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RP-HPLC method development and validation for evaluation of drug residue after cleaning of equipments of ointment formulation

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Manufacturing of Pharmaceutical drug products and drug substances shall demonstrate a control to reproduce consistently the desired quality of product, wherein the control of cross-contamination plays an important role. Residual materials from the previous batch of the same product or from different product may be carried to the next batch of the product, which in-turn may alter the impurity profile of the subjected product. An effective cleaning shall be in place to provide documented evidence that the cleaning methods employed within a facility consistently controls potential carryover of product. for the same purpose after cleaning of manufacturing equipments of ointment formulation swab sampling was done and A novel RP-HPLC method was developed and validated as per ICH guidelines for the quantitative estimation of critical drug Clioquinol found in swab sample of Ointmen formulation. A reverse phase HPLC-method was developed using Spherisorb Phenyl , 250x4.6 mm, 5 µm column and a mobile phase were and acetonitrile:methanol: Water (30:20:50 v/v) with Nickel Chloride(0.024%). The detector set at 273 nm with flow rate of 1 mL.min-1. The method is linear having limit of detection (LOD) is 0.125 µg/mL 0.and limit of quantification (LOQ) is 5 µg/mL. Specificity,Recovery,System Suitability, Precision, Stability Crieterieas were validated as per ICH guidelines.

Biography

Monika S. Sonawane has completed her M.Pharm in 2013 From Savitribai Phule, Pune University and presently working as PhD Scholar in same University.and postdoctoral studies from Stanford University School of Medicine.

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