

Impact of cartridge storage on the stability of 3D-printed oral dosage forms manufactured by semi-solid extrusion

Context Growing need for dose personalization

Current practice:

Manual / semi-automatic compounding

Operator-dependant variability & limited scalability



Innovative approach:

Automated compounding by 3D printing

Higher reproducibility & flexibility



Assess the impact of 6 months of cartridge storage on the chemical and microbiological quality of printed oral forms (POFs)

Material & Method

MED-U PROD® - MB Therapeutics



Printing files

Pharmaceutical cartridges



API assay and uniformity
Pharm. Eur. 2.9.40



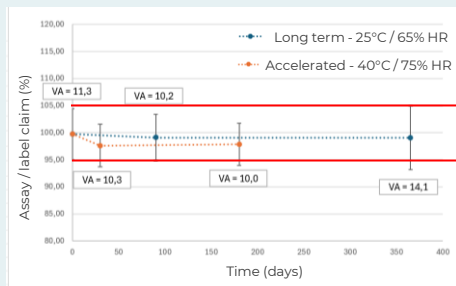
Microbiological quality
Pharm. Eur. 5.1.4

Résultats

POFs assay and uniformity of API

Spec : $\bar{X} \pm 5\%$

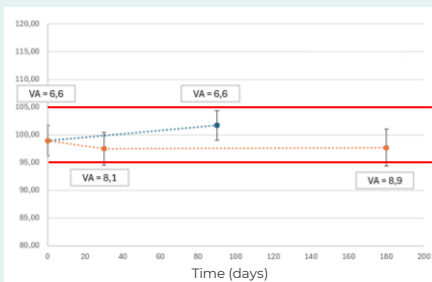
POFs made on fresh cartridges



Assay 
97,7 – 99,8 %

Uniformity 
VA : 10,0 – 14,1 (< 15)

POFs manufactured on cartridge stored for 6 months



Assay 
97,6 – 101,8 %

Uniformity 
VA : 6,6 – 8,9 (< 15)

Microbiological quality

Germes TAMC < 10²; Molds / Yeasts TYMC < 10¹; E. Coli absence

Conclusion & Discussion

6 months storage on cartridges:

Oral forms still compliant

Assay – Uniformity – Microbiology



Upstream storage
Printing on demand
Quick answer to the need

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Increase flexibility for pharmacies, particularly during supply shortages