Job title

Cleaning validation of Cyproheptadine Chlorydrade (CPH) on pharmaceutical manufacturing equipment surfaces

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Abstract:

Cleaning validation is a requirement in industries such as pharmaceutical manufacturing which adhere to Good Manufacturing Practice (GMP) and Quality Systems Regulations (QSR), and is specific to the cleaning method and cleaner employed.

Two methods was selected for the cleaning validation ; An HPLC method (USP32 method) with Rp-18 (3.9mm × 15cm) Column, the column using a mixture of methyl sulfonic acid as aqueous phase, methanol, and acetonitrile (0.1,52 ,24 ,24, V/V) as the mobile phase ,a flow rate of 1 ml/min ,UV detector was adjusted at 285 nm .

The second method a spectrophotometric UV-vis 1800 « SHIMADZU » which was the method of routine dosage using by the pharmaceutical manufacturing : an absorbance maxima at 286 nm; a mixture of 20 ml of ethanol 96°, 20ml of water, and 4ml of chlorhydric acid 2,5 N as solvent ; a quartz cells of 10 mm path length.

The methods are applied to the determination of CPH residues on manufacturing equipment surfaces. And the results of analysis are validated statistically as per the guidelines of ICH Q2A and SFSTP.

Key words: USP, HPLC, Cyproheptadine hydrochloride, cleaning validation, spectrophotometric, ICHQ2A, SFSTP.