

Development of a new spectrophotometric method for the analysis of metformin hydrochloride in drugs administered to patients with type II diabetes

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Determination of drug concentration is important, as a specific dose is needed to be administered to each patient. This dose is different from one person to another person since the effective dose (ED_{50}) for one person could be deadly for another person. Therefore, it is very important to ensure that the drug has the correct amount of active ingredients present in any drug component administered to a patient as overdosing or underdosing may create critical consequences to the patient.

In a Sri Lankan context, most of the drugs are imported from different countries. Therefore, the quality of the drug as well as the active ingredient concentration might be different from the labeled value. Here we are presenting a simple and fast method to determine the active ingredient concentrations of metformin hydrochloride, a drug administered to patients with type II diabetes, using UV-Visible spectroscopy. The method has been developed and validated according to the International Conference on Harmonization (ICH) guidelines and standard acceptance criteria for parameters such as linearity, range, accuracy and precision, limit of detection (LOD), and limit of quantitation (LOQ), and stability.

The scan of prepared standard stock solution of 100 ppm, showed that the λ_{max} value occurs at 233 nm with de-ionized water as the blank. A five point calibration curve was obtained within a concentration range of 2 ppm to 10 ppm with a regression equation $y = 0.0751x + 0.0075$ and a correlation coefficient (R^2) 0.9995. The accuracy analysis by spike recovery method at three levels (50%, 100%, and 150%) showed that the best mean recoveries occur from 92.14 % to 95.04% of the spiked drug. Furthermore, the developed method yielded the % Relative Standard Deviation (RSD) values for repeatability (1.98%) and intermediate precision (1.37%) which are accepted under 2% acceptance criteria of ICH. In addition, limit of detection (LOD) and limit of quantitation (LOQ) values for this study were 0.609 ppm and 1.845 ppm, respectively. Also, the developed analytical method can be used to determine the concentration of metformin hydrochloride in tablet formulations stored for 7 days under refrigerator conditions.

Test samples (8 brands) were purchased from local pharmacies located in the Colombo District and their labeled values of active ingredient was 500 mg. The developed method resulted that the actual concentration of the active ingredients ranged from 282.70 ± 2.76 to 454.19 ± 0.95 mg. The method demonstrated that test samples from Sri Lanka and Indonesia had significantly small amount of active ingredients per 500 mg tablet which causes underdosing. The test sample manufactured in Bangladesh had the highest amount of active ingredient component (454.19 mg) while the Indian brands had active ingredient ranged from 340.63 mg to 441.46 mg. The test sample from Pakistan had 419.28 mg of active ingredient per 500 mg tablet.

Keywords

Method validation, ICH guidelines, Metformin hydrochloride, UV-vis Spectrophotometry, Sample analysis