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Trace Level Determination of Potential Genotoxic Impurity (2, 4-Dichloro-5-Methoxyaniline) In Drug Substance

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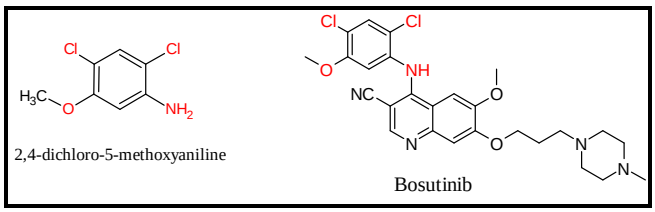
ABSTRACT

An analytical method has been developed for trace level determination of 2,4-dichloro-5-methoxyaniline (potential genotoxic impurity) in drug substances at pharmaceutical industry. The accurate quantitation of 2,4-dichloro-5-methoxyaniline was achieved on Hypersil BDS C18 column (150mm x 4.6mm, 3.0µm) with gradient elution at a flow rate of 1.0mL min^{-1}. Gradient elution containing mobile phase-A and mobile phase-B, 0.05% of Trifluoroacetic acid in water used as mobile phase-A and Acetonitrile used as mobile phase-B. The elution of 2,4-dichloro-5-methoxyaniline is monitored at 210nm, by using Ultra Visible / PDA detector at the level of 2.5 mg L^{-1}. The high correlation coefficient (R2>0.999) values indicated clear correlations between the investigated compound concentrations and their peak areas within the LOQ (limit of Quantitation) to 150% level. 2,4-dichloro-5-methoxyaniline is uses in manufacturing process of Bosutinib. Hence, 2,4-dichloro-5-methoxyaniline was major possible and potential genotoxic impurities of Bosutinib.

Graphical Abstract



Structure of 2,4-dichloro-5-methoxyaniline and Bosutinib.

Keywords: 2,4-dichloro-5-methoxyaniline, 5-Amino-2,4-dichloroanisole, Genotoxic impurity, HPLC, Bosutinib.