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Study Of Storage Conditions And Shelf Life Of Dry Extract "Prostad"

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Abstract: Under the influence of external factors, changes in the physical properties and chemical composition of medicinal plant extracts can occur, which in turn affects their stability and therapeutic efficacy. The shelf life of a dosage form is the primary quality indicator, determining its stability over the intended shelf life. It is known that the preservation of quality parameters depends on many factors, such as excipients, manufacturing techniques, and the type of packaging material.

Tablet stability is greatly influenced by the physical state of the substance, storage temperature, ambient atmosphere, light, packaging, preparation method, selection of excipients, and other factors. It should be noted that the intensity of these effects often manifests itself over time and to a greater or lesser degree. Given the above, studying the shelf life and storage conditions of developed dosage forms is the final stage of scientific research.

Keywords: Extract, extraction, various factors, maceration, percolation, caloriferous, biological, flavonoid, disintegration.

Introduction: The shelf life of a drug is the time interval during which the drug retains its medicinal properties and meets established standards.

This period is established based on experiments and studies conducted under conditions prescribed by regulations. Over time, as new data is obtained, this period may be adjusted. Various analytical methods are used to determine the shelf life, including chemical, physicochemical, and, if necessary, biological and pharmacological tests.

This article presents data obtained from a study of the stability of the qualitative and quantitative parameters of Prostad capsules. In accordance with the methodology of the State Pharmacopoeia of the Republic of Uzbekistan, the following parameters are used to assess the quality of hard gelatin capsules: description, authenticity, average capsule weight, average weight of capsule contents, disintegration, quantitative determination of biologically active substances, and microbiological purity [1-4].

Under the influence of external factors, changes in the physical properties and chemical composition of medicinal plant extracts can occur, which in turn affects their stability and therapeutic efficacy. The shelf life of a dosage form is the primary quality indicator, determining its stability over the intended shelf life. It is known that the preservation of quality parameters depends on many factors, such as excipients, manufacturing techniques, and the type of packaging

material.

Tablet stability is greatly influenced by the physical state of the substance, storage temperature, ambient atmosphere, light, packaging, preparation method, selection of excipients, and other factors. It should be noted that the intensity of these effects often manifests itself over time and to a greater or lesser degree. Given the above, studying the shelf life and storage conditions of developed dosage forms is the final stage of scientific research [5,6,7].

EXPERIMENTAL SECTION

METHODS

Research dedicated to determining the conditions and establishing the shelf life of the dry extract "Prostad" was conducted under natural conditions and "accelerated aging".

At the beginning of the experiment, the dry extract was analyzed for qualitative and quantitative properties. It was then packaged in the following containers:

-colorless glass jars (TU-64-228-84) with screw-on plastic lids and a liner (TU-64-2-250-75); (No. 1)

-orange glass jars (BDS-25 according to TU 64-228-84) with screw-on plastic lids and a liner (TU 64-2-250-75); (No. 2)

Experimental studies using the natural storage method were conducted in laboratory rooms at a temperature of 22±20°C.

Qualitative and quantitative parameters of the drug were determined every 3 and 6 months.

Studies under "accelerated aging" conditions were conducted in accordance with the recommendations of the Temporary Instructions for Conducting Work to Determine the Shelf Life of Medicines I-42-2-82 at a temperature of 400°C in a TS-80-MU42 thermostat.3.

RESULTS AND DISCUSSIONS

Compliance studies of recommended medicinal products with required standards were conducted every 46 days (at 40°C) [8-10].

Tables 1 and 2 present the results of experiments studying the shelf life of Prostad dry extract using natural storage and "accelerated aging" methods in various types of packaging at temperatures of 22±20°C and 40°C, respectively [11,12].

Tables 1 and 2 demonstrate that, when examining shelf life using both natural and accelerated aging methods, the above-mentioned packaging types ensure dry extract stability for 2 years. While Prostad dry extract meets the State Pharmacopoeia of the Republic of Uzbekistan requirements after 2.5 years of incubation, the resulting values demonstrate moisture content thresholds for the above-mentioned packaging types (4.96% and 4.89%). In the third year of incubation, the residual moisture content does not meet the requirement, exceeding the required moisture content (dry extract) of the powder (>5%). Therefore, the recommended shelf life for Prostad dry extract is specified in the regulatory technical documents as 2 years. Thus, the shelf life of the dry extract "Prostad" is 2 years.

