International Journal of PharmTech Research
CODEN (USA): IJPRIF, ISSN: 0974-4304, ISSN(Online): 2455-9563
Vol.9, No.7, pp 399-406, 2016

Analytical Quality by Design Approach for Development of UV-Spectrophotometric Method in the Estimation Of Lamivudine from Tablet Dosage Form

Sk. Mastanamma*, P. Saidulu, L. Prathibha

Department of Pharmaceutical Analysis, University College of Pharmaceutical Sciences, Acharya Nagarjuna University, Nagarjunanagar, Guntur–522510.Andhra Pradesh (India)

Abstract : Objective: The aim of present work is to develop and validate spectrophotometric method for lamivudine estimation in tablet dosage form using Analytical Quality by Design (QbD) approach as per ICH Q8 (R2) guidelines.
Methods: Variable parameters like type of sample preparation, solvent, wavelength, instrumental parameters such as slit width, scan speed and sampling interval etc. were designed into Ishikawa diagram and critical parameters were determined by observation as well as by using principal component analysis.
Results: In simple spectrophotometric method lamivudine was estimated at 270 nm using 0.01N NaOH and distilled water at 280nm using 0.01N HCl. Beer's law was obeyed in the concentration range 2-10 µg/ml (r^2=0.998) using 0.01N NaoH 2.5-17.5µg/ml (r^2=0.996) Using distilled water and 2-12 µg/ml (r^2=0.998) using 0.01N HCl.
Conclusion: The proposed method was found to be accurate, precise and economical and can be applicable for routine quality control analysis lamivudine on pharmaceutical dosage form. Implementation of QbD approach resulted in more robust methods which can produce consistent, reliable, and quality data throughout the process and also save time and money.
Keywords: Quality by Design (QbD), lamivudine, ICH Q8 (R2), Principal component analysis.

Sk. Mastanamma *et al* /International Journal of PharmTech Research**,** 2016,9(7),pp 399-406.

*****