

The stability of a solution of chlorothiazide injection diluted with sterile water and stored in polypropylene syringes under refrigerated conditions was investigated” McCluskey et al (2015).

Reference:

McCluskey, S.V., Gardner, B., Graner, K.K. and Vu, N. (2015) Stability of chlorothiazide sodium in polypropylene syringes. American Journal of Health System Pharmacy. 72(15), p.1292-1297.

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Abstract:

**Purpose:** The stability of a solution of chlorothiazide injection diluted with sterile water and stored in polypropylene syringes under refrigerated conditions was investigated.

**Methods:** Chlorothiazide solutions were compounded by adding 20 mL of sterile water for injection to a 500-mg vial of chlorothiazide sodium for injection. Six batches of chlorothiazide solution (25 mg/mL) were compounded; 0.5-mL portions were transferred to 1-mL polypropylene syringes, which were sealed with a Luer tip cap and stored at refrigeration temperatures (2–8 °C) protected from light. Three batches were potency tested by stability-indicating high-performance liquid chromatography (HPLC) assay using a 0.5-mL sample from each batch at designated time points. Visual and pH testing were performed using the three remaining batches; the contents of two syringes per batch were combined and visually inspected for container integrity and solution color and clarity, with duplicate pH testing performed at each time point.

**Results:** HPLC analyses showed that the remaining percentage of the initial chlorothiazide content declined at an average daily rate of 1.4%, decreasing to 93% by day 6. All samples remained intact, clear, and colorless, with no visible particulate matter or precipitation observed throughout the study period. For all samples of chlorothiazide solution, pH values remained within the range of 9.2–10.0 throughout the 10-day study period.

Conclusion: When packaged in 1-mL polypropylene syringes and stored protected from light at refrigerated conditions, a solution of chlorothiazide sodium injection in water was stable for six days.

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