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A Distinct Reversed-Phase High-Performance Liquid Chromatography Method for Simultaneous Quantification of Evogliptin Tartrate and Metformin HCl in Pharmaceutical Dosage Forms

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Abstract : A simple and accurate stability-indicating, reversed-phase high-performance liquid chromatography (RP-HPLC) method was developed and validated for the simultaneous quantitation of Evogliptin tartrate and Metformin HCl in pharmaceutical dosage forms, following ICH guidelines. Forced degradation was performed under various stress conditions including acid, base, oxidation, thermal, and photodegradation. The method utilized an Eclipse C18 column (250 mm × 4.6 mm, 5 µm) with a mobile phase of 5 mM 1-hexane sulfonic acid sodium salt in water and 0.2% v/v TEA (45:55 %v/v), adjusted to pH 3.0 with OPA, at a flow rate of 1.0 mL/min. Detection at 254.4 nm using a PDA detector showed good resolution of degradation products and both drugs. Linearity was observed within 1-5 µg/mL for Evogliptin tartrate and 100-500 µg/mL for Metformin HCl, with % recovery between 99-100% and precision within acceptable limits (%RSD < 2%). The method proved to be specific, precise, accurate, and robust for routine analysis of these drugs.

Keywords : stability indicating RP-HPLC, evogliptin tartrate, metformin HCl, validation
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