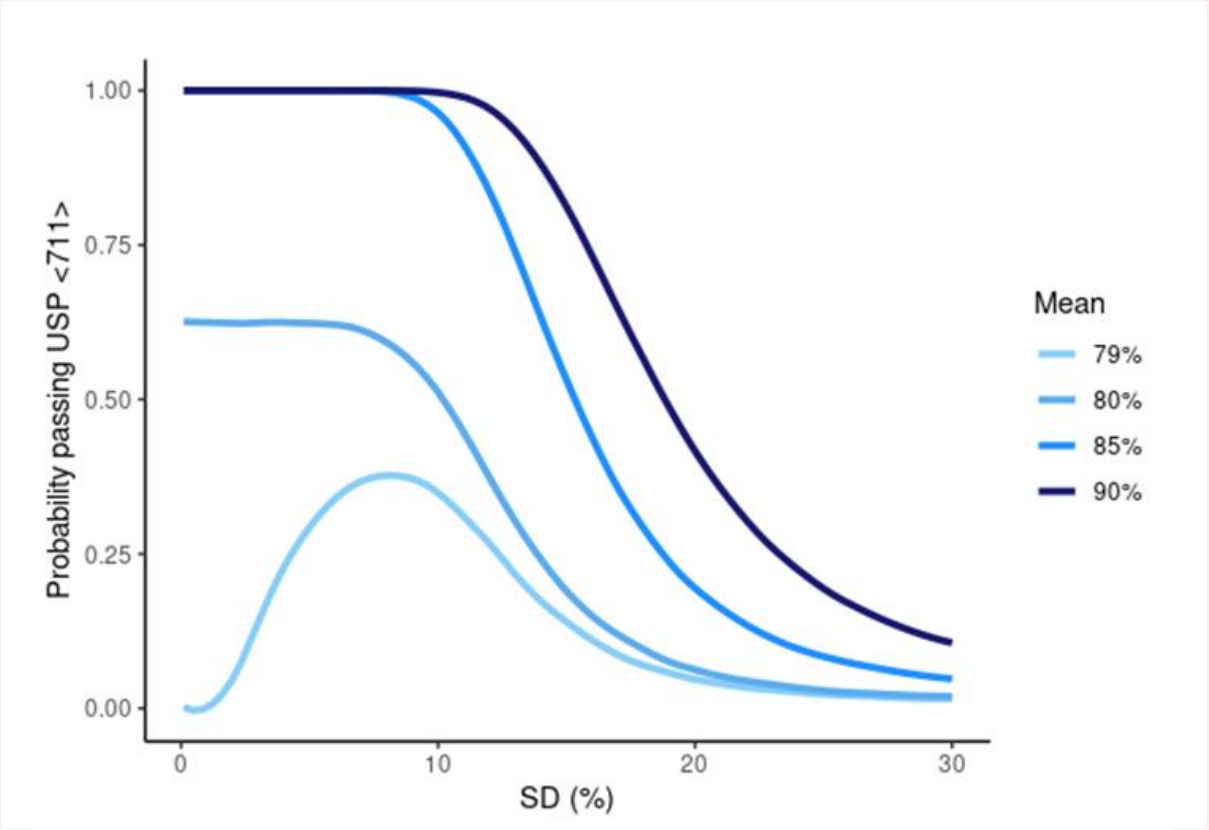
- All above Q + 5% **[Population]**

Stage 2: additional 6 tablets => work with total 12 tablets

- Mean above Q **[Mean]**
- None below Q – 15% **[Variability]**

Stage 3: additional 12 tablets => work with total 24 tablets

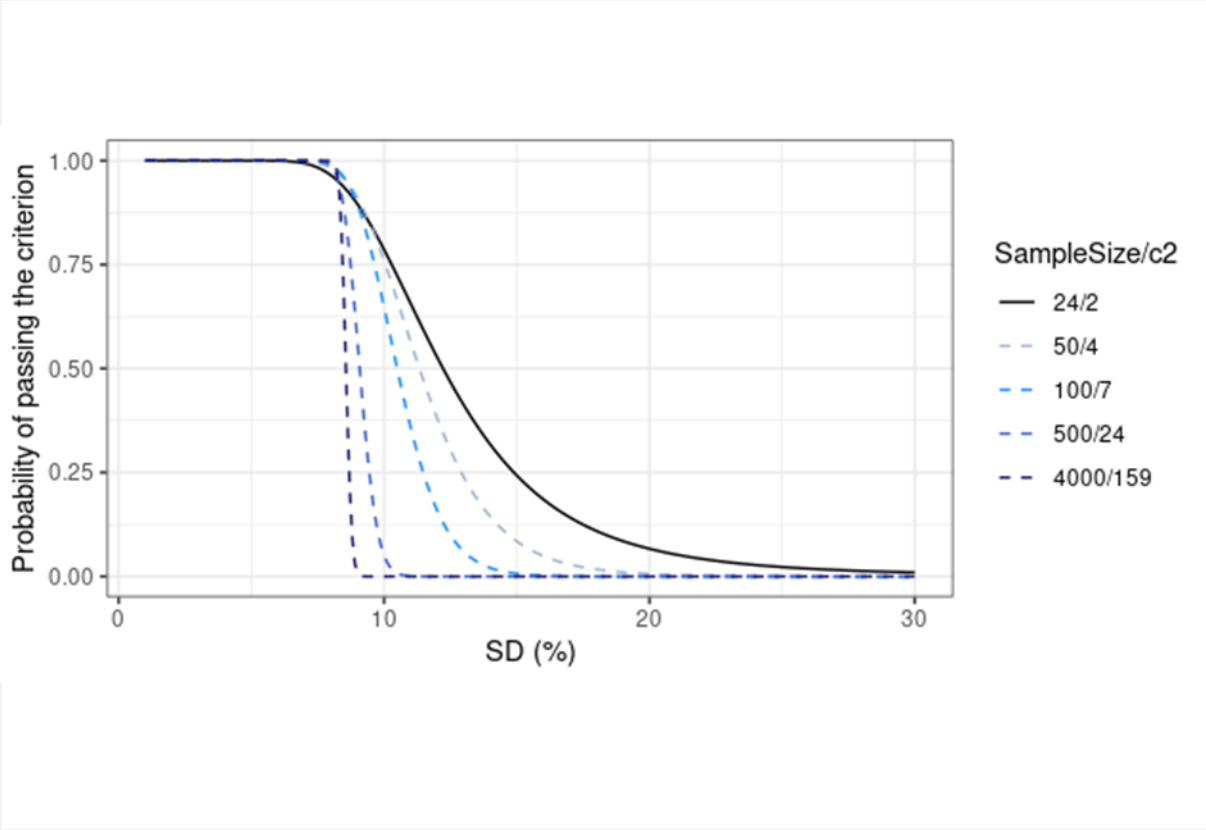
- Mean above Q **[Mean]**
- Max 2 below Q – 15% **[Variability]**
- None below Q – 25% **[Variability]**



Extend Stage 3 directly

Final criterion for N tablets

- Mean above Q **[Mean]**
- Max **k(N)** below Q – 15% **[Variability]**
- None below Q – 25% **[Variability]**

