Abstract

Stability Indicating High Performance Liquid Chromatographic Of DAPOXETINE In Bulk Drug And Formulation

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The purpose of this study was to develop a new high performance liquid chromatographic for determination of dapoxetine 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 optimized using Central Composite Design (CCD) after studying the physicochemical properties of dapoxetine (solubility, melting point, IR, UV). The Optimized mobile phase was [(250μl TEA/L), 34.5% acetonitrile and 28.5% methanol, The pH value was adjusted to 4.5 ±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 230nm.

The linearity range of the method was from 0.6 to 36μg/ml for dapoxetine. LOD was 0.0187μg /ml for dapoxetine, whereas LOQ was 0.0567μg/ml. The precision of the method was less than 2% which indicates highly precise result during the study. The accuracy of the method ranged between 99.39%-100.97%.

There were one degradation products of dapoxetine after exposure to hydrogen peroxide (25%) with retention time 5.04. While no degradation products of dapoxetine were observed after exposure to acidic (1N HCl, 60°C, 4h), Alkaline (1N NaOH, , 60°C, 4h), Ultraviolet light (2. h, 80w), Direct Sunlight (4h).

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.

Detailed view of the monograph

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