SRDHS
SOCIETY FOR RESEARCH DEVELOPMENT IN HEALTH SCIENCE

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Sponsored

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Theme:
"Invigorating Research in Pharmaceuticals: Reasonable Industrial Approach"

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Souvenir and Abstract Book

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DEVELOPMENT OF STABILITY INDICATING ASSAY METHOD FOR THE SIMULTANEOUS ESTIMATION OF NEBIVOLOL AND TELMISARTAN IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

To develop validated stability indicating analytical method for Nebivolol and Telmisartan in bulk and tablet dosage form. To develop a simple, accurate, specific and rugged RP-HPLC method for the simultaneous estimation of Nebivolol and Telmisartan in bulk and tablet dosage form and validate it. A stability indicating RP-HPLC method has been developed to estimate Nebivolol and Telmisartan. The separation was achieved using Fortis C-18 (id 4.6 x100 mm) with particle size 2.5 µm column as a stationary phase and mobile phase as Acetonitrile: 0.05 % o-Phtalaldehyde (OPA) (80: 20 v/v) pH 6.5 adjusted with 0.1% Triethylamine (TEA). A gradient programming has been done with a flow rate 1.0 mL/min at a wavelength of absorption 286 nm. The proposed method was validated for Linearity, Accuracy, Precision, Ruggedness, Robustness and stability studies. The chromatographic analysis time was approximately 10mins with complete resolutions at 3.0 min and 5.7 min for Nebivolol and Telmisartan respectively. The method exhibited good linearity range Nebivolol 5-25 µg/mL and Telmisartan 40-200 µg/mL. The force degradation studies were performed as per ICH guidelines under different conditions. The developed and validated RP-HPLC method can be applied for routine qualitative and quantitative analysis and for stability studies on pharmaceutical preparation of Nebivolol and Telmisartan in bulk and pharmaceutical formulation like tablet within pharmaceutical industry.

Keywords RP-HPLC, Nebivolol and Telmisartan, Force degradation

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DEVELOPMENT AND STABILITY STUDY OF METRONIDAZOLE BENZOATE SUSPENSION CONTAINING VARIOUS SUSPENDING AGENTS

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ABSTRACT

Study aimed to developed and study the stability profile of metronidazole benzoate suspension containing various suspending agent. Objective was to fully characterize the physicochemical properties of metronidazole benzoatesuspention and to conduct real-time and accelerated stability studies on the various suspensions in accordance with the ICH guidelines in order to determine which formulation is the most stable. Three categories of metronidazole benzoate suspension were developed using four suspending agent system. Combination of two suspending agents' carboxymethylcellulose sodium plus xanthan gum, aluminum magnesium silicate (veegum HV) plus xanthan gum and microcrystalline cellulose plus xanthan gum each suspending agent system was evaluated. The suspension each contained the equivalent of 100 mg of metronidazole benzoate per 5 ml. The suspensions containing xanthun gum and microcrystalline cellulose were found to be physically and chemically stable after the temperature cycle and over the 24 -week period whilst stored at 25 °C ± 2 °C / 60 % RH and 5 °C. The suspensions were chemically stable whilst stored at 40 °C ± 2 °C / 75 % RH at this accelerated condition. The metronidazole benzoate contained in these products remained in the anhydrous state under all storage conditions and were consequently concluded to be the most stable formulation of all the products analyzed in the current study.

Keywords Metronidazole Benzoate, Crystallization, Dissolution Property, Stability.