

SUMMARY OF UGC MINOR RESEARCH PROJECT FOR WEBSITE

Grant Details

File No. 47-867/13(WRO) dated 12 Feb 2015

Title: Establishment of Inherent Stability Indicating RP-HPLC Method for Bulk Drug and its Pharmaceutical Dosage Form.

Principal Investigator: Ms. Minal T. Harde

Duration: 2015-2017 (Two Years)

College: P E Society's Modern College of Pharmacy, Nigdi, Pune 411044.

Effective date of starting the period: 11th Feb 2015

SUMMARY OF THE RESEARCH PROJECT:

The present study was aimed to develop novel, rapid, accurate, linear, and sensitive stability indicating RP-HPLC method for estimation of Paliperidone in the bulk and pharmaceutical dosage form. The developed method was validated using parameters such as accuracy, precision, LOD, LOQ, Robustness and specificity as per ICH guidelines. Further degradation study was carried out on bulk drug, placebo and for marketed formulation using acid, alkaline, neutral hydrolysis, photo degradation, oxidative degradation and thermal degradation

A rapid, accurate, linear, and sensitive RP-HPLC method has been developed and validated for estimation of Paliperidone in the bulk and Pharmaceutical Dosage Form. The chromatographic separation was performed on C18 Column (250 mm ×

4.6 mm, 5 μm particle size) using a mobile phase Methanol: Phosphate buffer : Water (40: 35 : 25, v/v/v, pH 3.5) at flow rate of 1.0 ml/min and 25°C column temperature with the detection wavelength at 227 nm. The linearity study was performed in the concentration range of 5 to 25 $\mu\text{g/ml}$ for Paliperidone and correlation coefficient was found to be 0.999. The percentage purity of Paliperidone was found in the range of 98-101%. The limit of detection was 0.34 $\mu\text{g/ml}$ and limit of quantification was 1.01 $\mu\text{g/ml}$. The Proposed method was validated as per ICH guidelines. The obtained results using RP-HPLC-DAD indicates the develop method is specific. Forced degradation conditions like hydrolysis (neutral, acidic and alkaline), oxidation, photolysis and thermal stress was successfully studied.