Summary of UGC minor Research project for website

Grand Details

F.No. 47-863/13 (WRO) dated 17th October 2014

Title: An improve development and Validation of Stability Indicating HPLC Method of Antiviral drug in pure form and in Pharmaceutical Sample

Principal Investigator: **Dr. Pallavi M Patil**

Duration: 2014-2016 (Years)

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

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Total Grant approved: Rs. 215000 /-

Summary of the Research Project

In the present work **S**tability of Acyclovir (ACY) and (RITO) were investigated using a stability indicating HPLC method. Quality by Design (QbD) approach was used to facilitate method development. (ACY) and (RITO) were exposed to different stress conditions, including hydrolytic (acid, base, neutral), oxidative, thermal and photolytic. Relevant degradation was found to take place in all the conditions. The degradation of ACY) and (RITO) were followed (pseudo) first-order kinetics under experimental conditions. The kinetic parameters (rate constant, t1/2, and t90) of the degradation of ACY) and (RITO) were calculated.

Both the HPLC methods were validated in accordance with ICH guidelines. The methods were found to be sensitive, accurate, precise, selective and reproducible. The stability indicating property of the methods was evaluated by forced degradation study. The proposed HPLC methods were able to selectively quantitate drugs in presence of degradation products and hence can be considered as stability indication one. Hence, the proposed HPLC methods can be used for routine quality control of pharmaceutical formulation containing (ACY) and (RITO)

The stability indicating property of the methods was evaluated by performing forced degradation studies. The methods were able to selectively quantitate drugs in presence of their degradation products.

The kinetic parameters (rate constant, t1/2, and t90) of the degradation of ACY and RITO were calculated. This method was based on developed to separate the drug from the degradation products; (HPLC) assay method was developed and validated for quantitative determination of ACY and RITO in bulk drugs. These methods are based on developed. An isocratic reversed-

phase HPLC method with UV detector was developed for the assay and purity evaluation of ACY and RITO.

CCD were employed effectively for evaluation of robustness and statistical analysis showed that the model represents the phenomenon quite well and the variations in response were correctly co-related to the variations of the factors. From results of ANOVA and analysis of response surfaces plots; it can be concluded that response are robust.