Abstract

The purpose of this study was to develop a new high performance liquid chromatographic for determination of febuxostat in tablet dosage form. In the present study a rapid, simple, economical HPLC-PDA procedure has been developed and validated.

The HPLC method was developed and optimised using Box-Behnken-design (BBD), after studying the physicochemical properties of febuxostat (solubility, melting point, IR, UV). The Optimized mobile phase was [34% buffer (250μl TEA/L), 33% acetonitrile and 33% methanol , the pH value was adjusted to 3.0 ±0.10] using orthophosphoric acid. The flow rate was 1.0 ml/min, the signals were monitored using PDA detector ( set between λ 200-400 nm)using windows based LC solution software quantitation was carried out at wave length of 315 nm.

The linearity range of the method was from 5 to 50 μg/ml for febuxostat. LOD was 0.3201 μg/ml for febuxostat, whereas LOQ was 0.9702μg/ml. The precision of the method was less than 2% which indicates highly precise result during the study. The accuracy of the method were ranged from 99.39%-100.97%.

There were two minor degradation products of febuxostat after exposure to hydrogen peroxide (35%) with retention time 2.34 and 2.66 while exposure to alkaline stress resulted 5 different minor degraded products. No degradation products of febuxostat were observed after exposure to UV light.

In conclusion the method presented here is sensitive, rapid, accurate, precise, economic, robust, rugged and selective for the routine analysis of the drug in formulation (tablet) and raw material.

Development, optimization and validation of HPLC method for determination of Febuxostat using Design of Experiments (DoE)

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