Chemical Sciences Journal

Rahul, Chem Sci J 2017, 8:3
DOI: 10.4172/2150-3494.1000168

Short Communication Open Access

Characterization of Inconsistent Unspecified Impurity Associated with Specified Impurity and Adjacent to Other Detectable Impurities Who Have Not Listed in Pharmacopoeias in Ciprofloxacin Hydrochloride

Rahul H[1,2,3,4*]

[1]*Former Post-Doctoral Fellow 2013 (7 th Batch), Indian Council of Medical Research, New Delhi, India*

[2]*Former Trainee VLife Technologies (A division of Nova Lead Pharma Pvt. Ltd.), Pune, Maharashtra, India*

[3]*Former R & D Dept. Officer, Aarti Drugs Ltd., Tarapur, Mumbai, Maharashtra, India*

[4]*Department of QAT, Rajgad Dnyanpeeth's College of Pharmacy, Bhor, Pune, Maharashtra, India*

[*]**Corresponding author:** Rahul H, Department of QAT, Rajgad Dnyanpeeth's College of Pharmacy, Bhor, Pune, Maharashtra, India,. Tel: 91-9765704048; E-mail: rahulhajare@rediffmail.com

Received date: 27 Jul 2017; **Accepted date:** 01 Aug 2017; **Published date: 08** Aug 2016

Introduction

Pharmaceutical impurity has not accepted as monograph facility in pharmaceutical product and has shown extraordinary diversity, Drug regulator, USFDA 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 pharmaceutical and listed pharmaceutical in stock exchange have faced regulatory ire over quality and purity of medicines exported from India and sold in US and other overseas markets. We report here not listed impurity profile study of Ciprofloxacin Hydrochloride from API industry. Of these, Pharma impurity (A1), API impurity (B) is 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] inter-subtype recombination impurity has 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 of inconsistent unspecified impurity who have associated with specified impurity and adjacent to other detected impurity in pharmaceutical Ciprofloxacin Hydrochloride [4,5]. 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 product have been reported from many Pharmaceutical industry (Database form patent literature and market analytical survey).The Ciprofloxacin Hydrochloride was amplified using Aarti Drugs Limited, Mumbai store database and stored cocultured 84 hrs and drug Ciprofloxacin Hydrochloride by UPLC describe (Applied waters system acquit UPLC column). The recombination Ciprofloxacin Hydrochloride was amplified previously and sequenced directly from the structure of the incorporated species environmental impurity selenium (dust forms) is investigated using Se K-edge EXAFS (isotropic and polarization dependent) and results are compared to density functional theory (DFT) calculations. These investigations confirm structural incorporation of environmental impurity into Ciprofloxacin Hydrochloride by the substitution of carbonate for selenite (check the structure of carbonate selenite), leading to the formation of a $Ca(SeO3)_X(CO3)_{(1-X)}$. Cocultured product analyzed by the DMA 80 mercury analyzer [6]. The near-full-length Retention Time was initially analyzed for recombination using environmental impurity and raw material impurity for recombination breakpoints using ciprofloxacin Hydrochloride product Aarti Drug Limited. HPLC water Aarti Drug Limited showed an insertion of environmental impurity _selenium at six sites, RT 5.7 to 5.9 , 6.0 to 8.3 , and 8.8 to 8.9 into the backbone of raw material impurity C (standard acrylic acid examination) , whereas at positions 8.3 to 8.9 standard showed uncertainty between subtype C and B. A boot scan analysis in private R & D laboratory accredited by NABL showed similar breakpoints to those of impurity, with four more small insertions of selenite at positions 2.8 to 3.0 and 4.8 to 5.0. Combining the results obtained with identification of retention time in test sample versus standard sample Alon with cocultured sample impurity qualitative analysis has been identified and put on hold for next 48 hours to check any insertion of new impurity findings, so slightly increased in retention time with dope area of area under curve. Aarti Drug Limited sample ciprofloxacin Hydrochloride and Selenium sample showed recombination of subtype C1 into the backbone of subtype C. Both of UPLC and HPLC showed an insertion of subtype C1 into the backbone of subtype C. Of the insertion time of selenium generated for Ciprofloxacin Hydrochloride, six day mixture showed two small impurity insertions of subtype A1 into the backbone of subtype C and another same concentration mixture showed slightly different retention breakpoints (positions 4.8 to 5.2 and 5.4 to 5.5), and showed an insertion of subtype A1 at positions 4.8,6.2, 8.4 to 8.6 and uncertainty between subtype A1 and C, at positions 5.4,6.3 to 8.3, 12.2. Analysis of inconsistent unspecified impurity associated with specified impurity and adjacent to other detectable impurities using UPLC HPLC of sample from central stored, cleaning area, cupboard, working platform have investigated. The pharmacopeial literature suggests that the uncertainty re-impurity may be a result of the significant violations of current good manufacturing practice (CGMP) and has been forcefully implemented after the introduction into the subject and environment impurity listed even sectorial scenarios for the fifth carbon budget technical report November 2015. These violations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP. Analysis also showed breakpoints in concordance with impurity [7-9] for both products. All the breakpoints

