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Development and validation of a UPLC method for the determination of praziquantel residues on pharmaceutical manufacturing equipment surfaces

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In pharmaceutical industries, it is very important to remove drug residues from the equipment and areas used. The cleaning procedure must be validated, so special attention must be devoted to the methods used for analysis of trace amounts of drugs. A rapid, sensitive and specific reverse phase ultra performance liquid chromatographic (UPLC) method was developed for the quantitative determination of praziquantel in cleaning validation swab samples. The method was validated using an ACQUITY HSS C_{18}, 50x2.1 mm, 1.8 µ column with a isocratic mobile phase containing a mixture of 1.36 g of potassium dihydrogenphosphate in 1000 mL MilliQ water, 2 mL of triethylamine and pH adjusted to 2.3±0.05 with ortho-phosphoric acid, acetonitrile and methanol (50:40:10 v/v). The flow rate of the mobile phase was 0.5 mL min^{-1} with a column temperature of 35°C and detection wavelength at 210 nm using PDA detector. The injection volume was 2 µl. Cotton swabs, moisten with acetonitrile were used to remove any residue of drug from stainless steel, teflon, rubber and silicon plates which mimic the production equipment surface and the mean extraction-recovery was found to be 91.8. The selected chromatographic condition was found to effectively elute praziquantel with retention time of 1.37 min. The proposed method was found to be linear over the range of 0.3 to 150 µg/mL and correlation coefficient obtained is 0.9998. The proposed method was found to be accurate, precise, reproducible and specific and it can also be used for routine quality control analysis of these drugs in biological samples either alone or in combined pharmaceutical dosage forms.

Keywords: Cleaning validation, Praziquantel, Residues, Swab analysis, UPLC.

Biography

R. S. Chandan is perusing his Ph.D. in Dr. M. G. R. University, Maduravoyal, Chennai under the guidance of Dr. M. Vasudevan, Professor, Department of Industrial Biotechnology, Dr. M. G. R. University, Maduravoyal, Chennai. He has published 14 papers in reputed journals.

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