CHARACTERIZATION OF INCONSISTENT UNSPECIFIED IMPURITY ASSOCIATED WITH SPECIFIED IMPURITY AND ADJACENT TO OTHER DETECTABLE IMPURITIES WHICH HAVE NOT BEEN LISTED IN PHARMACOPOEIAS ACROSS CIPROFLOXACIN HYDROCHLORIDE

Rahul Hajare

Indian Council of Medical Research, India

Although pharmaceutical impurity has not yet been accepted as monograph facility in pharmaceutical products, it has shown extraordinary diversity. The US FDA has raised concerns on the quality, purity and efficacy of medicines being sold in India, throwing the issue back into spotlight. Over the last few years, many domestic majors, including multinational and listed pharmaceuticals in stock exchange have faced regulatory issues over quality and purity of medicines exported from India and sold in US and other overseas markets. We report here, the non listed impurity profile study of Ciprofloxacin Hydrochloride from API industry. Of these, pharma impurity (A1) and API impurity (B) are most prevalent in India, while raw material impurity (C) and cleaning impurity (D) have occasionally been reported. Apart from these A1/C (1, 2) and B/C (3) intersubtype recombination impurity have also occasionally been reported. The presence of these have listed, so specified impurity and other detectable impurity in ciprofloxacin hydrochloride, these substances present at a sufficient level, be detected by one or other of the test in the monograph European pharmacopeia. They are limited by the general acceptance criteria for other/ unspecified impurities and/or by the general monograph substance for pharmaceutical use. In this study, we characterize inconsistent unspecified impurity that has been associated with specified impurity and adjacent to other detected impurity in pharmaceutical ciprofloxacin hydrochloride. Here, we report for the first time in India, a unique impurity recombination between subtype C (raw material acrylic acid) and environmental impurity (C1) and novel recombination between subtype A1 and C1. Unique recombination formation impurity between crude and pure products have been reported many a times from pharmaceutical industries (Database form patent literature and market analytical survey).The ciprofloxacin hydrochloride was amplified using Aarti Drugs Limited, Mumbai store database and stored co-cultured 84 hrs and drug ciprofloxacin hydrochloride by UPLC describe (Applied waters system accuity UPLC column).

Biography

Rahul Hajare has completed his PhD from Vinayaka Missions University. He was a Post-Doctoral Fellow ((2013)) at the Indian Council of Medical Research New Delhi under the guidance and supervision of Dr. Ramesh Paranjape, Retd Director and Scientist 'G', National AIDS Research Institute, India.

rahulhajare@rediffmail.com