

Quality control – Qualitative testing of enrofloxacin

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Introduction: Enrofloxacin is a second generation fluoroquinolone, developed in the 80's with the chemical name acid 1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid and was the first fluoroquinolone introduced to veterinary medicine for the treatment of infections by various bacteria. The molecular formula of enrofloxacin is $C_{19}H_{22}FN_3O_3$ as CAS Register Number 93106-60-6 and molecular weight of 359.39 g/mol. Enrofloxacin is a slightly yellow crystal, entering the melting range 219-221 °C and is slowly soluble in water at pH 7.0, but since the molecule has acidic and basic groups it is easily dissolved in alkaline and acidic pH. In the literature there is little information on the characteristics of enrofloxacin. Therefore, a qualitative analysis is very important before doing any quantitative analysis, for it is better possible to understand the nature of the drug studied by analyzing it qualitatively. **Objective:** Perform tests for qualitative analysis with enrofloxacin drug product as well as the drug substance and the reference standard. **Methods:** The tests performed were: solubility as described in the Brazilian Pharmacopeia 5th edition (only drug substance), melting point using equipment LS Logen Scientific (drug substance and reference standard), moisture using the balance analyzer moisture IR Gehaka model IV2000 (drug substance), water by Karl Fischer method using the apparatus model AF8 from Orion[®] (drug product), average weight using a Mettler analytical balance, Model H10, thin layer chromatography (TLC) using plates and mobile phase composed of methanol : ammonium hydroxide (8:3) and qualitative analysis in the infrared spectrophotometer using IRPrestige-21 spectrophotometer from Shimadzu[®] (drug product, reference standard, drug substance and placebo). **Results:** The solubility was tested with 12 solvent using enrofloxacin drug substance. The results showed that the drug substance is not soluble in water and freely soluble in chloroform, according to the classification for solubility described in Brazilian Pharmacopeia 5th edition. The melting range found was 222-226 °C for the drug substance and 221-225 °C for the reference standard. The moisture performed with an infrared balance for 1 hour at 105 °C was determined at 1.51%. The amount of water obtained by analysis in the Karl Fischer apparatus for the drug product was 6.57% (w/w). The average weight carried out according to the Pharmacopeia Brazilian 5th edition obtained for the tablets of enrofloxacin was 60.6 mg. In the TLC analysis spots with the same R_f (0.78) were obtained for the reference standard, the drug substance and the drug product, which identify the enrofloxacin in the drug product. The infrared analysis identified enrofloxacin in the drug product, since the spectra of the standard, drug substance and drug product showed enrofloxacin's typical bands of transmittance. **Conclusion:** The results obtained in qualitative testing performed with sample, reference standard and drug substance of enrofloxacin meet the specifications found in literature and define characteristics of extreme importance to be able to start working with this drug, developing methods for its quantitative analysis.

Keywords: infrared, solubility, moisture, weight, melting point.

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