REVISITING THE REVIEW OF SOME EXTEMPORANEOUS MEDICAL SUBSTANCES SHELL LIFE

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Such medical dosage forms as "Ascorbic acid 1% solution for electrophoresis" 100 mL, "Iodine 10% solution" 50 mL and "Fennel water" 100 mL prepared in pharmacies conditions belong to unstable drugs of extemporal production. Thus, the shelf life of the first two forms is 10 days, and "Fennel water" is 30 days.

The aim of this study was to test the suitability of the proposed storage terms and identify opportunities to increase them. For this the extemporaneous formulations mentioned above were prepared in the pharmacy conditions and every 5 days over the period of 30 days (the observation), the content of the active pharmaceutical ingredient was monitored using quantification of analytical methods recommended by the State Pharmacopoeia of Ukraine. As the result, during the research it was found that "Iodine 10% solution" should be prepared for a short period that should not exceed 20 days when stored at 18-20 °C, during which time the iodine content in the product decreased by 0.45% (abs.), as required the content in the iodine preparation should be at least 9.5%. Content of iodine in the preparation was determinated by method using a standardized solution of sodium thiosulfate. The iodine is directly used as an oxidizing agent in slightly acidic medium and starch is used as indicator. The "Ascorbic acid 1% solution for electrophoresis" remained stable for 30 days (the loss of active pharmaceutical substance content does not exceed the permissible 5% (rel). The experiment involves an iodimetric titration in which iodine reacts with ascorbic acid, oxidizing it to dehydroascorbic acid. The redox titration endpoint is determined by the first iodine excess that is complexed with starch, giving a deep blue-violet color.

The study of the "Fennel water" drug stability prepared using fennel oils: fennel ether oil of Foeniculum vulgare- 0.05 g, sterile purified water - up to 1 liter, showed that the shelf life of 30 days is clearly not enough and can be increased up to 6 months. The definition of terpenoids was carried out by recommended iodochlorymetric method, as well as alternative peroxoacidimetric method that was developed before. Fennel essential oil (Foeniculum vulgare) is determinated indirectly : 1 ml of 1% KI solution is added to a known amount of iodine monochloride (4 ml of 0.002 M (1/2, IC1). The iodine formed is titrated with 0.003 mol/L the thiosulphate solution either visually using starth as indicator. Fennel oil was used as a standard sample standardized using pharmacopeia methods. The concentration of ether oil in the standard solution sample preparation was 0.005%. The concentration of ether oil in Fennel water for a period of 6 months kept under the dark place at a temperature not exceeding 25 °C, was 0.0045%. The drug was stored in a glass bottle of 100 mL, which was plugged with a plastic stopper. The solution of iodmonochloride was used as a titrant. It was freshly prepared by diluting of a concentrated iodmonochloride standard solution immediately before testing, which contained 0.00016236 g of iodmonochloride in 1.00 mL. It should be noted that in the analysis results of both methods used within the experimental errors coincide with each other very well. Thus, the obtained data can be applied for the review of analyzed extemporaneous forms shelf life for their increase.