Analytical Method Development and Validation for Simultaneous Estimation of Fluoxetine Hydrochloride and Sildenafil Citrate in Combined Tablet Dosage Form

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ABSTRACT

A simple, accurate and precise reverse phase high pressure liquid chromatographic(RP-HPLC) method has been developed for the simultaneous estimation of Fluoxetine Hydrochloride(Fluo) and Sildenafil Citrate(Sild) in tablet dosage form by reverse phase C18 column, Hypersil-BDS (250mm x 4.60mm), Particle Size 5µ. The samples were analyzed by using Potassium dihydrogen phosphate buffer(0.02 M) : Acetonitrile : Triethylamine in the ratio of 55:44:1 v/v (pH adjusted to 4.0 with 1% v/v Orthophosphoric acid) as a mobile phase at the flow rate of 1 ml/min in isocratic mode and detection wavelength 230 nm. Both the drugs give sharp peak with high theoretical plate count and low tailing factor. The retention time for Sildenafil Citrate and Fluoxetine Hydrochloride was found to be 3.250 min and 4.980 min respectively. The validation was carried according to ICH guidelines. In linearity curve correlation

coefficients for Sildenafil Citrate and Fluoxetine Hydrochloride were found to be 0.9999 and 0.9999 respectively. The percent recovery was 100.13% for Sildenafil Citrate and 99.78% for Fluoxetine Hydrochloride indicating accuracy and reliability of method. The limit of detection was 0.21µg/ml and 0.15µg/ml for Sildenafil Citrate and Fluoxetine Hydrochloride, respectively and the limit of quantification was 0.64µg/ml and 0.46µg/ml for Sildenafil Citrate and Fluoxetine Hydrochloride, respectively. Force degradation study was carried out on combined dosage form as per ICH guideline and it was exposed to acid and base hydrolysis, oxidative and thermal conditions to apply stress. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision and robustness for estimation of Sildenafil Citrate and Fluoxetine Hydrochloride in tablet dosage form. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Key words: Fluoxetine Hydrochloride, Sildenafil Citrate, RP-HPLC, Force degradation.