



## Trace Level Determination of Potential Genotoxic Impurity O-Toluidine (2-Methyl Aniline) in Drug Substance

Narasimha Rao Avupati<sup>1,2\*</sup>, Nageswara Rao Gollapalli<sup>1</sup>  
and Moses Babu<sup>2</sup>

1. Department of Chemistry, Andhra University, Visakhapatnam 530003, Andhra Pradesh, **INDIA**

2. Dr. Reddy's Laboratories Ltd. Active Pharmaceutical Ingredients, IPDO, Bachupally,  
Hyderabad-500090, Telangana, **INDIA**

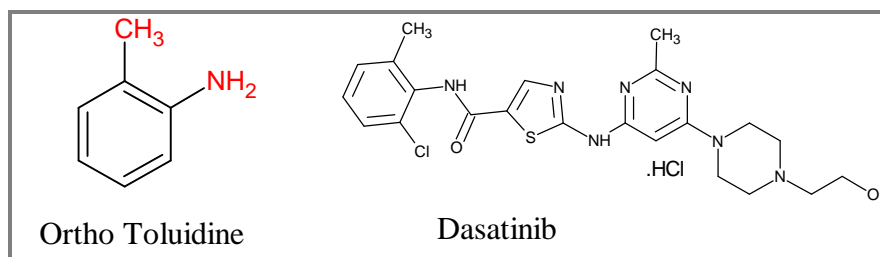
Email: [narasimharaoavupati@gmail.com](mailto:narasimharaoavupati@gmail.com), [rao\\_ans@yahoo.co.in](mailto:rao_ans@yahoo.co.in)

Accepted on 30<sup>th</sup> March, 2019

### ABSTRACT

An analytical method has been developed for trace level determination of O-Toluidine (potential genotoxic impurity) in drug substances at pharmaceutical industry. The accurate Quantitation of O-Toluidine was achieved on Inertsil ODS-3V column (250 mm x 4.6 mm, 5.0  $\mu\text{m}$ ) with gradient elution at a flow rate of 1.0 mL min<sup>-1</sup>. Gradient elution containing mobile phase-A and mobile phase-B, 0.015mM potassium dihydrogen phosphate in water used as mobile phase-A and Acetonitrile and water mixture was used as mobile phase-B. The elution of O-Toluidine is monitored at 210 nm, by using Ultra Visible / PDA detector at the level of 3 mg L<sup>-1</sup>. The high correlation coefficient ( $R^2 > 0.999$ ) values indicated clear correlations between the investigated compound concentrations and their peak areas within the LOQ (limit of Quantitation) to 150% level. O-Toluidine was uses in manufacturing process of dasatinib. Hence O-Toluidine was major possible and potential genotoxic impurities of dasatinib.

### Graphical Abstract



Structure of O-Toluidine and Dasatinib

**Keywords:** O-Toluidine, 2-methyl aniline, Genotoxic impurity, HPLC, Dasatinib.