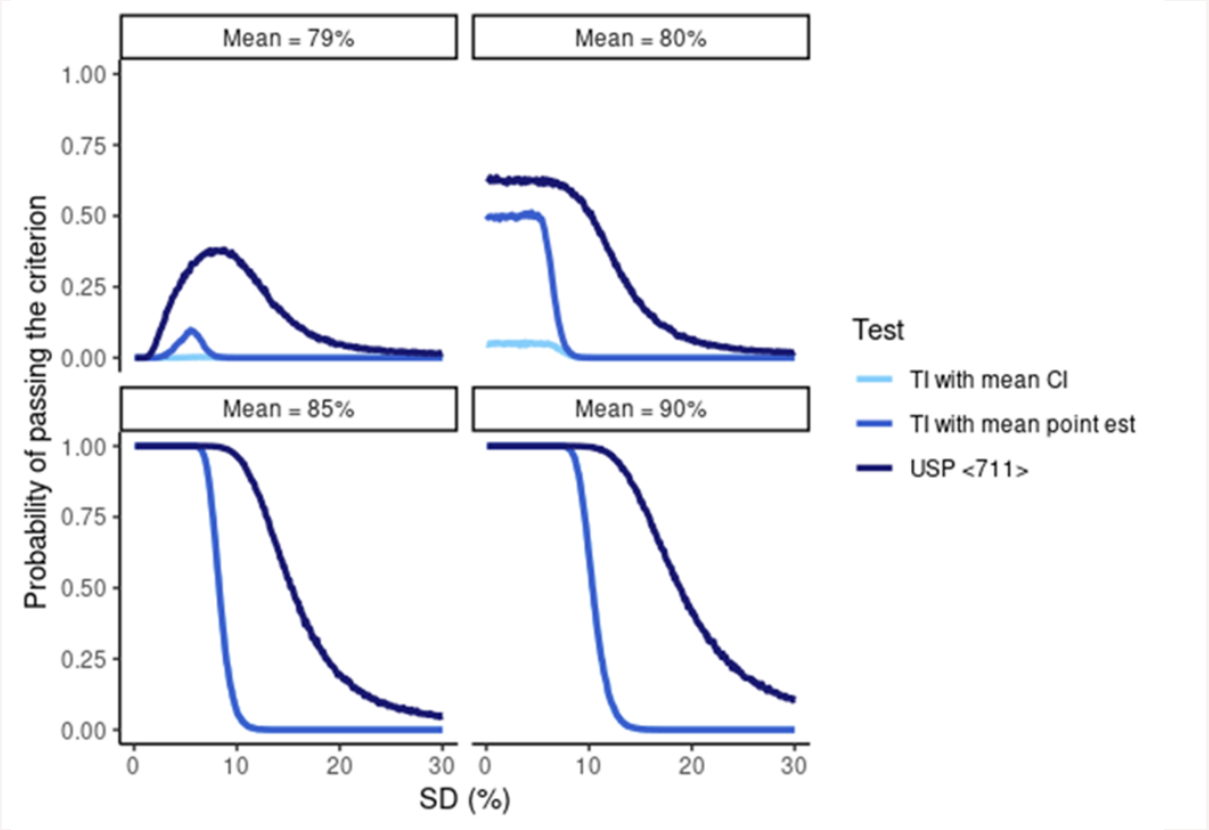


Direct quality: tolerance interval

Final criterion for N tablets

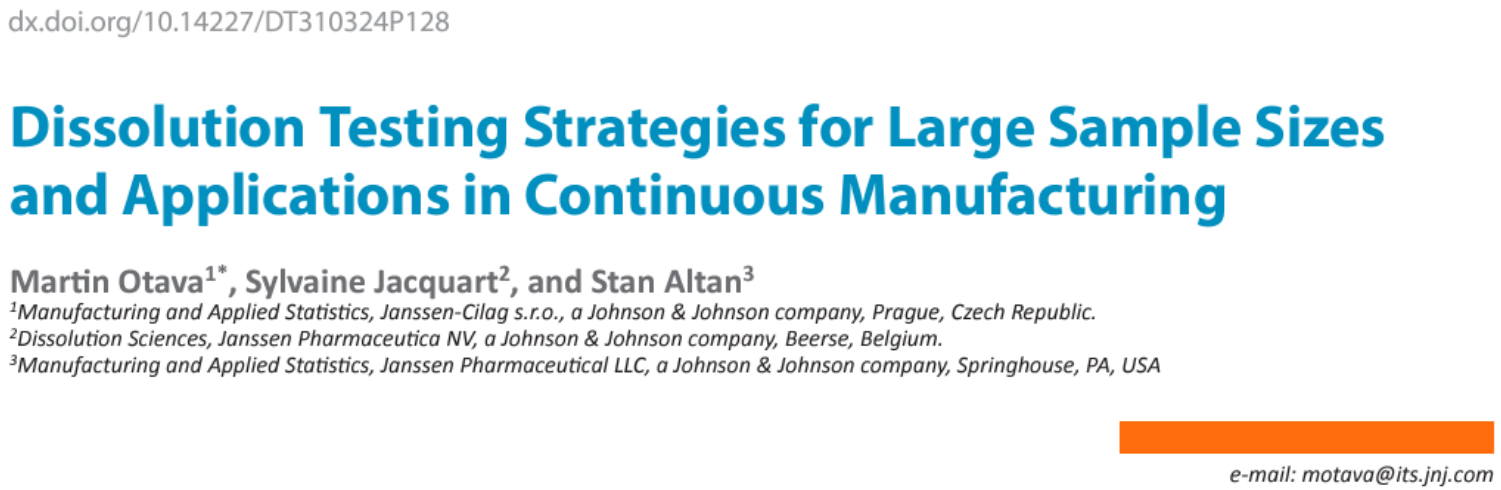
- Mean above Q **[Mean]**
- Lower 95%/97.5% TI ≥ Q – 15% **[Variability]**

Choice of TI calibrated against USP711 Stage 3



Thank you

Otava, M., Jacquart, S., Altan S. (2024)
Dissolution Testing Strategies for Large Sample Sizes and Applications in Continuous Manufacturing
Dissolution Technologies, August issue



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Dissolution Testing Strategies for Large Sample Sizes and Applications in Continuous Manufacturing

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