

STABILITY OF CONCENTRATED SOLUTION OF VANCOMYCINE HYDROCHLORIDE IN SYRINGES FOR ICU

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Introduction

- Vancomycin is administrated by continuous infusion.
- But the treatment of patient in intensive care need restricted volume to prevent fluid overload.

Aim of the study

- To determine the chemical stability of solutions of 40 mg/ml vancomycine in glucose 5 % or NaCl 0,9 %.

Méthode

- 8 syringes were prepared, containing 40 mg/ml of Vancomycine® Mylan in glucose 5 % or NaCl 0.9 % and stored at ambient temperature during 48 hrs.
- Immediately after preparation and during 48 hrs, vancomycine concentrations was measured by high-performance liquid chromatography (HPLC).
- Spectrophotometric absorbances at different wavelengths, pH measurement and microscopic observations were performed periodically during the storage.
- A forced degradation test with HCL 12M and NaOH 8M before and after heating at 100 °C was also performed.

Results

- All solutions were physico-chemically stable during the whole period storage at ambient temperature: no color change, absence of turbidity, precipitation or opacity in the solutions , no significant change in pH values or optic densities.
- Any crystals were seen by microscopic analysis.
- The concentrations of the solutions remain stable with a lower confidence limit superior to 90% of the initial concentration as recommended by the Food and Drug Administration until 48 hours.

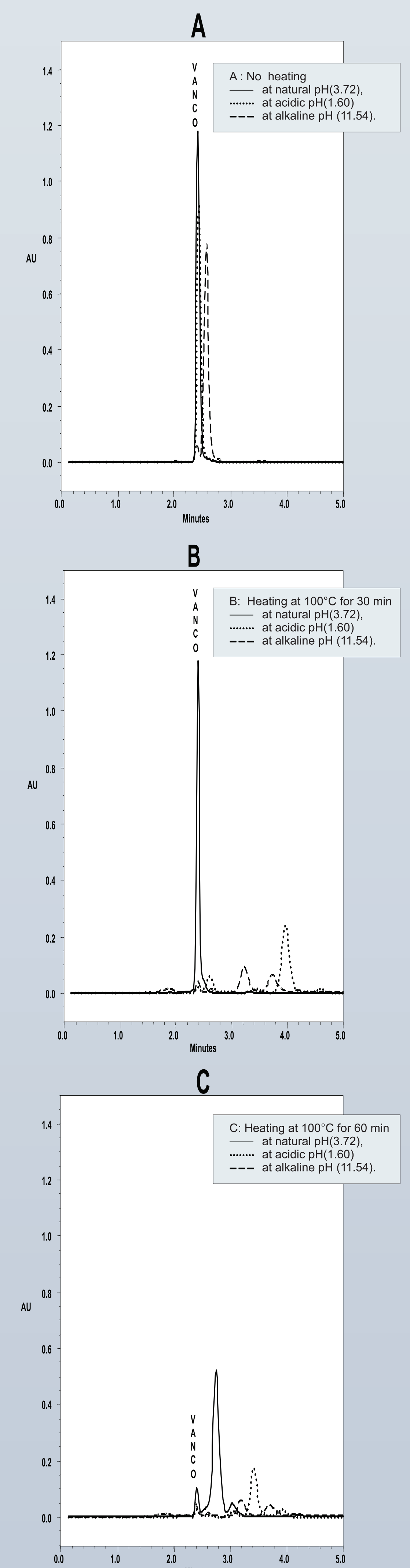
Table 1 – Vancomycine 2 g/48 ml Glucose 5 %

Hour	Mean Percentage of initial concentration	95 % lower one-sided confidence limit of mean percentage
0	100.0	99.0
2	99.9	98.9
4	99.8	98.9
6	99.6	98.8
8	99.5	98.7
22	98.7	98.0
24	98.6	97.9
26	98.5	97.7
28	98.3	97.6
30	98.2	97.4
48	97.2	95.7

Table 2 – Vancomycin 2 g/48 ml NaCl 0.9 %

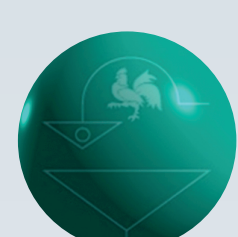
Hour	Mean Percentage of initial concentration	95 % lower one-sided confidence limit of mean percentage
0	100.0	97.5
2	100.1	97.8
4	100.2	98.0
6	100.3	98.3
8	100.4	98.5
22	101.1	99.5
24	101.2	99.5
26	101.3	99.5
28	101.4	99.5
30	101.5	99.4
48	102.4	98.7

Fig.1 Chromatograms showing degradation test



Conclusion

- Solutions of vancomycine 40 mg/ml of Vancomycine® Mylan in glucose 5 % or NaCl 0.9 % are physico-chemically stable during 48 hrs when stored in syringes at ambient temperature.



27ème Journée de l'AFPHB, 05/03/2016, Bruxelles

Possible conflict of interest : nothing to disclose.