Optimization and validation of assay method of vitamin C in composition of medicated chewing gums "Lysodent C"

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Introduction. Medicated chewing gums (MCGs) are official as drug delivery systems in the Pharmacopoeias (e.g.: USP, Ph.Eur. and SPhU [1]). MCGs are solid or semi-solid pharmaceutical dosage forms and contain one or more active pharmaceutical ingredients (APIs), that are released by chewing (Ph.Eur. 2014), and water-soluble/insoluble excipients blended with a water insoluble gum base (USP 2015). The local and systemic effect can be reached by using this type of dosage form. MCGs "Lysodent C" for use in dentistry with the inclusion of lysozyme hydrochloride and ascorbic acid as an APIs were developed at the Industrial Technologies of Drugs Department of NUPh. The purpose of this work was to study the conditions of sample preparation and to optimization of assay method of ascorbic acid in MCGs, which provide control the quality parameters of finished product.

Materials and methods. Lysozyme hydrochloride (LH), Netherlands; ascorbic acid (AsA), China. The main excipient used in the formulation of MCGs were directly compressible gum base Health in Gum®, Spain [2]. AsA assay was performed by redox-based iodatometric titration. Model mixtures were used during the optimization and validation of the analysis method. For their preparation, CRS of LH and AsA and a mixture of a placebo, the composition of which corresponds to the drug, were used. The adapted technique was used to control the quality of the experimental series MCGs. Validation was performed in accordance with the requirements of the SPhU.

Assay. Dissolve about 1.000 g of powder of 20 crushed unit in 20 mL of phosphate buffer (pH 6.2) and shake. The solution is incubated for 10 minutes on an ultrasonic bath, cool and filtered through a paper filter "white tape". Add 10 mL of 0.1M hydrochloric acid, 0.5 mL of a freshly prepared 10 g/L solution of potassium iodide R and 2 mL of starch solution R. Titrate with 0.0167M potassium iodate until a violet-blue colour is obtained. 1 mL of 0.0167M potassium iodate is equivalent to 8.8271 mg of $C_6H_8O_6$.

Results and discussion. The obtained linearity parameters: n=9, regression equation y=1.0015x-0.0489, S_a=±1.46, S_b=±0.01; R^2=0.9985, statistical results of precision: 20.05±0.12 mg (100.10±0.36%) do not exceed the eligibility criteria for tolerances of ascorbic acid content from 90% up to 110% ($max\Delta_{As}$=1.6%). The LOD=0.96 mg and LOQ=2.92 mg were estimated from the set of 9 calibration curves used to determine method linearity. Accuracy were tested using Standard Addition Method (SAM) was done by adding known concentrations of ascorbic acid to the experimental series of MCGs. The 1.59% RSD for analysis of formulation was found to be within the limit. Our studies revealed a recovery percentage of 98.74–101.92%, which indicates that the developed method was found to be accurate.

Conclusions. The proposed method for the determination of ascorbic acid in the developed solid dosage form was found to be precise, selective, and rapid.

References

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