VALIDATION OF ASSAY METHOD OF INDAPAMIDE 1.5MG SUSTAINED RELEASE TABLET BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY METHOD

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ABSTRACT

The aim of this analytical method validation was to validate the assay of Indapamide1.5mg SR tablet with high performance liquid chromatography (HPLC). According to the International Conference on Harmonization (ICH) guidelines, Specificity, Linearity, Range, Accuracy of recovery, System Precision, Method Precision, Robustness were found within the recommended range (Not more than 2.0%). Considering product's inherent nature, many critical parameters specially stability of solution were focused and performed a thorough analysis in ambient system. It was observed that the reference and the testing solution of the product tended to be stable in ambient condition during HPLC analysis of assay. All other parameters were found within the recommended ranges and considering all primary data found from this analytical method validation report was prepared. This validation process was carried out both in ambient and in cool condition. It was noted that, as per method validation, assay of Indapamide is recommended to analyze within 18 hour if the sample temperature is ambient. During routine analysis of Indapamide 1.5 mg SR film-coated tablet, it is also observed that sample tends to show stability up to 24 hours if cooler is used.

KEYWORDS: Assay, HPLC, Indapamide, Method Validation.