



14<sup>th</sup> INTERNATIONAL MEETING OF THE  
WORLD PHARMACOPOEIAS (IMWP)

Hybrid meeting  
Mexico City, Mexico  
08-10 November 2023



# The State Pharmacopoeia of Ukraine (SPhU)

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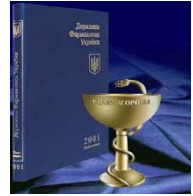
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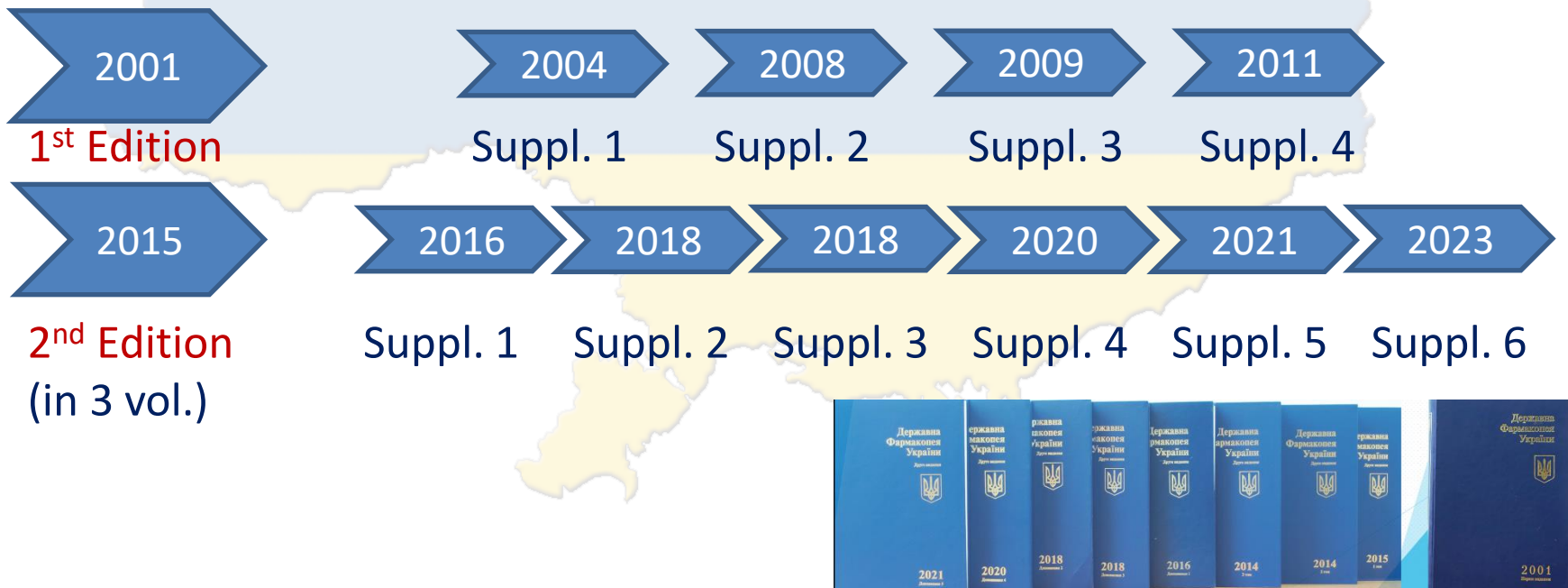
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# The State Pharmacopoeia of Ukraine

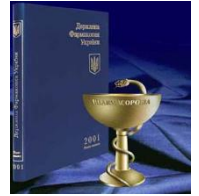


a legal document that contains binding requirements for the quality of medicines manufactured, stored, controlled and used in Ukraine

➤ 1<sup>st</sup> national pharmacopoeia among post-soviet countries



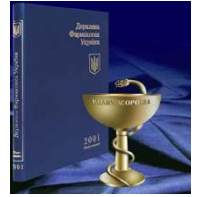
# Overview



## Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines (USPCQM)

- Leading scientific non-profit self-funded institution for standardization and quality control of medicinal products in Ukraine
- Founded by the order of the Ministry of Health of Ukraine on March 19th, 1992

# USPCQM: Mission



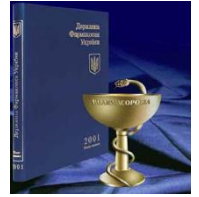
**Meeting the needs of society for effective, safe and high-quality medicinal products**

through:

- Elaboration of the State Pharmacopoeia of Ukraine (SPhU)
- Metrological support for pharmaceutical analysis
- Establishment of national system of reference standards
- Organisation of proficiency testing programs
- Quality control of medicines
- International cooperation
- Expert advice and professional training

The Quality Management System is certified for compliance with the requirements of ISO 9001:2015, IDT

# SPhU: metrological support for pharmaceutical analysis



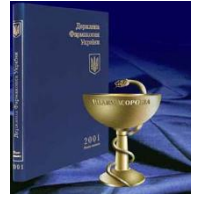
- Implementation of the uncertainty concept that rests on the pharmacopoeial standardization rules
- Development of the requirements for the target uncertainty for the basic pharmacopoeial tests

SPhU metrological concept has been applied to:

