eISSN: 2349-5715 pISSN: 2349-5707
Volume: 11, Issue 05, May-2024 SJIF 2019: 4.702 2020: 4.737 2021: 5.071 2022: 4.919 2023: 6.980 2024: 7,662

DETERMINATION OF SHELF LIFE OF MKS-LR (BAA) TABLETS

Atajanov N.R., Karayeva N.Y., Tadjieva A.D.

Tashkent pharmaceutical institute, Tashkent city, Republic of Uzbekistan
E-mail: Nurbek5566@icloud.com. phone: (94) 956 61 16

Annotation

This article presents the results of studies on the study of the stability of MKS-LR (BFQ) tablets developed at the Tashkent Pharmaceutical Institute and determining the shelf life.

Key words
MKS-LR, tablet, stability, shelf life, medical method, accelerated aging, packaging, humidity, stress

Introduction. The more stable any ready-made medicine is, at the same time, if its storage conditions are chosen correctly, the longer the shelf life of these medicines will be. The term "stability" refers to the physical, chemical, microbiological, therapeutic and toxicological properties of drugs, and it is determined by the extent to which the drug retains its properties at the time of production, within the limits specified in the specification, until the shelf life. During the storage of medicinal products, its chemical composition or physical properties (precipitation, color change, change of aggregate state) may change [1].

The final stage of the scientific research work on the creation or improvement of the technology of ready-made drugs is to determine the stability of the drugs prepared on the basis of the composition and technology, which are found to be appropriate in terms of technological and biopharmaceutical indicators. It is known that the excipients used in the preparation of medicines can gradually manifest their effect during the period of storage after preparation of the medicine. A similar effect can occur based on the technological method used. It should be emphasized that during the storage of prepared drugs, not only the medicinal substance is affected, its activity increases, decreases or disappears altogether, but also quality indicators specific to the type of drug: external Changes in appearance, hardness, decomposition time, and solubility can also be observed. On the basis of such changes, the chemical interaction that can be observed between the active substance and auxiliary substance or between the auxiliary substance and auxiliary substance, as well as the active substance and auxiliary substances under the influence of technological processes Effects can be observed such as chemical modifications in the form of acids, bases, salts, decomposition, oxidation-reduction processes, or physico-chemical changes, polymerization, changes in solubility, increase in hygroscopicity. When the type of drug has sufficient stability according to its characteristics, the use of packaging containers that do not match their characteristics or the storage of the types of drugs placed in containers in conditions that are not at the level of requirements (in rooms with high or very low relative humidity) , storage in conditions of high or low outdoor temperature or direct sunlight) can also have a negative effect on the stability of drug species. [1,2].

The purpose of the research: to determine the stability of the MKS-LR (BAA) tablet developed by the scientists of the Tashkent Pharmaceutical Institute on the basis of the microcrystalline cellulose extracted from the raw materials used by the scientists of the Tashkent Institute of Chemical

eISSN: 2349-5715 pISSN: 2349-5707
Volume: 11, Issue 05, May-2024 SJIF 2019: 4.702 2020: 4.737 2021: 5.071 2022: 4.919 2023: 6.980 2024: 7,662

Technologies in the extraction of biologically active substances from the raw materials of plants, as well as in the preparation of Galen preparations, and the purpose of studying the shelf life.

Research methods: in the experiments conducted to determine the storage conditions of MKS-LR (BAA) tablets, the influence of the external environment - temperature, humidity and the type of equipped container - on the quality indicators of the finished product was studied. The tablets were packed in the following containers approved for use in medicine: - a brown glass container with a twist plastic cap according to Tst 64-2-71-80; - container made of polyethylene DTS16338-85E;

Determining the stability of MKS-LR (BAA) tablets under natural conditions (for one and a half years at room temperature (in which the room temperature was in the range of 18-30^{0}C, and the relative humidity was 50-65%), in "accelerated" methods - in a thermostat (at 40^{o}C temperature and 15-20% relative humidity), as well as "Stress" experiments were carried out to describe the emergency situation (at 40^{o}C temperature and 58, 76, 90 and 100% relative humidity) in desiccators created using saturated salt solutions: sodium bromide (58%), spirit sulfate (79%), ammonium chloride (90%) and purified water (100%). appearance, trueness, average tablet mass and deviation, hardness to breaking and friction, disintegration) were determined [3,4].

The storage of MKS-LR (BAA) tablets in clinical conditions was monitored by studying quality indicators every 6 months for 1.5 years. Our packages are labeled with labels. Our primary packaging tablets were placed individually in cardboard boxes (secondary packaging), and in natural studies, the drugs in cardboard boxes were kept on the counters in the laboratory. It was observed that the temperature of the rooms under study is within the range of relative humidity throughout the year.

