STABILITY OF 1 MG/ML AND 4 MG/ML HYDROCORTISONE SODIUM SUCCINATE SOLUTIONS IN 0.9% SODIUM CHLORIDE AND 5% GLUCOSE

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OBJECTIVES

The aim of our study was to determine the physical and chemical stability of hydrocortisone sodium succinate in two concentrations (1 mg/ml and 4 mg/ml) at room temperature up to 24 hours after reconstitution and dilution.

METHODS

We used duplicate samples of hydrocortisone sodium succinate diluted in 0.9% sodium chloride and 5% glucose to concentrations 1 mg/ml and 4 mg/ml. Samples were stored at room temperature (25°C) and at elevated temperature (30°C). Another set of reconstituted and diluted solutions stored at room temperature was protected from light. Concentrations were measured by a validated high-performance liquid chromatography (HPLC) method to determine percentage of degradation.

RESULTS

Our study demonstrates that hydrocortisone is equally stable at concentrations 1 mg/ml and 4 mg/ml, in both 0.9% sodium chloride and 5% glucose, regardless protected from light or not. After 24 hours at room temperature, the average decline in concentration is at limit value 5%. Degradation is accelerated at elevated temperature.

CONCLUSION

Hydrocortisone sodium succinate is physically and chemically stable for 12 hours at 25°C.