

High concentration antibiotic eye drops administration (Ceftazidime, Amikacin, Vancomycin) are ophthalmic emergencies. The short stability at + 4°C leads to untimely production. A physico-chemical and microbiological^{1,2} stability study was performed to extend the stability to 90 days at -20°C, protected from light, allowing batch production. Thawing method (room temperature for 20 minutes) was also validated for the dispensation. The aim of our work was to implement batch production and measure added value in comparison to our prior manual on demand production method.



Patients treated : 2020 and 2021

N = 130 eye drop **bottle / drug**

Every 3 months



Sterility controls (Merck Symbio Steritest[®])



Sub visible particle counting (Beckmann Coulter HIAC 9703+)



Concentration determination (Qcrx[®])

Impact study of eye drop batch production

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Introduction

Reconstitution and repartition with peristaltic pump (Repeater[®] Baxter) in BSC grade A and in process gravimetric control

Destructive controls



Osmolality (Löser[®] type 15)



pH meter (CG 818 - Schott Geräte)

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Preparation Time production (h) 0.5 Total per year (h) 80 220 Wastage per year (units)

Conclusion

Batch production ✓ Enhancing quality of eye drop preparations : additional controls Cost optimization : human resources and stocks establishments.

1.Chédru-Legros V, Fines-Guyon M, Chérel A, Perdriel A, Albessard F, Debruyne D, et al. Stabilité à – 20°C des collyres antibiotiques renforcés (Amikacine, Ceftazidime, Vancomycine). J Fr 2.Ophtalmol. oct 2007;30(8):807-13

Lucile.P. Étude de la stabilité microbiologique de trois collyres renforcés en antibiotiques (Amikacine, Ceftazidime et Vancomycine). Université de Bordeaux ; 2020.



Quality improved by : ✓ in-process controls : controls on master bag (gravimetric, concentration) ✓ post-process destructive and non-destructive **controls** : gravimetric, final concentration, sterility, subvisible particles, pH and osmolality

| n (N = 104) | Batch production (N = 12) | |
|-------------|---------------------------|----------|
| ontrols | Preparation | Controls |
| 0.25 | 2.5 | 0.75 |
| | 39 | |
| | 84 | |

 \checkmark **Time spared** = (x2) batch size with equivalent human resources + development of new ophthalmic preparations for in-house needs or for others healthcare