The results are presented in Tables 1 and 2. The obtained results are at the level of the requirements of the respective MHs, and it was found that the container chosen for packing the tablets ensured their stability. Therefore, on the basis of scientific research, it is possible to recommend the above-mentioned containers for the packaging of MKS-LR (BAA) tablets in practice [5].

Studying the persistence of drug species in natural conditions is remarkable for its accuracy and simplicity, but it takes a lot of time. This is not appropriate in the time of market economy. The "accelerated" study of medicinal species is carried out in a thermostat at a high temperature. Experiments for MKS-LR (BAA) tablets were conducted at a temperature of 40^{0}C.

The packed tablets were placed in a thermostat. Their physico-mechanical parameters were checked every 46 days (corresponding to 6 months at room temperature) for 230 days (corresponding to 2.5 years at room temperature) for the first time.

Research results:

Table 1

Results of studying the shelf life of MKS-LR (BAA) tablets in medical conditions

№	Indicators determined by regulatory document	Preliminary results	storage period, month		
			6	**12**	**18**
1	2	3	4	5	6
1	Appearance	White tablets	Suitable	Suitable	Suitable
2	Truth reactions		Suitable	Suitable	Suitable

eISSN: 2349-5715 pISSN: 2349-5707
Volume: 11, Issue 05, May-2024 SJIF 2019: 4.702 2020: 4.737 2021: 5.071 2022: 4.919 2023: 6.980 2024: 7,662

3		IK spectrum -3500-3700	33,4	33,3	33,3
4	Proportion of tablet capacity to diameter	33,30%	0,5±4,0	0,5±4,6	0,5±4,3
	Average weight of tablets and deviation from it	0,5g±4,8	99,92	99,97	100
5	Hardness to friction	99,7 %±1	100	100	100
6	Fracture toughness	100 N	3,8	4,0	4,0
7	Disintegrates	3,5 minute			

2 -jadval

Results of an accelerated shelf-life study of MKS-LR (BAA) tablets (40^0S)

№	Indicators determined by regulatory document	Preliminary results	Storage period, days				
			46	92	138	184	230
1	2	3	4	5	6	7	8
1	Appearance	White tablets	Suitable	Suitable	Suitable	Suitable	Suitable
2	Truth reactions	IK spektr-3500-3700	Suitable	Suitable	Suitable	Suitable	Suitable
3	Proportion of tablet capacity to diameter	33,3%	33,3	33,4	33,3	33,2	33,3
4	Average weight of tablets and deviation from it	0,5g±4,8	0,5±4,6	0,5±4,5	0,5±4,6	0,5±4,8	0,5±4,5
5	Hardness to friction	99,7 %	99,96	99,98	99,95	100	100
6	Fracture toughness	100 N	100	100	100	100	100
7			3,8	4	4	4	4

eISSN: 2349-5715 pISSN: 2349-5707
Volume: 11, Issue 05, May-2024 SJIF 2019: 4.702 2020: 4.737 2021: 5.071 2022: 4.919 2023: 6.980 2024: 7,662

	Disintegrates	3,5 minute					

Research conclusions: When studying the storage of tablets in medical conditions, it was found that the obtained product is at the level of the requirements of relevant MHs, and it was found that a quality container for packing tablets, their stability is ensured. So, on the basis of research, it is possible to recommend high scientific support for the packaging of MKS-LR (BAA) tablets in practice. There is also an "accelerated" experience that interacts with tablets stored at room temperature, work continues in natural conditions.

List of used literature:

1. Atajanov N.R., Karayeva N.Y., Tadjieva A.D. Stability study of MKS-LR (BAA) tablet. Proceedings of the international scientific and practical conference on "Life sciences for the sustainable future-2024". Tashkent-2024.
2. State pharmacopoeia. Eleventh edition. Issue 2. General methods of analysis. Medicinal plant raw materials. Moscow. "Medicine". 1990
3. State Pharmacopoeia of the Republic of Uzbekistan. Tashkent-2021. 1 volume, 1 part.
4. "Standards of the quality of medicines. Basic rules" network standard TSt 42 - 01 : 2002 official publication.
5. Djalilov H.K., Xaydarov V.R. Evaluation of the quality of finished medicines, packing and packaging. Tashkent 2014. 368p.
6. Karayeva N.Y., Tadjieva A.D., Sharipova S.T., Ikromova G.M., Muhamedova B.I. Study of quality indicators and bioefficacy of rutin (MKS-L) tablet. Journal of Pharmaceuticals. Tashkent 2023. Volume 1. P.24-31