- Validation of analytical procedures
- Certification of reference standards
- Qualification of analytical instruments
- Proficiency testing schemes
- Quality assurance of measurement results

Standardized validation schemes for basic pharmacopoeial tests have been developed and introduced in the SPhU (*incl. criteria*)

# SPhU: standardized validation schemes



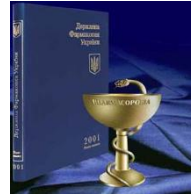
- assay using one concentration of an RS
- assay using a calibration curve
- assay by spectrophotometry using specific absorbance
- assay by titrimetry
- assay in the study of bioequivalence *in vitro* (dissolution profiles)
- assay for the tasks of cleaning validation
- determination of related impurities in finished drugs by instrumental chromatographic methods
- control of residual solvents

Criteria related to the target uncertainty are justified for all validation performance parameters

**Example:** validation characteristic - linearity.

Requirements are set for intercept, slope, residual SD, correlation coefficient

# SPhU: Reference Standards



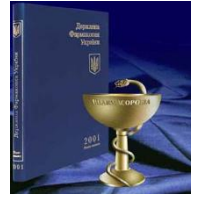
- combine the pharmacopoeial status and features characteristic of CRMs
- suitable for pharmacopoeial and non-pharmacopoeial quality control tasks
- can be certified regardless of the availability of a pharmacopoeial monograph
- **5.12<sup>N</sup>**: metrological rationale and criteria for certification and use of SPhU RSs
- certificate: all information for users to make a well-founded decision about the SPhU RS suitability

## Certificate:

- **intended use** (tests, assays, analytical methods)
- **assigned value** and its **maximum permissible uncertainty** (for quantitative RS)
- minimum test portion that provides sufficient **homogeneity** of the SPhU RS (if necessary)
- **expiry or re-certification date**
- **certification details**



# Proficiency Testing Schemes (PTS)



**Official PTS provider in Ukraine:** USPCQM (since 2004)

**Specificity:** requirements for the assessment of participants' results are set based on the **target uncertainty** for the given test

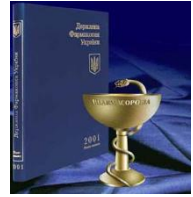
PTS test items are certified in the same way as SPhU RSs

**2001-2023:** 18 PTS rounds, approx. 60 participants in each round

**PTS as Feedback to the Pharmacopoeia:** a number of important practical recommendations have been introduced to the SPhU as a result of the PTS



# SPhU: international cooperation



**1998** Ph. Eur. Observer,  
approval to use Ph. Eur. texts



**2013** Ph. Eur. Member

**2010** A voting organizational member of USP Convention,  
Grant of Rights to Copy and Adapt the USP-NF (for 10 yrs.)  
(extended for another 10 years in 2021)



**2013** Co-operation agreement with MHRA (for 5 yrs.)



**2017** MoU with MHRA (for 5 yrs.)

**2023** Co-operation agreement with MHRA (for 5 yrs.)



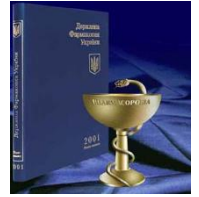
**Grant to use  
BP texts**

**2023** Permission to use DAB and GHP texts



Bundesinstitut  
für Arzneimittel  
und Medizinprodukte

# SPhU: concept



Translation of the Ph. Eur. texts

may be supplemented with national parts

National texts

## National parts

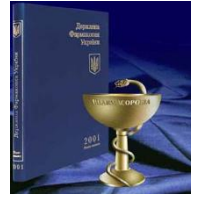
- do NOT contradict the Ph. Eur.
- provide additional information and recommendations for users

## National texts

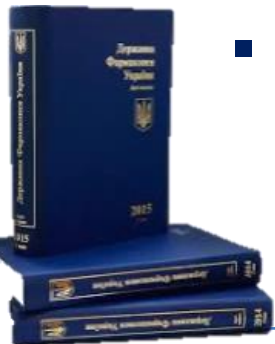
- address the needs of the Ukrainian pharmaceutical sector
- contribute to the quality and safety of medicines in Ukraine

The introduction or revision of texts is carried out in accordance with the corresponding changes in the Ph. Eur. and/or on the basis of acquired or enhanced knowledge, experience and scientific progress.

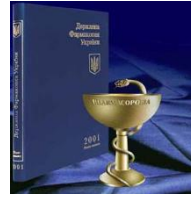
# SPhU: some national texts



- Statistical analysis of chemical test results
- Validation of analytical procedures and tests
- Cosmetic products
- Mesenchymal stem cells for human use
- Mesenchymal stem cells for use in veterinary medicine
- Compounding pharmaceutical preparations
- Metrological aspects of the certification and use of reference standards of the State Pharmacopoeia of Ukraine



# SPhU: contributors



**Developer:** USPCQM

**Scientific management:**

- Director, Deputy Directors, SPhU Department Head

**Operational management:**

- Experts in the research fields

**Experimental support:**

- Pharmacopoeial Analysis Lab
- Validation and Reference Standards Department
- Department of experimental support for the development of monographs on herbal medicines

# Thank you for your attention

