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Development and Validation of an Analytical Method by HPLC for the Determination of Water-soluble Vitamins (Thiamine, Riboflavin, Nicotinamide, Pyridoxine and Ascorbic Acid) in a Syrup at NEOFARMACO CIA. LTDA. †

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Abstract: This work describes the development, optimization, and validation of a reversed-phase HPLC method using ion pair chromatography (IPC) for the identification and quantification of ascorbic acid, thiamine, riboflavin, nicotinamide, and pyridoxine in a syrup. A LiChrospher 100 RP-18 column (125 x 4,6 mm 5 µm) was used. UV detection was performed with the maximum wavelength for each vitamin. The mobile phase consisted of an IPC 7 (50 mM) buffer pH 2.0, methanol and acetonitrile gradient: 0-16 min (80: 17,5: 2,5), 16-21 min (17,5: 80: 2,5), and 21-24 min (80: 17,5: 2,5). The flow was 1 mL/min at 35 °C. The injection volume was 10 µl. After the development and optimization of the method, it was validated, according to the parameters established in the book of Validation of analyte methods of the AEFI; proving to be selective with a percentage of discrepancy (< 3,4%), linear (r> 0,998), precise (RSD <1,8), accurate (recovery of 97,3% for ascorbic acid, 98,4% for thiamine, 99,9% for riboflavin, 97,9% for nicotinamide and 99,0% for pyridoxine), suitable and robust. According to these results, it was demonstrated that the analytical method is appropriate for the identification and quantification of water-soluble vitamins in a syrup.

Keywords: ion pair; chromatography; validation; analytical method; multivitamins.

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Conflicts of Interest

The authors declare no conflict of interest.