**Storage Stability Assessment of Gentamicin in IV solution**

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**Background and Aims**

Aminoglycosides are bactericidal antibiotics that treat infections by binding to bacterial ribosomes, disrupting protein synthesis and causing cell death1,2. Due to poor oral absorption, they are usually administered intravenously or intramuscularly. This study focuses on the aminoglycoside gentamicin, which is parenterally administered to very sick children. It aims to provide stability data for diluted gentamicin solution at both refrigerated (4°C) and ambient temperatures with and without light exposure. The data is generated to potentially support the preparation of single-use syringes at accredited compounding facilities in order to mitigate risks associated with on-site dilution to obtain weight appropriate paediatric doses.

**Methods**

Gentamicin solution (40 mg/mL) was diluted with saline solution to 10 mg/mL and stored at ambient temperature and refrigerated (4 °C), both protected from light and exposed to artificial light. Samples were monitored over a six-month period for drug content, pH, and turbidity. A novel High-Performance Thin-Layer Chromatography (HPTLC) assay was developed and validated according to ICH Guidelines to measure drug content3,4. pH and turbidity were measured using a calibrated pH meter (Ohaus STARTER 3100) and nephelometer ([NTU 1100](https://www.sigmaaldrich.com/AU/en/product/mm/118324)).

**Results**

The study found that over three months gentamicin content in the saline diluted test solutions remained within the British Pharmacopoeia-accepted range (98.50–99.54%)5 under all investigated storage conditions. pH and turbidity also remained stable over this period, with turbidity values ranging from 0.00 to 0.07 and pH remaining stable.

**Discussion**

Given the stability of the diluted gentamicin solution at all investigated storage conditions, the project’s findings support the preparation of ready-to-use, patient-specific gentamicin syringes that can be compounded to the required strength by accredited compounding facilities. This approach will enhance medication safety and accessibility as it avoids ad hoc on-site preparation and with this potential dosing errors.

**References:**

1. Kotra, L. P., Haddad, J., & Mobashery, S. (2000). Aminoglycosides: perspectives on mechanisms of action and resistance and strategies to counter resistance. Antimicrobial Agents and Chemotherapy, 44(12), 3249–3256.
2. Vakulenko, S. B., & Mobashery, S. (2003). Versatility of aminoglycosides and prospects for their future. Clinical Microbiology Reviews, 16(3), 430–450.
3. C. P. Bhogte, V. B. Patravale and P. V. Devarajan (1997). Fluorodensitometric evaluation of gentamicin from plasma and urine by high-performance thin-layer chromatography. Journal of Chromatography B: Biomedical Sciences and Applications 694(2), 443-447
4. International Conference on Harmonization (2005) Validation of analytical procedures: text and methodology, Q2 (R1). Geneva 1:1–15
5. British Pharmacopoeia Commission. British Pharmacopoeia 2024. London: TSO (The Stationery Office); 2023. Available from: https://www.pharmacopoeia.com