# Physicochemical validation of the sterile filtration process for hospital-compounded gentamicin eye drops

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## INTRODUCTION / OBJECTIVE

During routine analytical quality control of hospital-compounded gentamicin eye drops (15 mg/mL), out-of-specification results were detected in the first sample unit.

Given the recurrent nature of this discrepancy, a physicochemical validation of the sterile filtration process was deemed necessary.

**Objective : To understand the origin of these repeated analytical discrepancies and to assess th potential impact of the sterile filtration process on gentamicin content.**

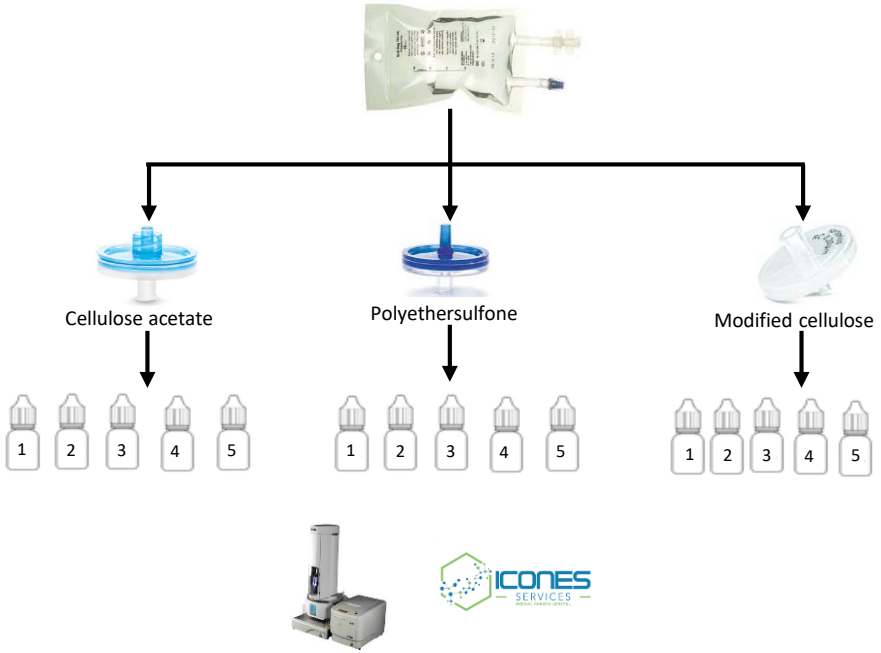
## MATERIALS AND METHODS

1-Preparation of gentamicin 15 mg/mL solution

2-Sterile filtration of 50 mL gentamicin 15 mg/mL

3-Collection of filtrate every 10 mL

4-Quantification of collected samples by UV-Raman spectrometry

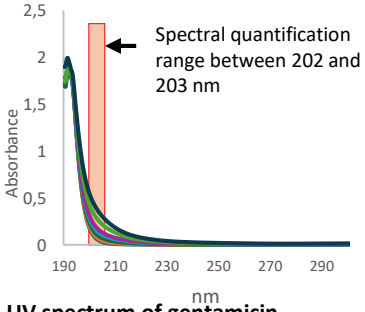



## RESULTS

### 1-Calibration model

| | | | Calibration range | 1,5 -30 mg/mL |
|---|---|---|---|---|
| **Theorical concentration (mg/mL)** | **Mesured Concentration (mg/mL)** | **Observed relative error (%)** | **Predicted Concentration (mg/mL)** | **Predicted relative error (%)** |
| **30** | 30.01 | 0,05% | 30,04 | -0,14% |
| **21** | 21,01 | 0,09% | 21,02 | -0,12% |
| **12** | 11,91 | -0,74% | 11,89 | 0,86% |
| **9** | 9,02 | 0,27% | 9,02 | -0,32% |
| **6** | 5,99 | -0,13% | 5,99 | 0,16% |
| **3** | 2,99 | -0,01% | 2,99 | 0,02% |
| **1.5** | 1,53 | 2,64% | 1,55 | -3,81% |
| | | | **R²** | **0,9999** |
| | | | **Residual standard deviation** | **0.04216** |
| | | | **Predicted standard deviation** | **0.05391** |

Quality control at 15 mg/mL gentamicin: CV repeatibility = 0,12% ; CV accuracy : 0,52%




**UV spectrum of gentamicin**

### 2-Assay of filtred solutions

| | | | |
|---|---|---|---|
| Mean content Vial 1 (mg/mL) | 9,94 (± 0,004) | 14,30 (± 0,02) | 14,88 (± 0,01) |
| Mean content Vial 2 (mg/mL) | 14,14 (± 0,002) | 14,62 (± 0,01) | 14,92 (± 0,01) |
| Mean content Vial 3 (mg/mL) | 14,58 (± 0,02) | 14,65 (± 0,01) | 14,88 (± 0,04) |
| Mean content Vial 4 (mg/mL) | 14,84 (± 0,04) | 14,66 (± 0,04) | 14,92 (± 0,15) |
| Mean content Vial 5 (mg/mL) | 14,86 (± 0,06) | 14,81 (± 0,13) | 14,88 (± 0,02) |

## CONCLUSION

The physicochemical validation showed that polyethersulfone and modified cellulose filters ensured consistent and reproductible gentamicin concentrations. In contrast, cellulose acetate led to a marked decrease in the first fraction, probably due to initial adsoption. Sterivex polyethersulfone filters are currently used routinely.