

DEVELOPMENT AND VALIDATION OF A METHOD FOR THE DETERMINATION OF VANCOMYCIN EYE DROPS BY ULTRAVIOLET-VISIBLE SPECTROPHOTOMETRY



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Background

Vancomycin is used as a **fortified eye drops** for the treatment of bacterial keratitis.

Given the absence of an equivalent speciality available, the hospital pharmacy prepares these eye drops under aseptic conditions. A **content uniformity is required** before the batch is released.

Objective

The aim of this study is the development and validation of a method vancomycin eye drops dosage by UV-VIS spectrophotometry.

Materials and Methods

- Spectrophotometer SPECORD 200 Plus (Analytik Jena)
- Software ASPECTPlus
- Quartz cuvette (HellmaAnalytics)
- Analyses are performed at 280 nm

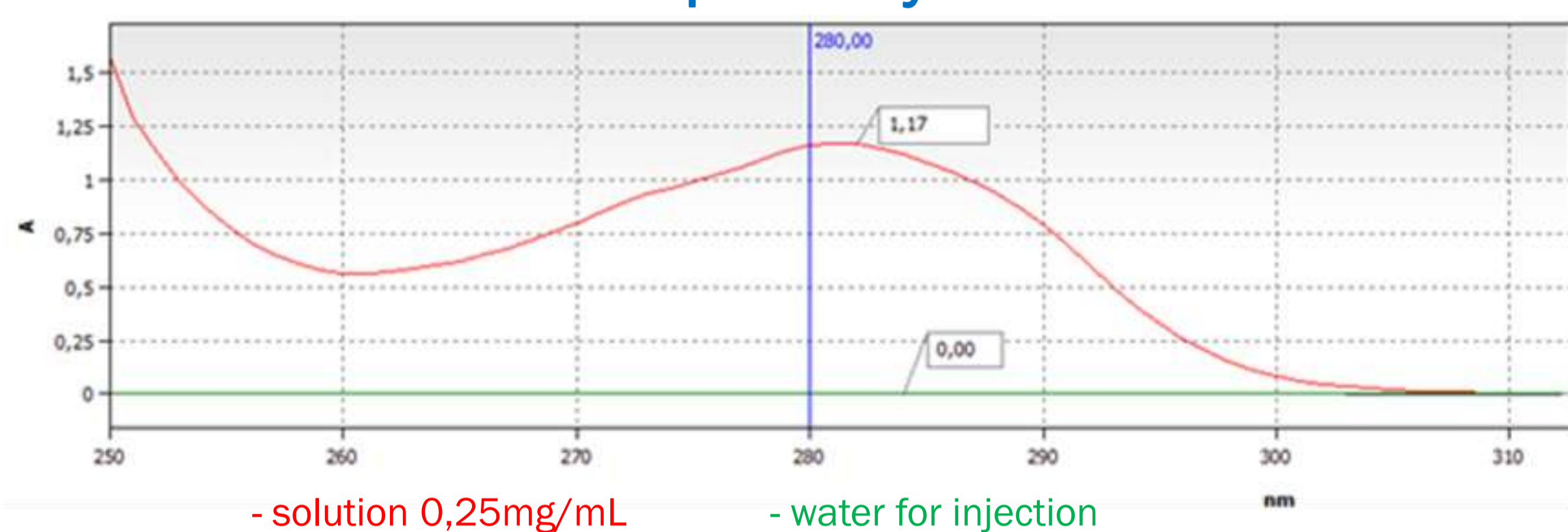
Validated according to the ICH Q2(R1) : **Specificity, Linearity, Repeatability, Intermediate precision, Accuracy, Limit of detection, Limit of quantification. Memory effect, vial equivalence and background noise** are studied.

5 standard solutions are performed from 0.1 to 0.4mg/mL and a 200th dilution in water for injection to analyse the samples.

