DETERMINING THE QUALITY INDICATORS OF THE KLAVIS TABLET

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ABSTRACT

Antibiotic therapy and gastroprotectors play a key role in the treatment of Helicobacter pylori infection. Specifically, for the effective eradication of Helicobacter pylori, the macrolide antibiotic clarithromycin and bismuth tricalcium disitrate, which effectively affects the flame bacterium surrounding the gastric mucosa, are widely used, which ensures high efficacy in combination therapy.

Relevance: Antibiotic therapy and gastroprotectors play a key role in the treatment of Helicobacter pylori infection. Specifically, for the effective eradication of Helicobacter pylori, the macrolide antibiotic clarithromycin and bismuth tricalcium disitrate, which effectively affects the flame bacterium surrounding the gastric mucosa, are widely used, which ensures high efficacy in combination therapy.

In this regard, in today's rapidly developing pharmaceutical industry, special attention is paid to ensuring the quality, safety, and therapeutic efficacy of antibiotic-based drugs.

Purpose of the study: The primary objective of this study is to determine the quality indicators of the combined "Klavis" tablets, created based on the substance of clarithromycin belonging to the antibiotic group, using modern pharmaceutical analysis methods and to scientifically evaluate their compliance with the requirements of current regulatory documents.

The quality indicators of the "Klavis" tablet were evaluated in accordance with the requirements of the first edition of the State Pharmacopoeia of the Republic of Uzbekistan. Specifically, indicators such as appearance, authenticity, average tablet weight, decomposition, dissolution, and microbiological purity were determined.

Results: The appearance of "Klavis" duplex tablets is evaluated visually. White or almost white, round, flat cylindrical tablets with slanted edges.

The mass of each tablet should not deviate from the average mass by more than ± 5%. A maximum of 2 tablets may deviate from this norm, but none of them must differ from the average mass by more than ±10%. The average mass of the "Klavis" duplex tablets and deviations from it were evaluated based on pharmacopoeia requirements. According to the

study results, the average mass for tablets with a dosage of (500 mg clarithromycin + 240 mg bismuth tricalcium disitrate) was 1000 mg, with a relative deviation of ±2.43% (1024.3–975.7); these values were within the permissible range of ±5%.

Determination of cleavage is carried out in accordance with the requirements of the General Pharmacopoeia Article "Cleavage of Tablets" of the State Pharmacopoeia (DF RUz, 2.9.1).

To determine the decomposition of bismuth-tricalyum disitrate, the laboratory identifier is filled with a 0.1M hydrochloric acid solution at a temperature of 37 ± 2 °C. The laboratory identifier is triggered and the tablets are observed to decompose.The tablets must be completely decomposed within 15 minutes in a 0.1M hydrochloric acid medium. The upper part of the tablet disintegrated in 9 minutes and 36 seconds.

To determine the decomposition of clarithromycin, the laboratory identifier is filled with a phosphate buffer solution with a pH of 6.8, preheated to a temperature of 37 ± 2 °C. The laboratory identifier is triggered, and the tablets are observed to decompose. The tablets must be completely decomposed within 60 minutes in a phosphate buffer solution with a pH of 6.8. Due to the fact that the core part of the duplex tablet is covered with an intestine-soluble shell, it decomposed in 42 minutes and 53 seconds.

The authenticity of the "Klavis" tablet is verified for each active substance in its composition. According to the results obtained, the chromatogram showed the same retention time of the test solution as the standard solution of clarithromycin. The conducted qualitative reactions for bismuth tricalcium disitrate fully complied with the requirements of the State Pharmacopoeia of the Republic of Uzbekistan. Microbiological purity indicators also met regulatory requirements; the total number of bacteria did not exceed 1000 CFU/g, and no Escherichia coli were detected.

Conclusions. According to the results of the conducted research, it was established that the qualitative and quantitative indicators of "Klavis" tablets fully comply with the requirements of the 1st edition of the State Pharmacopoeia of the Republic of Uzbekistan.