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Stability-Indicating Spectrophotometric Method for Determination of Dienogest in Pure form and Pharmaceutical Preparation

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Abstract: A simple, rapid, sensitive, accurate and precise stability-indicating spectrophotometric methods were developed for the determination of dienogest and its degradants in bulk powder and in pharmaceutical preparation. The methods were validated over a linear range of 1 – 5 µg/mL and successfully applied to the determination of dienogest at 297 nm with an average percent recovery of 93.9 – 100.3. dienogest were subjected to stress degradation under different conditions recommended by ICH. The samples so generated were used for degradation studies using the developed method. The proposed methods were validated and can be used for analysis of formulation containing dienogest.

Keyword: Stability-indicating, dienogest, formulation, ICH.

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