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A Simple Validated Stability Indicating RP-HPLC Method for the Determination of Three Antiparkinsonism Compounds in Oral Contraceptive Tablet Formulations

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Abstract: The present study describe the simple, novel stability-indicating assay method was developed and validated for determination of Levodopa, Carbidopa and Entacapone along with their degradation products in pharmaceutical formulation (Tablet) by Reverse Phase High-Performance Liquid Chromatography (RP-HPLC). During the ICH prescribed stress study, Levodopa, Carbidopa and Entacapone were found susceptible to degrade under oxidative (Peroxide) and hydrolytic (acid and base) conditions. The separation was achievedwithHypersil BDS (250 x 4.6 mm, 5µm) column using 0.1% orthophosphoric acid as a buffer and acetonitrile containing 35% of 0.1% orthophosphoric acid (95:5 v/v%) as mobile phase, at a flow rate of 1.2 mL min^{-1}column temperature kept at 30°C and photodiode array detector at 282 nm. The average retention times for Levodopa, Carbidopa and Entacapone, were 2.4, 4.6 and 8.0 min, respectively. The optimal condition, method was validated according to the ICH and USP guidelines. The method were linear in the concentration range for Levodopa, Entacapone were 50-300 µg $mL^{-1}$for Carbidopa 12.5-75 µg mL^{-1}(r^2 > 0.999)and all three compounds recoveries were above 99%. There were no chromatographic or spectral interferences from excipients and proposed method suitable forthe routine quality control of analysis.

Keywords: Levodopa, Carbidopa, Entacapone, ValidationandPharmacutical formulations.

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