used in the study were relative to the crude Ciprofloxacin Hydrochloride to pure to pharmaceutical to formulation. A comparison of the ciprofloxacin Hydrochloride characterized in this study with the earlier reported selenium carbonate and associated, adjacent impurity recombination forms suggest that all three characterized selenium impurity are novel recombination. The detection of a selenium recombination also points to the fact that impurity belonging to multiple subtypes are circulating and giving rise to new impurity then there is other a danger. This clearly indicates that the impurity epidemic in pharmaceuticals is still evolving it has and needs close monitoring through pharmaceutical national regulatory *authority* (PNRA) of *India*. Also advancement initiate in new norms and limitations bring out by the investigation is that the diagnosis of environmental impurity. Also participation of Indian Pharmaceutical industry encourages to their co-concern to attend the technical guidance. The environmental samples are arranged from environmental laboratory Boisar. We investigate the interactions occur between adsorb impurity from environment at the surface of compound and merged into associated impurity by a series of experimental methods with the aim to qualify environmental impurity in pharmaceutical product through adopting GLP practices. Environmental forces can produce impurity and make clone the impurity environmental and entrapment that has reduced appearance and texture of product will affect stability and strength newly synthesize product.

Conclusion

A source of environmental impurity is air and has many toxic impacts upon human product. The atmosphere plays an important role in the biogeochemical cycling of selenium.

Acknowledgments

I Thank my fellow lab mates of Aarti Drugs Limited for arrangement of sample and Q Acid a key solid raw material KSRM for Ciprofloxacin Hydrochloride.

References

1. Rahul H, Smita K, Madhuri T, Ramesh P (2016) Technology development and design of novel 1, 3, 5 tri substituted-1H-indole-2, 3-dione HIV-1 inhibitors with displays strategic nanomolar cytotoxicity. World J Pharm Pharm Sci 5: 391-397.
2. Rahul H (2016) pre-DR Technology. KJACT-100106 2: 1-3.
3. Rahul H (2017) E-IPA-Encyclopedia of Impurity Profile (IP) for API. The Pharma Innovation Journal 6: 05-06.
4. Rahul H (2017) Matrix Impurity, Disregards Impurity, Specified Impurity Associated Undetectable Impurity: Monograph. World J Pharm Pharm Sci 6: 242-246.
5. Rahul H (2017) Classical Technology Can Run Away Impurity in Pharmaceuticals Frugal Innovation Lesson from Classic Innovation System. Opinion article. Organic & Medicinal Chem IJ 2: 4.
6. Rahul H (2017) Tertiary Care in Impurity Trends New Pattern Discovery: Letter to Editor. Organic & Medicinal Chem IJ 2: 4.
7. Rahul H (2017) UPLC technology re-discover the techniques for characterization of impurities and impurities emission. 9th Annual Congress on Drug Design & Drug Formulation 2017. Seoul, South Korea.
8. Rahul H, Gaurkhede RM, Chinchole PP, Deshmane SV, Chandewar AV, et al. (2009) Development and validation of Gas Chromatographic Method for Estimation of Organic Volatile Impurities in Some Ayurvedic Preparation. Asian Journal of Chemistry 21: 6993-6998.
9. Rahul H, Gaurkhede RM, Chinchole PP, Deshmane SV, Chandewar AV, et al. (2009) Validation of gas chromatographic system for estimation of organic volatile impurities in hydro-alcoholic formulation. Int J Chem Sci 7: 689-708.