

Method development and validation of lipid lowering drug Atorvastatin using UV-Visible spectroscopy

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With the high risk for cardiovascular diseases, statin drugs have become the life saver for millions of people around the world. Atorvastatin Calcium is one of the most commonly used lipid lowering drugs. Since this drug has been extensively used, it is essential to know the exact active ingredient concentration as the dose itself might cause negative impact on the patients. Present study describes the development and validation of a simple, sensitive, specific and an economically viable UV-Visible spectroscopic method to evaluate the drug Atorvastatin Calcium in the tablet dosage form. In the current study, validation was performed according to Good Laboratory Practices (GLP) in accordance with the guidelines of the International Conference of Harmonization (ICH) using a secondary standard.

To develop an acceptable analytical method, it was required to prepare a soluble form of the drug component. Initially water was used as the vehicle but it turned out that methanol:water (50:50) solvent system functions better due to high solubility and the stability. Using UV Visible spectrum it was found that the maximum absorbance of the drug was at 245 nm and calibration curves were prepared measuring absorption values at 245 nm for the standard samples. For the calibration curve a range of concentrations starting from 5 ppm to 15 ppm was prepared using a 100 ppm stock solution. The developed method obeyed the Beer's law and the linear regression coefficient of the calibration plot was 0.998. The method was validated in terms of linearity, accuracy, range, precision, robustness, limit of detection (LOD), limit of quantification (LOQ) and stability. Precision studies were done under two main levels as repeatability and intermediate precision.

For all the standard samples, it was discovered that the percentage relative standard deviation (%RSD) was less than 2% which was within the acceptance criteria. Recovery studies for the analysis revealed that the concentration range is 90-110% for all the prepared samples. The limit of detection of the drug Atorvastatin Calcium was found to be 0.909 ppm and limit of quantification was found to be 2.754 ppm. Stability studies carried out under two conditions, refrigerator

and room temperature for 14 days, showed that the drug component was stable for 14 days under room temperature without refrigerator conditions. Several market samples collected from suburbs of Colombo were also analyzed using the validated method and the concentrations of them were determined. The percentage label claim for the brands varied from 90.0 to 98.8. This shows that the method developed can be adapted to the routine method of estimating Atorvastatin Calcium in tablet dosage form.

Keywords

Atorvastatin Calcium, UV-Visible spectroscopic, GLP, ICH guidelines, validated, method developed