



Physicochemical and microbiological stability study of amikacin in polypropylene syringes for intrathecal administration

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Background and importance

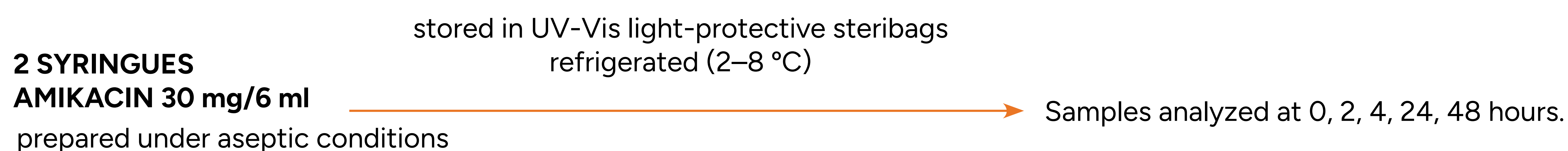
Intrathecal amikacin is prescribed for the treatment of central nervous system infections caused by Gram-negative bacteria. There is no commercially available formulation for this method of administration.

Aim and objectives

To establish the aseptic preparation process of a 5 mg/ml sterile amikacin formulation in polypropylene syringes for intrathecal use, and to conduct a stability study to confirm a 48-hour shelf life.

Material and methods

A preparation process was established using AMIKACIN 5 mg/ml 100 ml, Luer Lock 10 ml sterile polypropylene syringes, 0.22 µm syringe filters and sterile female-to-female Luer Lock connectors.



Physicochemical stability: no organoleptic changes, pH variation < 0.5 units, and osmolarity between 280–310 mOsm/L.

Chemical stability: 90–110% recovery of the initial amikacin concentration by particle-enhanced turbidimetric inhibition immunoassay.

Microbiological stability: sterility testing was performed according to the European Pharmacopoeia.

Results

Physicochemical stability	Organoleptic changes	Solutions remained clear, without precipitation or color changes
	pH	4.37 ± 0.05 (0 h) 4.28 ± 0.06 (2 h) 4.21 ± 0.08 (4 h) 4.27 ± 0.07 (24 h) 4.08 ± 0.11 (48 h)
	Osmolarity	306 ± 16.97 mOsm/L (24 h) 292.5 ± 3.54 mOsm/L (48 h)
Chemical stability	Amikacin recovery percentage	99.78 ± 0.99% (2 h) 100 ± 0.35% (4 h) 95.88 ± 0.28% (24 h) 93.49 ± 0.49% (48 h)
Microbiological stability	Sterility test	negative at all time points

Conclusion and relevance

The 5 mg/ml amikacin formulation in polypropylene syringes met the stability requirements for intrathecal administration. It demonstrated physical, chemical, and microbiological stability for up to 48 hours when stored at 2–8 °C under light protection.