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Analytical Method Development and Stability Studies for Estimation of Oseltamivir In Bulk and Capsules Using RP-HPLC

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Abstract : A simple and reproducible method of isocratic reverse phase liquid chromatography (RP-LC) was developed for the quantitative determination of oseltamivir phosphate in bulk drug and capsules, used to treat antiviral (influenza). The proposed RP-HPLC method uses X terra C_{18}, 4.6 mm, 150 mm 4.6 mm i.d. column (at room temperature), using 0.1% octa-sulfonic acid: acetonitrile 30: 70 v / v, effluent flow rate (1.0 ml / min) and UV detection at 237 nm for oseltamivir analysis. The method was validated according to the ICH guidelines in terms of specificity, linearity, precision and accuracy. The retention time for oseltamivir was 2.31 min. The recovery determinations allowed the calculation of a confidence interval from 99.79 to 101.30% with a relative standard deviation value of 0.5%. LOD and LOQ were estimated at 2.98 and 9.98 µg/mL respectively. The validated method was successfully applied to the determination of oseltamivir in dosage form in capsules (Tamiflu 75 mg, Roche). Oseltamivir was exposed to conditions of acid, basic, oxidative and thermal stress and the stressed samples were analyzed with the proposed method. The chromatographic peak purity results indicated the absence of elution peaks with the main oseltamivir peak, which demonstrated the specificity of the test method for estimating oseltamivir in the presence of degradation products. This method has advantages that include a short execution time, a simple and rapid sample preparation which makes this method used for routine oseltamivir analysis in quality control laboratories.

Key words : Oseltamivir phosphate, X terra, octa-sulfonic acid, acetonitrile, Tamiflu.

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