

Development and Validation of Analytical Method for Simultaneous Estimation of Preservatives in Polyherbal Cough Syrup

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ABSTRACT

A rapid, simple, accurate, and precise method for the determination of propyl paraben, methyl paraben, sodiumbenzoate, and bronopol in Polyherbal cough syrup by means of reverse phase high performance liquid chromatography coupled to UV detector was developed. Best separation was achieved using a Phenomenex Luna C18(2) (250 mm × 4.60 mm, with particle size of 5 µm) as well as isocratic elution consisting of sodium dihydrogen

phosphate buffer/ acetonitrile (63:37) at pH 4.0 adjusted with ortho phosphoric acid at a flow rate of 1.5 mL/min. The optimized and applied chromatographic conditions permitted separation of Propylparaben, Methylparaben, Sodiumbenzoate, and Bronopol from interacting matrix with good sensitivity. The method validation was carried out with regard to the guidelines for analytical procedures demanded by the International Conference on Harmonisation (ICH). Limits of detection was found to be 2.21 μ g/mL, 5.54 μ g/mL, 0.34 μ g/mL, 0.46 μ g/mL and LOQ was found to be 3.72 μ g/mL, 16.08 μ g/mL, 1.07 μ g/mL, 1.39 μ g/mL for Bronopol, Sodiumbenzoate, Methyl paraben, Propyl paraben respectively. Retention time of Bronopol, Sodiumbenzoate, Methylparaben, Propylparaben obtained was 2.5, 4.4, 5.05, 13.6 minutes respectively. Specificity experiments revealed the absence of interference from excipients, interacting matrix could be eliminated by the chromatographic procedure with excellent performance of system suitability having $RSD \leq 2$ for all four analytes. The linearity was found to be in the range of 2-30 μ g/mL, 66-990 μ g/mL, 26-390 μ g/mL, 5-78 μ g/mL for Bronopol, Sodiumbenzoate, Methylparaben, Propylparaben respectively. Accuracy was achieved with %recovery within 98%-102% for all preservatives. Analysis of marketed formulation gives %assay results of 98.99 ± 0.58 , 98.54 ± 0.72 , 98.27 ± 0.445 , and 100.54 ± 0.27 for Bronopol, Sodiumbenzoate, Methylparaben, Propylparaben respectively.

Keywords: Sodium benzoate, Bronopol, Methylparaben, Propylparaben, RP-HPLC, Zeal Cough Syrup