The State Pharmacopoeia of the Russian Federation
XII Edition
Part 1

Current state and strategy for the future
Before 12th edition of the State Pharmacopoeia of the Russian Federation there were following editions:

1st – 1866 year
2nd – 1871 year
3rd -1880 year
4th – 1891 year
5th – 1902 year
6th – 1910 year
7th – 1925 year
8th -1946 year
9th – 1961 year
10th – 1968 year
11th – 1987 year (1st part), 1990 year (2nd part)

After publication of 11th edition of the State Pharmacopoeia General monographs, Monographs and amendments were enacted. They had the same official status as the State Pharmacopoeia.

In 2007 1st part of 12th edition of the State Pharmacopoeia was developed by the Institute of standardization and quality control of medicinal products “Federal State Budgetary Institution “Scientific centre for expert evaluation of medical products”, with collaboration of “Scientific Research Institute of Pharmacy” Moscow Medical Academy named after I.M. Sechenov (now I. M. Sechenov First Moscow State Medical University) and specialists of leading scientific centers and manufacturing enterprises.

1st part of 12th edition of the State Pharmacopoeia includes monographs of methods of analysis (physical and physicochemical methods), biological tests, reagents, general monographs and monographs for APIs.

Rules of elaborating general monographs and monographs and including them in the State Pharmacopoeia are enacted by Federal Law No. 61-FZ of August 26, 2010.
In accordance with the Federal program “Pharma-2020” strategic aim of Russian pharmaceutical industry is to bring domestic medicinal products to the international pharmaceutical market. For realization this aim it is necessary to harmonize domestic drug quality standards with requirements of leading world pharmacopoeias.

The Centre of Pharmacopoeia and International collaboration is the department of the Federal State Budgetary Institution «Scientific centre for expert evaluation of medical products» Ministry of Health and Social Development of the Russian Federation.

Main areas of activity of the Centre of the Pharmacopoeia and International collaboration:

- Elaborating the State Pharmacopoeia, organizing appropriate studies and elaborating general monographs, monographs and other materials for further including them in the State Pharmacopoeia;
- Collaboration with leading world pharmacopoeias in order to harmonize requirements to quality standards of medicinal products;
- Developing and publishing guidelines in the field of standardization and quality control of medicinal products;
- Establishing domestic bank of reference standards of APIs and impurities and providing them with appropriate documentation;
- Participating in training specialists in the field of standardization and quality control of medicinal products;
- Organizing, holding, participating in conferences, meetings and other events on domestic and international levels.

In 2006 the Russian Federation got status of the observer in the European Pharmacopoeia.

Plan of elaborating new parts of 12th edition of the State Pharmacopoeia is prepared by the Centre of Pharmacopoeia and International collaboration:

- 2011 year – 2nd part, including monographs for finished dosage forms, monographs for APIs, methods of analysis (physical, physicochemical and chemicals methods).
- 2012 year – 3rd part, including general monographs for biologicals and their methods of analysis.
- 2013 year – 4th part, including monographs for herbal products and their methods of analysis.
- 2014 year – 5th part, including monographs for homeopathic products and their methods of analysis.

Elaborating 12th edition of the State Pharmacopoeia is important step in achieving the high quality of domestic medicinal products and key condition for bringing them to the international pharmaceutical market and increasing their competitiveness.
Establishing domestic bank of pharmacopoeial reference standards is another important aim for the national system of standardization and quality control of medicinal products.

**Picture 1.** Structure of departments of Ministry of Health and Social Development of the Russian Federation, engaging in developing the State Pharmacopoeia
Picture 2. Structure of the Centre of Pharmacopoeia and International collaboration