

Identification of the Excipients of Dexamethasone Sodium Phosphate Injection-UNC (IDX-UNC), Subjected to Degradation, by HPLC, and their Impact on the Main Drug, Dexamethasone Phosphate [†]

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Abstract: Dexamethasone Sodium Phosphate Injectable contains parabens, creatinine, Sodium citrate and Sodium bisulfite as excipients. One of the controls carried out to define its suitability in determining the concentration of the main drug. Its specificity must be demonstrated by evaluating whether or not the excipients interfere with the main peak of the chromatogram. These excipients are identified, and their interaction with the main drug is determined after being subjected to degradation. HPLC. Solutions of each excipient are prepared and subjected to Alkaline hydrolysis, heat, and no treatment. A spectrophotometric scan (200-400 nm) is performed to verify which excipients absorb at 254 nm. Post degradation, the samples are analyzed to determine which excipients correspond to the peaks in the chromatogram. From the scan, the only excipient that does not absorb is sodium bisulfite. The secondary peaks observed in the chromatogram were differentiated and identified. Creatinine and sodium citrate are not altered by degradation. The main peak of parabens decreases while the secondaries increases. In IDX stability t = 48 months, the same behavior of parabens is observed without altering the peak of the main drug. None of the excipient peaks identified, after degradation, affect the quantification of the main drug Dexamethasone Phosphate in the IDX-UNC.

Keywords: dexamethasone sodium phosphate injectable; Hemoderivatives, excipients degradation.

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Conflicts of Interest

The authors declare no conflict of interest.