QUANTITATIVE DETERMINATION BY POTENTIOMETRIC TITRATION METHOD OF ACTIVE PHARMACEUTICAL INGREDIENTS IN COMPLEX DOSAGE FORM

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Introduction. The most easily understood and most studied form of drug instability is the loss of drug through a chemical reaction resulting in a reduction of potency. Loss of potency is a well-recognized cause of poor product quality. The factors that determine the chemical stability of drug substances include intrinsic factors such as the molecular structure of the drug itself and environmental factors, such as temperature, pH, buffer species, ionic strength, light, oxygen, moisture, additives, and excipients.

Aim. Working out a method for the quantitative determination of active compounds was one of the important tasks of our study in accordance with existing modern requirements for establishing the stability of drugs.

Materials and Methods. *Instrumentation:* The automatic titrator was used with glass electrode for proposed method. Saturated calomel electrode was used as reference electrode. The potentiometer measurements were carried out using I-135 pH meter, which was more convenient to be used. All measurements were carried out at 25º C. *Chemicals:* A 0.100 g. of complex dosage form was weighted. It was transferred into a clean beaker. Methyl orange was used as an indicator, which is convenient for fixing the point of equivalence of the reaction taking place in the aqueous phase. The titration was carried out with 0.1 M hydrochloric acid in automatic titrator.

Results and discussions. To determine sodium hydrogen carbonate and sodium benzoate in a complex dosage form was used aqueous potentiometric titration. Potentiometric titration system using glass electrode is the simplest electroanalytical technique for determination of stability constants.

X,g recovery of active pharmaceutical ingredients was obtained by using equation.

$$X, g\ assay = \frac{Amount\ of\ titrant \cdot K \cdot T \cdot 7{,}25}{0{,}100}$$

Conclusions. The sensitive and simple potentiometric titration method was carried out for sodium hydrogen carbonate and sodium benzoate in a complex dosage form. The standard 0.1 M hydrochloric acid was used as titrant for quantification. The standard deviation has shown sensitivity. The results of quantitative determination were subjected statistical processing.