PATENT NO. 354372

VALIDATED HPTLC AND STABILITY INDICATING HPLC METHOD FOR PRASUGREL HYDROCHLORIDE

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APPLICANT
Panjab University, Chandigarh, Punjab

ABSTRACT
The present invention relates to stability indicating assay method of active pharmaceutical ingredient (API) Prasugrel hydrochloride and related substances, more particularly, the present invention relates to a method of detennining the shelf-life of prasugrel hydrochloride as well as dosage form and also relates to method of estimation of prasugrel hydrochloride and its degradation products.

INVENTOR
Sinha, Vivek Ranjan
Kaur, Ramandeep
University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, Punjab

CLAIM 1

A stability indicating assay method for an active pharmaceutical ingredient (API) wherein the method is High Performance Thin Liquid Chromatography (HPTLC) the said method comprising the steps of (a) dissolving the drug solution in a solvent and mobile phase (b) applying the various concentration of the drug solution of step (a) to plates (c) preparing the application in the form of bands of 4 mm width and allowing to dry for 15 min., (d) saturating a twin-trough chamber with the mobile phase of step (a), (e) developing the plates in step (b) in linear ascending manner by running the plates up to a distance of 80 mm, (f) air-drying and (g) analysing the contents after step (f) wherein, the solvent in step (a) were selected from a group compnsmg of methanol, chloroform, toluene, dichloromethane, ethyl acetate, ethanol, butanol, cyclohexane and acetone and the mobile phase of cyclohexane acetone in the ratio of 82.