Table 1

Results of shelf life studies of Prostad dry extract using natural storage at 22±20°C

Indicators	Standards according to the State Pharmaceutical Code of the Republic of Uzbekistan	
Appearance	Fine powders from brown to dark brown in color with a specific odor	
Authenticity	*Yellow-green coloration*	
Humidity,%	< 5	
Loss on drying, %	No more than 10%	
Heavy metals, %	No more than 0.01%	
Quantitative content of active ingredients, %	Not less than 10%	
Original sample		
Appearance	Fine powders from brown to dark brown in color with a specific odor	
Authenticity	*Yellow-green coloration*	
Humidity,%	4.12	
Loss on drying, %	3.48	
Heavy metals, %	0.008	
Quantitative content of active ingredients, %	9.52	
Time	*3 months*	*6 months*

Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	4.16	4.14	4.28	4.19
Loss on drying, %	3.43	3.45	3.52	3.50
Heavy metals, %	0.008	0.008	0.0079	0.0075
Quantitative content of active ingredients, %	9.52	9.52	9.54	9.55
Continuation of table 4.1				
Time	*9 months*		*12 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	4.31	4.23	4.42	4.37
Loss on drying, %	4.02	3.98	4.52	4.35
Heavy metals, %	0.0074	0.0073	0.0071	0.0070
Quantitative content of active ingredients, %	9.54	9.52	9.53	9.55
Time	*18 months*		*24 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	4.46	4.42	4.51	4.48
Loss on drying, %	4.02	3.98	4.52	4.35
Heavy metals, %	0.0074	0.0073	0.0071	0.0070
Quantitative content of active ingredients, %	9.54	9.52	9.53	9.55
Time	*30 months*		*36 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	4.96	4.89	5.26	5.33
Loss on drying, %	4.02	3.98	4.52	4.35
Heavy metals, %	0.0074	0.0073	0.0071	0.0070
Quantitative content of active ingredients, %	9.54	9.52	9.53	9.55

Table 2
Results of studies on the shelf life of dry extract "Prostad" by the "accelerated aging" method at a temperature of 40 ^{0}C

Indicators	Standards according to the State Pharmaceutical Code of the Republic of Uzbekistan
Appearance	Fine powders from brown to dark brown in color with a specific odor
Authenticity	*Yellow-green coloration*
Humidity,%	< 5
Loss on drying, %	No more than 10%
Heavy metals, %	No more than 0.01%
Quantitative content of active ingredients, %	Not less than 10%
Original sample	
Appearance	Fine powders from brown to dark brown in color

	with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity,%	3.25			
Loss on drying, %	3.52			
Heavy metals, %	0.008			
Quantitative content of active ingredients, %	9.47			
Time	*3 months*		*6 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	3.28	3.26	3.33	3.33
Loss on drying, %	3.50	3.51	3.56	3.53
Heavy metals, %	0.008	0.008	0.0079	0.008
Quantitative content of active ingredients, %	9.35	9.37	9.53	9.57

Continuation of Table 4.2

Time	*9 months*		*12 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	3.59	3.54	3.65	3.61
Loss on drying, %	3.56	3.54	3.56	3.54
Heavy metals, %	0.0079	0.008	0.0079	0.008
Quantitative content of active ingredients, %	9.53	9.57	9.53	9.57
Time	*18 months*		*24 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	3.74	3.69	3.95	3.89
Loss on drying, %	3.55	3.54	3.57	3.58
Heavy metals, %	0.0079	0.0078	0.0079	0.0079
Quantitative content of active ingredients, %	9.73	9.82	9.88	9.86
Time	*30 months*		*36 months*	
Package	*No. 1*	*No. 2*	*No. 1*	*No. 2*
Appearance	Fine powders from brown to dark brown in color with a specific odor			
Authenticity	*Yellow-green coloration*			
Humidity, %	4.97	4.94	5.43	5.35
Loss on drying, %	3.56	3.57	3.57	3.58
Heavy metals, %	0.0078	0.0079	0.0078	0.0079
Quantitative content of active ingredients, %	9.79	9.81	9.75	9.76

Study of the storage conditions and stability of the recommended Prostad capsules. The shelf life of a medication is the period during which the drug retains its therapeutic properties and meets established standards.

This period is established based on experiments and studies conducted under conditions prescribed by regulations. Over time, as new data is obtained, this period may be adjusted. Various analytical methods are used to determine the shelf life, including chemical, physicochemical, and, if necessary, biological and pharmacological tests.

This article presents data obtained from a study of the stability of the qualitative and quantitative parameters of Prostad capsules. In accordance with the methodology of the State Pharmacopoeia of the Republic of Uzbekistan, the following parameters are used to assess the quality of hard gelatin capsules: description, authenticity, average capsule weight, average weight of capsule contents, disintegration, quantitative determination of biologically active substances, and microbiological purity [2-6].

