STABILITY STUDIES OF DENTAL GEL "ROTRYN-DENT" IN ALUMINIUM TUBES

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At present there is a problem of expanding the range and choice of packaging that meets the current requirements of the pharmaceutical market for storage of soft medicinal forms. Therefore, topical is to provide proper storage of a medicinal form with minimum costs when choosing an inexpensive and safe packaging.

Aluminum tube is an economic package, which is most commonly used for drugs in dental gel form. All internal volume of the tube is filled with drug at packaging. In fact, the volume of the tube is equal to the volume of the packed product and it ensures tightness during prolonged storage.

Aluminum tubes are resistant to fats, moisture resistant, serve as barrier for oxygen and UV radiation Ease in applying for a consumer is that opening a tube, he uses as much gel as he needs. The rest of the product remains protected inside the tube without contact with air. Another property that significantly affects the quality of the gel is the absence of suction effect after tube compression.

As it is known in the aluminum tube there is no so-called "shape memory", i.e. after compression the tube its walls deform and do not return to the original shape. While in plastic laminate tube it happens just the opposite. At the same time plastic tube sucks back, first air, which leads to the oxidation of content, and secondly squeezed and not completely used partly contaminated part of drug. It may be concluded that the most useful properties of aluminum tubes remain hidden from end users.

Choosing an aluminum tube for a given dosage form among other types of containers, we have noticed a number of benefits for consumers, namely that an aluminum tube does not affect the quality of the developed dental gel, it is easy to use and has lightproof properties and absence of absorbing effect.

So as containers for developed dental drug we have used, aluminum tubes with metal membrane with a long nose, bushonnes and inner varnish coating of type Paclac 11-15-000.

The study of the stability of the gel was performed on five series for over 30 months by analyzing studied samples every 6 months by the following parameters:

organoleptic and physical-chemical properties (appearance, color, odor, pH, thermal and colloidal stability), average weight of the packaging contents. Methods of selected indicators study and their characteristics are governed by SPU and other regulations.

Also performed identification and quantification of active substances (main components of phytosolution "Rotokan" and triclosan) and preservative by HPLC. Shelf-life of the gel was determined at two temperatures, namely (8-15) °C (cool place) and at (15-25) °C (room temperature).

The results of the pilot stability study of series of dental gel under different storage conditions for the above indicators were satisfactory, namely gel had homogeneous mass without impurities, yellowish- brown in color with a pleasant taste and odor that met the standard of developed gel, pH was within 5,00-7,00.

To determine the behavior of the gel at temperature and storage conditions deviations studied colloidal and thermal stability. Studies have confirmed that colloidal and thermal stability of the dental gel for two years remained unchanged.

Identification of active substances and excipients, which are part of the gel, has been confirmed during controlling shelf life. It was established that during the expected shelf life the quantitative content of the active substances and preservative in the gel remained within acceptable limits.

The mass of the contents of the tube was also stable during the observation period and amounted to 30,2 ± 0,5, ie gel did not dry out.

In developing dental gel additionally studied the structural and mechanical properties. According to the research were plotted full rheograms of flow of the developed gel samples (6, 12, 18, 24, 27 months) and concluded that the gel in the test interval did not change its rheological properties and was stable.

Also carried out tests of the dental gel on the microbiological purity by SPU 1 ed. (Section 2.6.12, 2, 6, 13) by the following criteria: absence of bacteria family Enterobacteriaceae, P. aeruginosa, S.aureus in 1 g of the drug, the total number of viable nonpathogenic microorganisms (not> 100 aerobic bacteria and fungi in total). The results have shown that the total number of bacteria in 1 g of the drug did not exceed 15, fungi 20.

Proceeding from this it has been found that concentration of preservative taken had provided microbiological purity of dental gel during storage at room temperature. The results of the drug stability study of the other four series studied were identical.