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QUALITY CONTROL OF "MEKSI-SEEM" TABLETS

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Annotation: In this article, the results of scientific research on the quality assessment of the "Meksi-SEEM" tablets recommended for use in neurological disorders are presented [1]. For the first time, the technology of coated tablets was studied based on scientific investigations. The quality indicators of the tablet were evaluated in accordance with the relevant Normative document (ND).
Keywords: "Meksi-SEEM" tablets, quality indicators, appearance, identity, average weight, disintegration, quantitative analysis, dissolution, microbiological purity.

Relevance. One of the pressing tasks for pharmaceutical specialists is to partially meet the domestic market of the Republic of Uzbekistan with high-quality, affordable, and targeted medicinal products. The development of coated tablet formulations and the improvement of their quality, as well as organizing the production of medicinal products according to Good Manufacturing Practice (GMP) guidelines, are among the crucial tasks facing local pharmaceutical enterprises. Currently, the national standard of Uzbekistan — O'zDSt 2766:2018 "Good Manufacturing Practice (GMP)" — has expanded the opportunities for local pharmaceutical manufacturers to align their production with global standards. To evaluate the quality indicators of coated tablets, samples were taken from the finished product and tested according to the PM requirements.

Experimental Part: First, the tablets' appearance, organoleptic properties, were determined. Twenty tablets were taken for testing, and quality indicators were evaluated. Using a caliper, the height and diameter of the tablets were measured. The diameter of the tablets ranged from 8.99 to 9.03 mm ± 0.04 mm, and the height ranged from 3.3 to 3.4 mm ± 0.02 mm. The tablets had a uniform white color, biconvex shape, smooth and even surface, and were not stuck to each other. No excessive markings were found on the surface. The coating material was evenly distributed over the tablet core. The tablets were split in half to verify uniform coating thickness, which was confirmed.

Determination of Identity: The ultraviolet absorption of the solution prepared for quantitative analysis was measured within the wavelength range of 220–380 nm. The highest absorption peaks were recorded at wavelengths of 287 nm and 297 nm.

Determination of Average Mass: The mass of uncoated and coated tablets was measured using an analytical balance with 0.001 g accuracy. The uncoated tablets weighed between 0.246–0.257 g ± 0.02 g. After coating, each of the 20 tablets was individually weighed, ranging between 0.256–0.276 g, with an average mass of 0.259 g.

Determination of Resistance to Abrasion: To determine the resistance to abrasion, 10 uncoated tablets were taken from each sample and weighed with 0.001 g precision. The tablets were placed in a drum-type friabilator rotating 100 times within 5 minutes. After the test, the tablets were dusted and weighed again:

Uncoated tablets:

$$I = \frac{P_2}{P_1} \times 100 = \frac{2492}{2508} * 100 = 99.36 \approx 99\%$$

The friability of uncoated tablets was found to comply with the requirements of the Republic of Uzbekistan Pharmacopoeia, Chapter 2.9.3. [2].
Disintegration Test: This was performed in accordance with the Uzbekistan Pharmacopoeia Chapter 2.9.1. A total of 18 tablets were tested at 37±2°C. Of these, 14 tablets began disintegrating within 20–30 minutes, while the remaining 4 started after 35 minutes. The experiment was repeated three times: in one trial, 10 tablets disintegrated in 17 minutes, 7 in 25 minutes, and 1 in 27 minutes. The results met the pharmacopeial requirements.
Quantitative analysis: The content of the active pharmaceutical ingredient, ethylmethylhydroxypyridine succinate, in the coated tablets was determined by ultraviolet spectrophotometry in accordance with the Uzbekistan Pharmacopoeia (2.2.25).
Method Principle: Ethylmethylhydroxypyridine succinate absorbs ultraviolet light in the 284–297 nm range. Twenty tablets were ground to a fine powder, and exactly 0.250 g of the sample was placed in a 100 ml volumetric flask. Then, 20 ml of 0.01M hydrochloric acid was added and stirred until fully dissolved. The volume was brought up to 100 ml with hydrochloric acid and filtered through filter paper (GOST 12026-76). From the filtrate, 1 ml was taken and diluted to 100 ml with 0.01M hydrochloric acid. The absorbance of the resulting solution was measured using a Beckman DU 65 spectrophotometer at a wavelength of 297±2 nm with a 10 mm cuvette. 0.01M hydrochloric acid was used as the blank solution. The absorbance of the standard solution was measured simultaneously.
The content of ethylmethylhydroxypyridine succinate (X g) in one tablet was calculated using the formula:

$$X = \frac{A_2 \, x \, m \, x \, 1 \, x \, 100 \, x \, 100 \, x \, 250 \, x \, P}{A_1 \, x \, 100 \, x \, 100 \, x \, M \, x \, 1 \, x \, 1000 \, x \, 100}$$

Where:

- **A_2** – optical density of the test solution
- **A_1** – optical density of the standard solution
- **M** – mass of the test sample in grams
- **P** – potency (%) of the standard ethylmethylhydroxypyridine succinate
- **m** – mass of the standard sample in grams

The absorbance of the reference solution was measured, and the average value was calculated. The amount of active ingredient per tablet should be between 0.125 g and 0.127 g. The results are presented in Table 1.