The initial stage of the study examined the qualitative and quantitative characteristics of the original samples. Qualitative indicators such as appearance, average weight and deviation from it, disintegration, dissolution, and the quantitative content of the active ingredient were assessed in accordance with the State Pharmacopoeia of the Republic of Uzbekistan. Then, in the second stage of the study, the dry extracts were packaged in four types of packaging:

- a jar made of colorless glass (TU-64-228-84), having a plastic lid with a thread, together with a gasket (TU-64-2-250-75) (U-No. 1);

- a jar made of orange glass (BDS-25 according to TU 64-228-84), having a plastic lid with a thread, together with a gasket (TU 64-2-250-75) (U-No. 2);

- contour packaging without cells, made of laminated paper, which is covered with polyethylene TU13-7308001-477-85 (U-No. 3);

- contour packaging with cells, made of PVC film EP-73 and aluminum foil coated with varnish (TU 48-21-270-78) (U-No. 4).

Under normal conditions, the studies were conducted by storing the capsules in the aforementioned packaging on shelves and cabinets in the laboratory. The capsule parameters were determined initially after 3 months, then every 6 months.

The results of stability studies using the natural storage method are presented in Table 4.3.

The "accelerated aging" study was conducted over a period of 276 days. During the experiment, samples were taken for analysis every 46 days, which, according to instruction letter I-42-2-82, corresponds to the same period of time during normal storage [3,4].

The obtained data indicate that Prostad capsules are stable for 3 years. However, during the incubation period of 3 years of storage, the obtained results are within the limits required by the State Pharmacopoeia of the Republic of Uzbekistan. Also, in the 4th year of the study, the disintegration indicator did not meet the requirements of the State Pharmacopoeia of the Republic of Uzbekistan.

A three-year study of Prostad capsules revealed changes in their quality based on disintegration. During this time, other parameters remained unchanged, indicating consistency in the qualitative and quantitative properties of the recommended capsules, both under natural storage conditions and under accelerated aging for 2.5 years.

Based on the above results, the shelf life of the recommended Prostad capsules obtained according to the recommended composition and technology has been established, and the types of packaging used ensure the stability of their qualitative and quantitative indicators for 2.5 years, both in studies using the “accelerated aging” method and when stored under natural conditions.

Table 3

The results of the study of the shelf life of the capsule "Prostad" by the natural method storage at a temperature of $22\pm2\ ^0C$

Indicators for the State Fund of the Republic of Uzbekistan	
Original sample	
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor
Average weight and deviations from the average weight , g , %	0.502 ± 3.35
Disintegration ,	14

minutes								
Solubility , %	88.95							
Quantitative content of active ingredients, %	99.89							
Time	*3 months*				*6 months*			
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.502 ± 3.42	0.502 ± 3.39	0.50 1 ± 3,25	0.502 ± 3.33	0.499 ± 3.29	0.502 ± 3.11	0.50 1 ± 2 , 76	0.498 ± 3.09
Disintegration , minutes	14	14	14	14	1 4	14	14	14
Solubility , %	88.9 3	88.9 6	88.9 4	88.95	88.9 3	88, 89	88, 88	88.9 0
Quantitative content of active ingredients, %	99, 92	99.8 7	99, 91	99, 88	99.8 5	99, 92	99, 90	99.8 7
Time	*12 months*				*18 months*			
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Continuation of Table 4.3								
Average weight and deviations from the average weight , g , %	0.500 ± 3.09	0.500 ± 3.11	0.50 1 ± 2.76	0.499 ± 3.02	0.499 ± 3.33	0.502±2. 45	0.500 ± 2.34	0.498 ± 3.00
Disintegration , minutes	14	15	15	15	1 4	14	15	15
Solubility , %	87.99	88.75	88.54	88.86	88.9 3	88, 8 3	87, 8 9	88.32
Quantitative content of active ingredients, %	99.96	99.92	99, 91	99.97	99.89	99, 9 1	99, 9 6	99.9 7
Time	*24 months*				*30 months*			
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.500 ± 2.21	0.499 ± 2.81	0.502 ± 2.54	0.498 ± 3.86	0.499 ± 3.09	0.499±3. 15	0.501±3.09	0.498 ± 2.74
Disintegration , minutes	16	17	16	17	1 8	17	16	17
Solubility , %	87.99	88.75	88.54	88.86	88.9 3	88, 8 3	87, 8 9	88.32
Quantitative content of active ingredients, %	99.96	99.92	99, 91	99.97	99.89	99, 9 1	99, 9 6	99.9 7
Time	*36 months*				*42 months*			
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.499 ±3.0 1	0.499 ± 2.45	0.500 ± 2.23	0.498 ± 3.86	0.499 ± 2.57	0.499±2. 48	0.499±2.52	0.498 ± 3.02

