

A validated HPLC method for determining of inhaler residues on pharmaceutical manufacturing equipment surfaces

M. Esmailpour*, H. Ahmad Panahi

Department of Chemistry, School of Science, Islamic Azad University of Sciences, Center Branch, Tehran, Iran

Background and Aims: A rapid, sensitive and reproducible reversed-phase high-performance liquid chromatographic method was developed for the simultaneous determination of residues of Salbutamol Sulfate, Salmeterol Xinafoate, Fluticasone Propionate, and Beclometasone Dipropionate on swabs collected from pharmaceutical manufacturing equipment surfaces and in aqueous solution collected after rinsing equipment.

Methods: Any residues of the compounds abiding on process equipment after cleaning were sampled by swabbing with wet polypropylene-swabs, that pre moistened with ethanol. Residues were extracted from the swabs and rinse samples and were determined by HPLC.

Results: The isocratic mode of chromatography was performed on a RP-18 column. The mobile phase was consisted of 0.01 M ammonium acetate buffer and acetonitrile with ratio of (25:75, v/v). UV detection was performed in order to improve the method's sensitivity. The method was validated by specificity, linearity, limit of detection, limit of quantification, accuracy, precision of method, precision for the residues of Salbutamol Sulfate, Salmeterol Xinafoate, Fluticasone Propionate, and Beclometasone Dipropionate.

Conclusions: This approved that the desired level of cleanliness was achieved by the current cleaning procedures, which are consequently validated.

Keywords: HPLC; Residues; Inhaler; Cleaning validation