L. Lemierre[a,b], D. Stefanelli[a], S. Roulon[a], I. Soulairol[a, b, c]

[a] MB Therapeutics, Montpellier, France
[b] ICGM, University of Montpellier, CNRS, ENSCM, Montpellier, France
[c] Department of Pharmacy, Nîmes University Hospital, Nîmes, France

# Robustness Evaluation of a Semi-Solid Extrusion 3D Printing Process for Oral Dosage Forms: A Case Study with Melatonin

## Context

Growing need for dose personalization

**Current practice:**
Manual / semi-automatic compounding

*Operator-dependent variability & limited scalability*

**Innovative approach:**
Automated compounding by 3D printing

*Higher reproducibility & flexibility*

Evaluate process robustness :
Pharm. Eur. compliance & process capability indices (Cp/Cpk)

## Material & Method

Production of 3 batches of 600 Printed Oral Forms (POFs) - Melatonin (3 mg)


*MED-U PROD – MB Therapeutics*

| | |
|---|---|
| Production speed<br>*In house protocol* | Content Uniformity<br>*Pharm. Eur. 2.9.40* |
| Process capability<br>*Assess in MiniTab®* | Mass Uniformity<br>*Pharm. Eur. 2.9.5* |

## Results

### Production speed

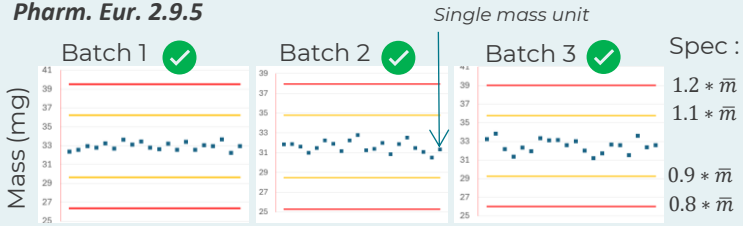
Operator effective time : 13 min

1 POF / 10 sec
Production time 1h 40min

Printed batch: 600 POFs

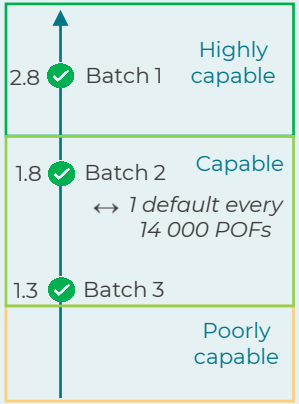
### Pharm. Eur. compliance

**Pharm. Eur. 2.9.5**




| **Pharm. Eur. 2.9.40** | Batch 1 | Batch 2 | Batch 3 | Acceptation value |
|---|---|---|---|---|
| Theorical dosage (mg) | 3.1 | 2.9 | 3.0 | NA |
| ETR (%) | 1 | 1 | 2 | ≤ 2 |
| VA | 6 | 12 | 5 | < 15 |

### Process capability




## Conclusion & Discussion

Study performed at T0 of process dev :
**baseline capability assessment**

Already **Pharm. Eur. compliant**

Already **capable process** (Cp/Cpk ≥ 1.3)

Next step : process optimization & continuous improvement

6 sigma performance :
Cp/Cpk ≥ 1.7
by end of validation