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Original Article

DEVELOPMENT AND VALIDATION OF STABILITY INDICATINGMETHODSFOR THE ESTIMATION OFDASATINIB BY UVSPECTROSCOPY AND RP-HPLC METHOD BY QbD APPROACHES

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ABSTRACT

The objective of this work was to create a simple, rapid, and sensitive spectrophotometric and RP-HPLC method for estimating Dasatinib. Using methanol as a solvent, the absorbance peaks of Dasatinib were determined to be 323nm, this approach follows Beers law in the concentration ranges0.1-0.6µg/ml with correlation coefficient (r^2=0.999) respectively. ICH recommendations were adopted to evaluate analytical parameters such as linearity, accuracy, precision, limit of detection and limit of quantification. The % recovery was 99.66%-100%. %RSD was 0.811761 and 0.90261. LOD and LOQ were reported to be 0.028µg/ml and 0.086µg/ml. Targestil C18 (4.6mmx150mm, 2.5µm) was used to run the chromatogram. The solvent methanol: acetonitrile (60:40) was fed via column at a rate of 1ml/min. The optimal wavelength chosen was 310nm.The retention time were determined to be 1.830 min. %RSD was found to be 0.015796 and 0.024601. Dasatinib recovered at rates of 99.4% to 100.2%. The LOD and LOQ values obtained using regression equations were 0.36 µg/ml and 1.11 µg/ml. Dasatinib was subjected to alkali, acidic, oxidation, thermal, UV and fluorescent light and was validated as per ICHQ2 (R1). QBD studies are also performed for the method development of HPLC.

Keywords: Dasatinib, method development, UV spectroscopy, RP-HPLC and stability indicating studies.

INTRODUCTION

The chemical name of dasatinib N-(2-chloro-6-methylphenyl)-2-{{6-{4-(2-hydroxyethyl) piperaz-in-1 –yl]-2-methylpyrimidin-4-yl]amino]-1,3-thiazole-5-carboxamide. Fig 1.

Dasatinib is a member of the class of kinase inhibitors. It works by blocking the action of an abnormal protein that proliferation of cancer cells. In several nations, Dasatinib has been approved by medical use. The world health organization lists are one of the fundamental medicines. It can be taken orally. Dasatinib in the biological fluids and pharmaceutical dosage forms includes LC-MS/MS, LC-MS, and HPTLC-LC, HPTLC, UPLC-MS, HPLC-MS, RP-HPLC and UV-Visible Spectrophotometric method.

This work describes the validation parameters stated by the International Conference on Harmonization [ICH] guidelines Q2 (R1), The chemical structure of dasatinib is shown in Fig.1.

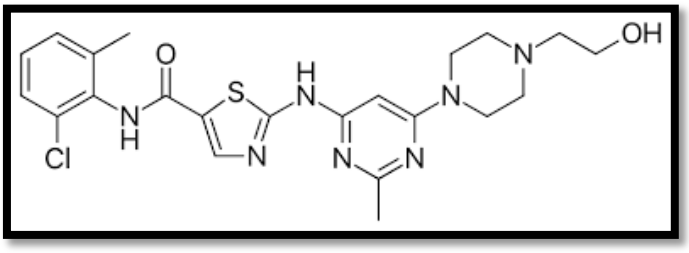

Fig.1 Chemical structure of Dasatinib

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