



Development and Validation of RP-HPLC Method for the Quantification of Potential Genotoxic Impurities in Anti-psychotic drug Aripiprazole

Vijaya Gouri Korlakunta^{1,2*}, N. Sreenivas¹, Hemant Kumar Sharma¹, Annapurna Nowduri², Kishore Babu Bonige² and Ramadas Chavakula¹

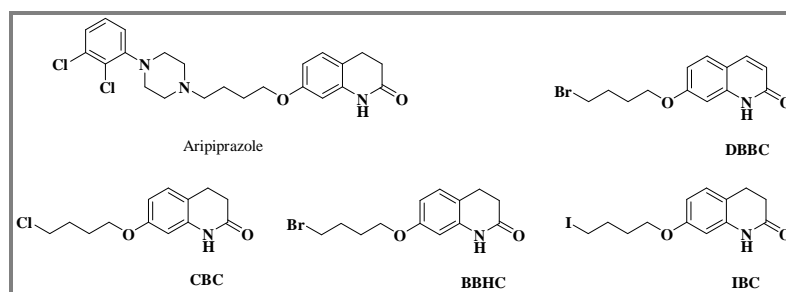
1. APL Research Centre-II, Aurobindo Pharma Ltd, Survey No. 71 and 72, Indrakaran Village, Kandi Mandal, Sangareddy District, Telangana State, -502329, **INDIA**
2. Department of Engineering Chemistry, A. U. College of Engineering (A), Andhra University, Visakhapatnam, Andhra Pradesh-530003, **INDIA**
Email: vijayagourikorlakunta@gmail.com

Accepted on 2nd August, 2019

ABSTRACT

A simple, sensitive and validated RP-HPLC method is developed for the quantification of potential genotoxic impurities of Aripiprazole (APZ) drug substance, namely 7-(4-bromobutoxy)quinolin-2-(1H)-one (dehydrobromobutoxycarbostyryl) (DBBC), 7-(4-chlorobutoxy)quinolin-2-(1H)-one (chlorobutoxycarbostyryl) (CBC), 7-(4-bromobutoxy)-3,4-dihydro-2(1H)-quinolinone [7-(4-bromo butoxy)-3,4-dihydrocarbostyryl] (BBHC) and 7-(4-iodobutoxy)-3,4-Dihydro-2(1H)-quinolin-2-one (iodobutoxy carbostyryl) (IBC). The analysis is performed on Alliance-Waters 2695 Separations Moldule® on C18, (150mm x 4.6mm, 5µm) (Make: Sunfire), maintained at temperature 45°C and UV detection at 215nm. The separation is accomplished using mobile phase, prepared by mixing a buffer (diluted 3 mL of orthophosphoric acid in 1000 mL of water) and acetonitrile in the ratio of 60:40%v/v. Flow rate is kept as 1.0 mLmin⁻¹ and injection volume is 20µL. The proposed method is validated as per ICH guidelines in terms of limit of detection (LOD), limit of quantification (LOQ), linearity, precision, accuracy and specificity. The achieved limit of detection (LOD) values are 1.06, 1.22, 1.35 and 2.00; limit of quantification (LOQ) values are 3.20, 3.69, 4.08 and 6.07 µg g⁻¹ and the average of accuracy values are 96.6, 93.5, 96.1 and 94.9 % for DBBC, CBC, BBHC and IBC respectively.

Graphical Abstract



Keywords: Aripiprazole, Anti-psychotic drug, Genotoxic impurities, Quantification, RP-HPLC method.