OMICS Group Conferences
Accelerating Scientific Discovery

4th World Congress on
Bioavailability and Bioequivalence:
Pharmaceutical R&D Summit
May 20-22, 2013 DoubleTree by Hilton, Beijing, China

Quantification of genotoxic impurity 4-Chloro-1-Hydroxy butane sulfonic acid sodium salt by LCMS/MS in sumatriptan succinate

Narayana MBV
Johnson and Johnson Ltd., India

The objective of present research work is to develop a suitable LCMS/MS method for the quantitative determination of genotoxic impurity 4-Chloro-1-Hydroxy Butane Sulfonic Acid Sodium Salt at ppm level present in Sumariptan dug substance. The LCMS/MS method was developed on Zorbax SB-C8 column using the mobile phase consists a mixture of 0.05% (v/v) Formic acid in water and Acetonirile using a isocratic composition of 90:10 (v/v) at a flow rate of 0.8 mL/min. Ion source is electospray ionization (ESI), source temperature is 325°C, gas flow is 8 L/min, Nebuliser pressure is 40 psi, capillary voltage is 4000 V. Under these conditions impurity was quantified by selecting most stable MRM pair (187/81). The limit of detection and the limit of quantitation for the impurity were established. Validation of the developed LCMS/MS method was carried out as per ICH requirements and the data shows that the proposed method is specific, linear, accurate, precise and robust. This method has been tested in a number of Sumatriptan samples and used successfully for quantification of the impurity at ppm level. The developed LCMS/MS method was found to be suitable to quantify the genotoxic impurity 4-Chloro-1-Hydroxy Butane Sulfonic Acid Sodium Salt at ppm level present in Sumatriptan Succinate.

balajimachireddy@gmail.com