

# Origin Determination of Impurities Occuring During the Preparation of Fortified Vancomycin Eye Drop

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## Context

**Fortified eye drop preparation** : Ceftazidime, Vancomycin, Amphotericin B, Gentamicin. **Packaging** : Tinted glass vials (Somatherm F02115) washed and sterilized in our sterilization unit (washer-disinfector on a classic cycle using DLM Maxi Anios detergent and a RHW Anios lubricant to facilitate drying). **Problem** : Appearance of flocculation when filling the vials with the reconstituted Vancomycin solution (the vials were then discarded and not released). This reaction seems to be caused by a deposit on the wall of the vials and the flocculation disappears after a few seconds in solution. Flocculation does not occur with other molecules.



## Objective

To identify the origin of the impurities and to fix it.

## Results

15 collectively washed and sterilized vials -> 6 containing flocculations (i.e. 40%).  
15 individually washed and sterilized vials -> 2 displaying flocculations (i.e. 13%)  
5 sterilized without washing vials -> 4 presenting flocculations (i.e. 80%)  
No flocculation was found in the 10 vials washed without sterilization process (with or without lubricant) or in the 5 vials neither washed nor sterilized.

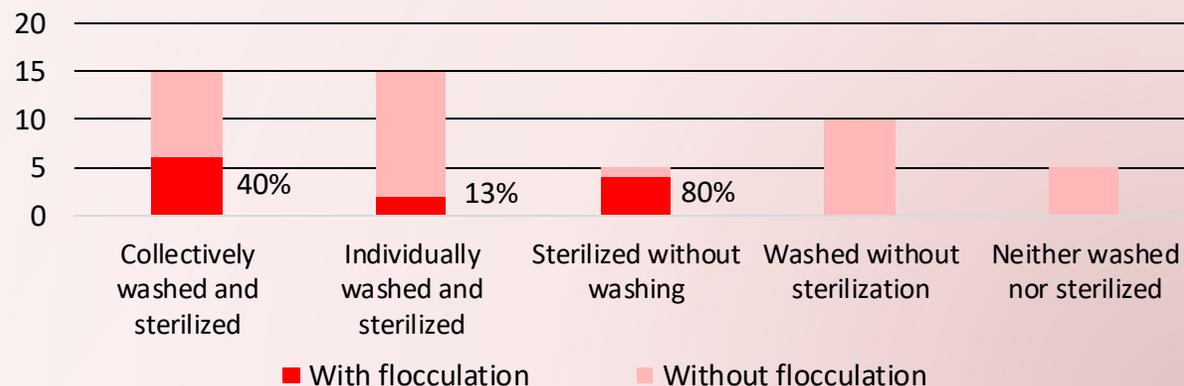
## Materials and Methods

We investigated washing and sterilization methods. After an unsuccessful bibliographic search, we carried out 3 series of preparations packaged in vials undergoing different treatments in order to identify the source of the problem.

		1st serie	2 <sup>nd</sup> serie	3rd serie	Total
Collectively washed and sterilized		5	5	5	15
Individually washed and sterilized		5	5	5	15
Sterilized without washing				5	5
Washed without sterilization	With lubricant		5		5
	Without lubricant		5		5
Neither washed nor sterilized		5			5
					50

Number of vials

## Flocculation repartition



## Conclusion

**Hypothesis** : impurities derive from the condensation of salts contained in the sterilization water.

**To go further** : Increase in the number of vials tested, identify the nature of the impurities, ensure the safety of the impurities.

**Another possibility** : use of a ready-to-use container that is already sterile with a benefit / cost study to be carried out.