Disintegration , minutes	19	18	19	18	21	20	22	21
Solubility , %	88.21	88.43	87.98	88.45	88.22	88, 38	88, 09	88.11
Quantitative content of active ingredients, %	99.97	99.98	99.89	99.90	99.92	99.99	99, 9 3	99.95

Table 4

Results of studies on the shelf life of the Prostad capsule

by the "accelerated aging" method at a temperature of 40 ^{0} C

Indicators for the State Fund of the Republic of Uzbekistan								
Original sample								
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.502 ± 3.35							
Disintegration , minutes	14							
Solubility , %	88.95							
Quantitative content of active ingredients, %	99.89							
Time	*3 months*			*6 months*				
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.499 ± 3.65	0.502 ± 3.72	0.50 1 ± 2.34	0.502 ± 2.17	0.499 ± 2.72	0.501 ± 3.56	0.499 ± 2.93	0.49 9 ± 3.28
Disintegration , minutes	14	14	14	14	1 4	14	14	14
Solubility , %	88.9 7	88.9 9	88.9 2	88.89	88.9 0	88, 78	88, 92	88.94
Quantitative content of active ingredients, %	99, 9 7	99.91	99.87	99.94	99.89	99.88	99, 9 2	99.89
Time	*12 months*			*18 months*				
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Continuation of Table 4.4								
Average weight and deviations from the average weight , g , %	0.499 ± 3.12	0.501± 2.94	0.498 ± 3.56	0.499 ± 3.54	0.499 ± 3.78	0.499±3.22	0.501 ± 2.11	0.49 9 ± 3.08
Disintegration , minutes	15	15	16	15	1 5	15	16	15
Solubility , %	88.28	88.11	87.99	88.74	88.31	87, 74	88, 15	87.55
Quantitative content of active ingredients, %	99.87	99.74	99, 9 5	99.92	99.87	99.89	99.96	99.85
Time	*24 months*			*30 months*				
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.501 ± 2.55	0.499 ± 3.32	0.499 ± 2.93	0.499 ± 3.46	0.499 ± 2.74	0.499±3.22	0.499±2.79	0.49 9 ± 3.15
Disintegration , minutes	17	17	16	17	1 7	18	17	18
Solubility , %	88.32	88.28	88.17	88.44	88.52	88, 62	88, 91	87.66
Quantitative content of active ingredients, %	99.91	99.89	98, 9 9	99.99	99.78	98, 9 4	98, 9 4	99.88
Time	*36 months*			*42 months*				
Package	*No. 1*	*No. 2*	*No. 3*	*No. 4*	*No. 1*	*No. 2*	*No. 3*	*No. 4*
Appearance	White gelatin capsules, the encapsulated mass is pale brown in color with inclusions and a peculiar odor							
Average weight and deviations from the average weight , g , %	0.499± 3.01	0.499 ± 2.45	0.500 ± 2.23	0.498 ± 3.86	0.499 ± 2.57	0.499±2.48	0.499±2.52	0.498 ± 3.02

Disintegration , minutes	19	18	19	19	22	22	23	23
Solubility , %	87.56	88.11	88.09	87.78	87.59	88, 91	87, 87	87.90
Quantitative content of active ingredients, %	99.96	99.91	99.84	99.87	99.81	99.82	99.79	99.92

CONCLUSIONS

This section of the dissertation presents the results of the final studies on the development of drug technology.

Biopharmaceutical studies and studies to determine the stability and conditions of the recommended drugs were conducted.

Biopharmaceutical studies were conducted using the in method In vitro experiments were performed using a rotating basket apparatus. To select the optimal pH of the dissolution medium, the following dissolution media with different pH values were used: purified water as the neutral medium, 0.1 N hydrochloric acid as the acidic medium, and 0.1 N sodium hydroxide as the alkaline medium. The volume of the dissolution medium in the experimental studies was 500 and 1000 ml.

Based on the obtained results of studying the influence of pH of the medium on the dissolution rate of Prostad capsules, the use of a neutral medium - purified water - is recommended for further research.

In the experiments, the volume of the dissolving medium was set to the amount

1000 ml, which was chosen taking into account the sensitivity of the method we developed for the quantitative determination of active substances.

At a basket rotation speed of 100 rpm, the concentration of active ingredients released into solution within 45 minutes was over 75%, which meets the requirements of the State Pharmacopoeia of the Republic of Uzbekistan. Under these conditions, active substance release kinetics were observed according to a first-order equation. Based on this, a basket rotation speed of 100 rpm is recommended for further quality testing of finished products from a biopharmaceutical perspective.

The study to determine the shelf life of recommended medicinal products was conducted using natural storage methods and under “accelerated aging” conditions.

Based on the research results, the shelf life for the dry extract was 2 years and for Prostad capsules 2.5 years.

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