



From 18.04.2024 № 11/075-5
To _____ № _____

**To the heads of medicine quality
control laboratories**

Regarding the 19th round
of the Professional Testing Scheme

Dear colleagues,

The 19th round of the Professional Testing Scheme of Medicines Quality Control Laboratories, organized by the Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines with the support of the State Service of Ukraine on Medicines and Drugs Control, will be held from April 19, 2024.

Participation in external independent testing programs is an important and mandatory element of the quality assurance system of analytical laboratories following ISO and GMP/GLP requirements. Since 2001, eighteen PTS rounds have been successfully conducted, in which interested laboratories of the pharmaceutical industry participated.

The 19th round of the Professional Testing Program continues the topic of controlling the uncertainty of the analytical system as a whole and evaluating the analyst's work when performing standard analysis operations.

Information about each participant's test results is confidential. Participants receive a certificate of participation in PTS and report on test results, which provide a critical analysis of obtained test results, investigate the causes of problems, and provide recommendations for their elimination.

In the 19th PTS round, participants are offered the following tasks:

1) Work of an analyst with a volumetric flask.

The participant in the round is provided with a 100.0 ml test measuring flask containing a volume with a certified value (known only to the provider). The precision of the flask filling to the volume and the deviation of the contained volume from the certified value are evaluated.

The participating laboratory can involve up to five analysts in this test (paid as per one participant).

2) Quantitative determination of an analyte in solution by liquid chromatography.

The participant in the round is provided with two test solutions of metronidazole, which simulate the pharmaceutical finished product, and a liquid chromatography quantification

procedure (State Pharmacopoeia of Ukraine (SPhU), 2.2.29). The correctness of the laboratory's conclusion regarding the compliance of the metronidazole content with the given specification ($\pm 5\%$ from the nominal value) is evaluated.

Test samples for the task "Quantitative determination of an analyte in solution by liquid chromatography" are provided in the amount for one test. An additional set of samples for testing more than one analyst can be purchased by the laboratory for an additional fee.

Acceptability criteria for test results are established based on SPhU recommendations for the maximum permissible uncertainty of quantitative tests (target uncertainty, U^{ts}).

Information about each participant's test results is confidential. Participants receive a certificate of participation in the PTS round and report on the results of the test, which provides a review of the obtained test results, investigates the causes of problems, and provides recommendations for their elimination.

To participate in the 19th round of PTS, it is necessary to fill out the [Application form](#) and send it to the Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines at the email: svetl.chikalova@gmail.com. The organizational fee for participation in the 19th PTS round is:

No	Test task	Price
1	Work of an analyst with a volumetric flask	\$360
2	Quantitative determination of analyte in solution by liquid chromatography	\$380
	An additional set of samples	\$130 /per unit

Please, regarding payment and delivery of samples, contact the official distributor:

"FK"BIOTEK" Ltd

7, Poshtovyi alley, Kharkiv, 61001, Ukraine

Tel.: [+38 050 3640331](tel:+380503640331)

Email: akv0503640331@gmail.com

Representative:

Kostiantyn Adrianov

Ph.D. in Pharmacy

Test samples/flasks will be mailed upon receipt of the application and payment of the organizational fee.

The test results should be sent to the organizers electronically (in PDF) at svetl.chikalova@gmail.com.

Deputy Director for Science



Dmytro LEONTIEV

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