DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP HPLC METHOD FOR MYCOPHENOLIC ACID IN TABLE DOSAGE FORM.

S. P Shelke, D. Mundhe ,R.G Diware

Rajarshi Shahu College of Pharmacy Buldana

ABSTRACT:

Simple stability-indicating RP-HPLC method was developed and validated for the determination of Mycophenolic acid and its alkali degradation product. Forced degradation of the drug was carried out under thermolytic, photolytic, acid/base hydrolytic, and oxidative stress conditions.This study was designed to develop and validate a stability indicating simple, sensitive, precise and specific RP-HPLC method for the determination of Mycophenolic Acid in tablet dosage form. The Assay method was carried out by reverse phase chromatography on Agilent HC C 18 250×4.6 mm, 5µ column with a mobile phase composed of 0.1% aqueous solution of Ortho phosphoric acid (88%) and Acetonitrile (50:50) using isocratic mode at a flow rate of 1.5 ml/min. The detection wavelength was 250nm at column temperature 30°C and sample temperature 10°C. The final proposed method is specific. The calibration curve for Mycophenolic Acid was linear from 10µg/mL to 75µg/mL. The method is accurate over the range of 50% to 150%.The inter day and intraday precision was found to be within limits. The proposed method has adequatereproducibility for the determination of its tablet dosage forms. The method is robust. The proposed methods are simple, fast, accurate and precise for the quantification of Mycophenolic Acid from dosage form. The validated method is Specific, Linear, Precise, Accurate, Rugged and Robust for Assay of Mycophenolic acid in Mycophenolic acid DR tablets. Hence this method can be introduced into routine use for the assay of Mycophenolic acid in Mycophenolic acid DR tablets.

KEYWORDS: Mycophenolic acid, Mycophenolate sodium, Reverse phase chromatography,stability , Validation.

Corresponding Author: S. P Shelke

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