Comparative Study of Content Uniformity Between Capsules and 3D-Printed Oral Forms Manufactured by Semi-Solid Extrusion

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Context

Growing need for dose personalization

Current practice:
Manual / semi-automatic compounding

Operator-dependent variability

Innovative approach:
Automated compounding by 3D printing

Automated & flexible

Evaluate batches quality: compare both approaches via Pharm. Eur. compliance + statistical assessment of variability

Material & Method

Production of 60 oral forms   API content : 1.5 mg

1 industrial

Innovative compounding by 3D printing
MED-U PROD MB Therapeutics

3 hospital pharmacies

PUI 1   PUI 2   PUI 3

Traditionnal compounding
Semi-automatic capsule filler

Content Uniformity
Pharm. Eur. 2.9.6
Pharm. Eur. 2.9.40

Content Variability
Assessed in MiniTab®
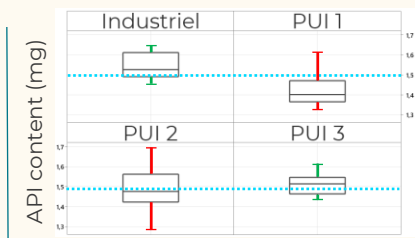
Results

Pharm. Eur. 2.9.6

$\overline{X} \pm 25\%$
$\overline{X} \pm 15\%$
Target dosage

Single unit dosage

PUI 1 ✅   PUI 2 ✅   PUI 3 ✅   Indus ✅

Pharm. Eur. 2.9.40

	PUI 1	PUI 2	PUI 3	Indus	Acceptation value
Mean dosage $\overline{X}$ (mg)	1.43	1.49	1.51	1.54	NA
Std deviation s (mg)	6.47	8.44	3.57	4.26	NA
VA	19 ❌	20 ❌	9 ✅	12 ✅	< 15

Statistical assessment

All participants compliant with Ph. Eur. 2.9.6
PUI 1 / PUI 2 : not compliant with Ph. Eur. 2.9.40
PUI 3 / Indus : lowest variability intra-batch

Pharm. Eur. 2.9.40 better reflects intra-batch variability

Conclusion & Discussion

All formulations **complied** with at least one applicable **pharmacopoeial monograph** on content uniformity

3D-printed forms uniformity ≥ PUI capsules

Next step:
multiple industrial participants to assess process robustness