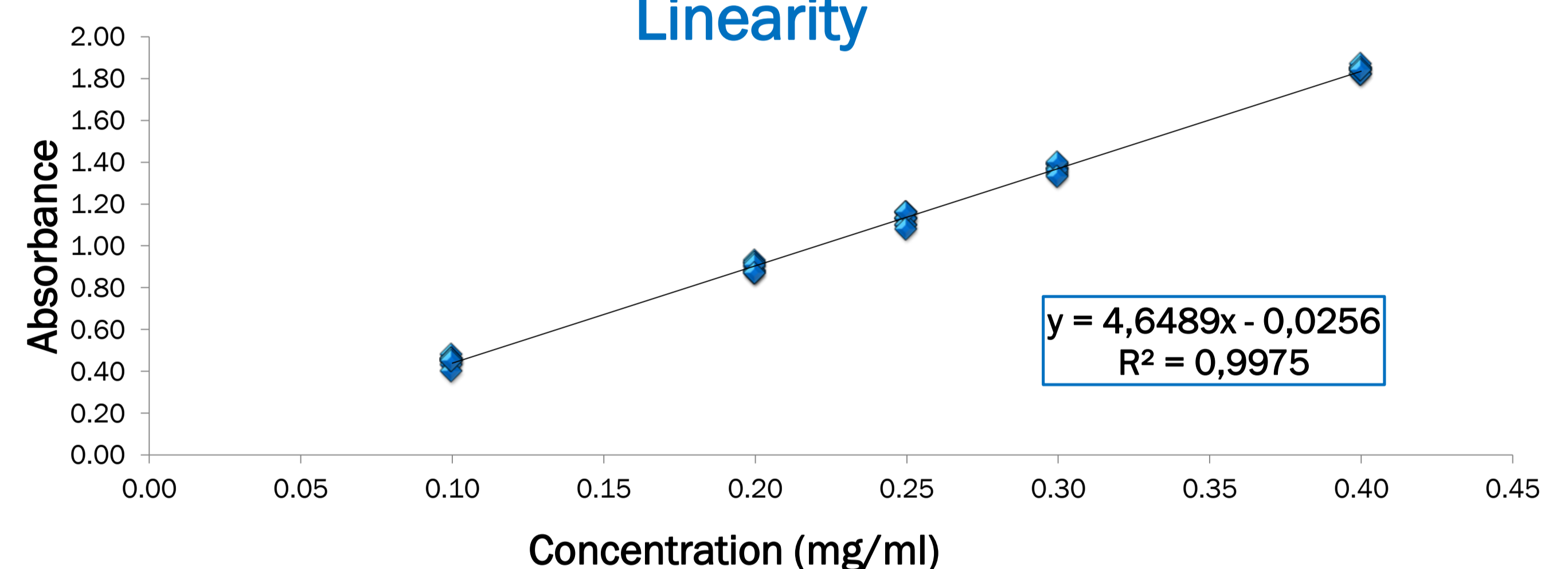
A relative standard deviation (RSD) of 5% is accepted for each criteria.

Results

Specificity



Linearity



Repeatability

	0.1 mg/ml	0.2 mg/ml	0.25 mg/ml	0.3 mg/ml	0.4 mg/ml
Average (mg/ml)	0,46	0,91	1,14	1,37	1,83
Standard error	0,00874	0,00874	0,0104	0,00688	0,0134
Coefficient of variation (%)	1,91	0,96	0,91	0,50	0,73

Intermediate precision

	0.1 mg/ml	0.2 mg/ml	0.25 mg/ml	0.3 mg/ml	0.4 mg/ml
Average (mg/ml)	0,45	0,90	1,13	1,37	1,84
Standard error	0,0208	0,0227	0,0283	0,0230	0,0156
Coefficient of variation (%)	4,65	2,53	2,51	1,69	0,85

Accuracy

Eyes drops		
	Min	Max
Recovery (%)	98,5	101,9

Theoretical concentration 45mg/mL

Solution obtained by direct weighing		
	Min	Max
Recovery (%)	95,1	101,2

Theoretical concentration 50mg/mL

Discussion

When measuring accuracy, the prepared eye drops have a vancomycin concentration of 45mg/mL and not 50mg/mL as expected. After questioning our manufacturing protocol, we asked our supplier.

The **powder vials contain a quantity of vancomycin base equivalent to an antimicrobiological activity of 1.000.000UI/vial**. Legislation require presentation in milligrams and UI.

The amount of vancomycin base in a vial therefore **varies between 850mg and 950mg** depending on the initial content of active ingredient and not really 1g as indicated.

Conclusion

The analytical method is validated. The method is suitable for routine use due to its speed and accuracy allowing a control before release of each batch of our eye drops.