Development and Validation of Analytical Method for Simultaneous Estimation of Amikacinsulphate and Dexamethasone in Parenterals

Submitted By

Divyesh M Patel

Supervised By

Mrs. Pinkal Patel

M. Pharm.,

AssistantProfessor , Dept. of Pharmaceutical Quality Assurance

Parul Institute of Pharmacy& Research

Limda, Ta. Waghodia, Dist. Vadodara 391760

ABSTRACT

A simple, specific, accurate and precise reverse phase high pressure liquid chromatographic(RP-HPLC) method has been developed for the simultaneous estimation of AmikacinSulphate and Dexamethasone in Parenterals by reverse phase Phenomenexluna BDS C_{18} (250mm X 4.6 mm i.d., 5 µm particle size. The samples were analyzed by using Water : Acetonitrile in the ratio of 90:10 v/v (pH adjusted to 3.0 with 1% v/v Orthophosphoric acid) as a mobile phase at the flow rate of 1ml/min in isocratic mode and detection wavelength 225 nm. Both the drugs were eluted within 10minutes and give sharp peak with high theoretical plate count and low tailing factor. The retentiontime for Amikacinsulphateand Dexamethasonewas found to be 2.25 and 6.16 min respectively.The validation was carried according to ICH guidelines. In linearity curve correlation coefficients for Amikacinsulphate and Dexamethasone were found to be

0.999and 0.998 respectively. The percent recovery was 100.33% for Amikacinsulphate and Dexamethasone 100.52% for indicating accuracy and reliability of method.The limit of detection was 3.80µg/ml and 0.0265µg/ml forAmikacinsulphate and Dexamethasone, respectively and the limit of quantification was 11.40µg/ml and 0.07µg/ml for Amikacinsulphate and Dexamethasone, respectively. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision and robustness for estimation of Amikacinsulphate and Dexamethasone in commercially available parenteral form and results were found to be satisfactory.

So the method can be used for estimation of combination of these drugs in parenteral form.

Key words: Amikacinsulphate, Dexamethasone, Reverse phase high pressure liquid chromatography.