

Determination of oxytocin in pharmaceutical dosage forms available in drug market of Iran

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Background and Aims: Quality control of medicinal products, especially considering the amount of active ingredient of toxic side effects and complications is important. The present study was performed to measure oxytocin in commercially available drug products containing OT in the drug market of Iran for quality and quantity assurance.

Methods: In this study pharmaceutical dosage form of OT with different brands at a concentration of 5 and 10 IU/ml was purchased from a local pharmacy. A previously published method was optimized for the conditions in our laboratory. The OT solution was injected directly into column without further preparation. High Performance Liquid Chromatography (HPLC) was used as the preferred analytical tool. The method uses a C18 Hypersil, column 5 μ m packing, .6 mm \times 150 mm. The mobile phases consist of acetonitrile – phosphate buffer with (pH 5; 0.08 M) (20:80) and UV detection at 220 nm.

Results: The results of these experiments showed that the standard curve for OT was linear over the range 0.5 - 8 IU/ml. The corresponding regression equation was $y=124.7+21.44x$ with an r^2 value of 0.99. The within day coefficient of variation for the method ranged between 0.06 IU/ml and 31.93 IU/ml% and the between day value ranged between 1.1 IU/ml and 10.99 IU/ml%. The accuracy of method ranges between 84.49 % and 111% for within day analysis and 86.98 % and 104.25 % for between days analysis. The lower limit of quantification was 0.25 IU/ml. The percentage content, taking one of the bulk samples as 100% reference, was 129.16 % and 122.8% recovery of the label claim for OT 10 IU/ml and OT 5 IU/ml, respectively. These findings confirm that good quality control method is required over the pharmaceutical industrial.

Keywords: Oxytocin; HPLC; Pharmaceutical dosage form