



Received on 11 September 2019; received in revised form, 20 April 2019; accepted, 22 August 2020; published 01 September 2020

DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF FLUTICASONE PROPIONATE AND MUPIROICIN IN A COMBINED TOPICAL DOSAGE FORM

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Keywords:

Fluticasone Propionate, Mupirocin,
RP-HPLC, Validation

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ABSTRACT: The objective of the present study was to develop and validate a precise and accurate reversed-phase high-performance liquid chromatography for simultaneous estimation of for Fluticasone Propionate (FUP) and Mupirocin (MUP) in combined topical dosage form as per ICH guidelines. Chromatographic separation was achieved using HPLC Shimadzu, Japan, with column synchronis C₁₈ (250 × 4.6 mm, 5 μm). The mobile phase was comprised of 0.01% OPA: Acetonitrile (30:70v/v) (pH: 5) pumped at a rate of 1.0 mL/min. About 20 μL of sample solutions were injected and monitored at 232 nm. Column temperature and sample compartment were maintained at 25° and 5°, respectively. Repeatability, intra, and inter-day precision results were well within the tolerable limits. The linearity was found for range 2.5μg/mL - 7.5μg/mL and 100μg/mL - 300 μg/mL for FUP and MUP respectively. The correlation coefficient of linearity was found to be 0.998 and 0.994 for FUP and MUP, respectively. The limit of detection was found to be 0.3527, and 0.5077 and limit of quantification was found to be 1.0690 and 1.538 for FUP for MUP, respectively. This method appeared to be rapid, easy, accurate, specific, and robust. Therefore, the method could be applied for regular examination.