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# DEVELOPMENT OF A DRAFT PHARMACOPEIA ARTICLE FOR SUBSTANCES

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**Annotation:** this research work pharmaceutical substances for pharmacopoeia article project work to go out dedicated is a medicine of the means quality , safety and efficiency in providing important to the point owner was normative documents preparation issues cover takes . The current on the day local pharmaceuticals industry development , import instead pusher medicine tools work to release and the population qualitative and safe medicine drugs with provision current from tasks one This is considered point out of sight pharmaceutical substances for modern to the requirements answer giving pharmacopoeia articles work exit in the name of Allah importance profession will do .

During the research, the appearance, solubility, physicochemical properties, purity, foreign impurities, moisture content, residual organic solvents, and quantitative analysis parameters of the substance were studied. Modern physicochemical methods were used in the analysis, including high- performance liquid chromatography (HPLC), ultraviolet spectrophotometry, titrimetric and chromatographic methods. Based on the results obtained, the quality parameters of the substance were evaluated and their normative limits were determined.

Also, by validating the analysis methods, their specificity, linearity, accuracy, reproducibility and accuracy were evaluated. Validation results confirmed that the analytical methods are reliable and suitable for practical use. Based on the research results, a draft pharmacopoeia article was developed in accordance with the requirements of the current State Pharmacopoeia and international pharmacopoeias.

The developed pharmacopoeia article project serves to standardize pharmaceutical substances, improve their quality control system, and guarantee the quality of drugs prepared by local manufacturers. The results of this research can be widely used in the activities of the pharmaceutical industry, scientific research institutions and control-analytical laboratories.

**Keywords:** Pharmacopoeia article, pH determination, sterility and microbiological purity, therapeutic efficacy, identification, high- performance liquid chromatography (HPLC), ultraviolet spectrophotometry, titrimetric and chromatographic methods

**Introduction.** Pharmacopoeia documents are the main regulatory and legal framework in the pharmaceutical industry for ensuring the quality, safety and efficacy of medicines. A pharmacopoeia article (monograph) is an official regulatory document containing established quality indicators, analysis methods, storage conditions and control criteria for a particular medicinal product, substance or excipient.

Pharmacopoeia articles are divided into several main types according to their content and scope:

General monographs - these types of articles define test methods, laboratory techniques, reagents, equipment, and control principles that are common to all drugs. For example, tests such as loss on drying, ash content, pH determination, sterility, and microbiological purity are covered in general articles.

Specific (individual) pharmacopoeial articles are dedicated to a specific drug or pharmaceutical substance and contain all the quality indicators specific to that product. They clearly define identification tests, quantitative analysis, purity criteria, solubility, stability, and storage conditions.

Provisional pharmacopoeial articles are developed temporarily for newly developed or newly introduced drugs. These articles will later be brought into line with the full pharmacopoeial standards.

Regional and national pharmacopoeia articles - some pharmacopoeia systems have special monographs developed at the regional or national level, which serve to meet the needs of local pharmaceutical production and control.

The main function of pharmacopoeial articles is to standardize and control the quality of pharmaceutical products. They are important for the following reasons:

all manufacturers;
guarantees the safety of medicines;
serves to ensure therapeutic efficacy;
eliminates quality differences between products ;
international trade and export processes.

At the same time, pharmacopoeial articles act as a bridge between scientific research and industrial production.

**Aim of the study:** The main function of pharmacopoeial articles is to standardize and control the quality of pharmaceutical products. They are important for the following reasons:

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**Materials and methods:** The Pharmacopoeia article is based on scientifically sound, accurate and reproducible standards. It includes the following main sections:

appearance and physical description;
identification (authenticity) tests;
determination of purity and impurities;
moisture content or drying loss;
quantitative analysis (amount of active ingredient);
solubility and physicochemical properties;
microbiological cleanliness requirements;
storage conditions and stability;
packaging and labeling requirements.

These requirements allow for quality control throughout the entire life cycle of a drug.

**Results:** Pharmacopoeia articles are a key component of the pharmaceutical quality assurance system. They allow for quality control at all stages of production - from the selection of raw materials to the release of the finished product.

Pharmacopoeia requirements:
Supports GMP (Good Manufacturing Practice) principles;
evaluates the stability of the product on a scientific basis;
ensures uniformity of quality control;
guarantees consumer safety.

Therefore, pharmacopoeial documents are not only a means of laboratory control, but also the normative basis of the entire pharmaceutical system.

Currently, there are several major national and regional pharmacopoeia systems in the world, which play an important role in shaping global pharmaceutical standards.

The United States Pharmacopoeia is one of the most authoritative pharmacopoeias in the world. It is recognized not only in the United States, but also in many other countries. The USP sets comprehensive standards for pharmaceutical substances, biological products, and food additives.

The European Pharmacopoeia is maintained by the Council of Europe and forms a single pharmacopoeial system for the member states of the European Union. It establishes uniform quality standards for pharmaceutical products and ensures regional integration. The British Pharmacopoeia is a set of official standards of the pharmaceutical system of Great Britain, which is also used in many Commonwealth countries.

the World Health Organization does not publish a complete pharmacopoeia, it develops model pharmacopoeias and guidelines that are used to establish international quality standards, especially for developing countries.

The Japanese Pharmacopoeia is among the most advanced pharmacopoeias in Asia and sets clear standards for high-tech pharmaceutical products.

The Chinese Pharmacopoeia is one of the fastest growing pharmacopoeias in the world, combining traditional Chinese medicine and modern pharmaceuticals.

Global pharmacopoeia systems ensure that medicines meet international standards. They:

facilitates international trade;

homogenizes quality;

increases the safety of medicines;

supports scientific research and innovation.

Today, the process of harmonization between pharmacopoeia systems is also actively developing, that is, different state pharmacopoeias are bringing their requirements closer together.

**Conclusion:** Pharmacopoeia articles are an important regulatory and legal basis of the pharmaceutical system and play a key role in standardizing and controlling the quality of medicines and pharmaceutical substances. They serve to ensure the safety, efficacy and consistent quality of medicines. The precise definition of criteria for identification, purity, quantitative analysis, physicochemical properties, microbiological requirements, storage conditions and packaging in pharmacopoeia documents creates a unified system for the production and control of pharmaceutical products.

Pharmacopoeia articles also support GMP principles, ensuring quality control at all stages of production and guaranteeing consumer safety. Modern international pharmacopoeia systems - the United States Pharmacopoeia (USP), the European Pharmacopoeia (Ph. Eur.), British Pharmacopoeia (BP), Japanese and Chinese Pharmacopoeias play an important role in shaping global pharmaceutical standards. Their mutual harmonization allows for the development of international trade, simplification of export-import processes, and unification of the quality of medicines.

In conclusion, the development and improvement of pharmacopoeia articles is of significant scientific and practical importance for the sustainable development of the pharmaceutical industry, increasing the competitiveness of local medicines, and providing the population with high-quality, safe, and effective medicines.

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