Results of the Quantitative Determination of the Active Pharmaceutical Ingredient in Tablets
Table 1

№	Sample Mass Taken (g)	Absorbance Value	Determined API Content (g)	Content, %
1	0.2580	0.458288	0.1244	0.9952
2	0.2596	0.454453	0.1251	1.0008
3	0.2583	0.457005	0.1246	0.9968
4	0.2598	0.453367	0.1253	1.0024
5	0.2578	0.460317	0.1240	0.9920
6	0.2596	0.454453	0.1251	1.0008
7	0.2585	0.453368	0.1252	1.0016
8	0.2585	0.456093	0.1247	0.9976
9	0.2579	0.459392	0.1242	0.9936
10	0.2580	0.458288	0.1244	0.9952

11	0.2585	0.456093	0.1248	0.9984
12	0.2587	0.455909	0.1248	0.9984
13	0.2587	0.455909	0.1248	0.9984
14	0.2583	0.457005	0.1246	0.9968
15	0.2579	0.459392	0.1242	0.9936

Results and Discussion: Determination of the Active Pharmaceutical Ingredient in Tablets. The analysis results indicate that the amount of active pharmaceutical ingredient (API) present in the tablet meets the requirements of the relevant regulatory documentation. Based on the obtained results, it can be concluded that the proposed spectrophotometric method is suitable for quantitative analysis of the tablet content and provides satisfactory result 3].

In Vitro Evaluation of the Bioavailability of Meksi-SEEM Tablets.

It is well known that the release rate of active substances from solid dosage forms, including tablets, depends on several factors such as the excipients used, the pH of the dissolution medium, and the rotation speed of the paddle. To develop a scientifically based dissolution test to evaluate the therapeutic effectiveness of tablets by in vitro methods, it was necessary to study the effect of paddle rotation speed on the release rate of the active ingredient. The release rate of the active substance from the tablets was investigated. According to the results of the experiments, when using 0.01 M hydrochloric acid as the dissolution medium and a paddle rotation speed of 100 rpm, more than 75% of the active substance was released within 45 minutes. The absorbance of the resulting solution was measured using a “Beckman” DU-65 spectrophotometer at a wavelength of $\lambda = 352 \pm 2$ nm using a 10 mm path length cuvette. A reagent mixture without the active ingredient was used as a blank solution.

Dissolution. Dissolution is a critical parameter for evaluating the release rate and extent of the active substance from the dosage form in the body. The dissolution test of Meksi-SEEM tablets plays a significant role in quality control and in the evaluation of bioequivalence.

Determination of Dissolution Rate and Amount of Meksi-SEEM Tablets under Standard Conditions

Equipment and Reagents:

- USP Dissolution Tester (paddle method)
- UV-Vis spectrophotometer
- 0.1 M HCl solution or phosphate buffer solution (pH 6.8)
- Water bath (37 ± 0.5°C)
- Stopwatch, test tubes, filters

Test Conditions:

- Dissolution medium volume: 900 ml
- Temperature: 37 ± 0.5°C
- Paddle speed: 50 rpm
- Sampling times: 5, 10, 15, 30, 45, 60 minutes
- Wavelength (λ): 284 nm

Test Procedure and Evaluation: The dissolution of the tablets is evaluated based on the criterion that at least 75% of the active substance should be released within the first 45 minutes. The test was performed on at least 5 tablets.

Calculation Formula:

$$X = \frac{A_2 \, x \, m \, x \, 1 \, x \, 900 \, x \, 100 \, x \, 250 \, x \, P}{A_1 \, x \, 100 \, x \, 100 \, x \, M \, x \, 1 \, x \, 1000 \, x \, 100} =$$

$$\frac{0.366*0.139*1*900*100*250*100}{0.457*100*100*0.25*10*1000*100} = 0.10019 = 80.15\%$$

Dissolution testing was conducted on five tablet samples, and the results were averaged.

Dissolution Results of Meksi-SEEM Tablets
Table 2

№	Amount of Active Ingredient (g)	Amount of Released Active Ingredient (%)
1	0.0944	75.5
2	0.0955	76.42
3	0.0980	78.4
4	0.0999	79.9
5	0.1000	80.15
6	0.1000	80.15

According to the obtained results, the average dissolution rate of the tablets was **77.92%**.
Microbiological Purity: The microbiological purity of the tablets was evaluated in accordance with the requirements for non-sterile pharmaceutical products as outlined in Volume I of the State Pharmacopoeia of Uzbekistan. The results confirmed compliance with the specified standards.
Discussion: For the first time, the quality indicators of the newly developed Meksi-SEEM tablets were scientifically evaluated in accordance with the requirements of the State Pharmacopoeia. The obtained results demonstrate the potential for standardization of the tablets [3].

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