The Latest Progress of Chinese Pharmacopoeia 2020 and Overview of ChP International Cooperation

Chinese Pharmacopoeia Commission

Strasbourg, France

20,February, 2020

国家药典委员会
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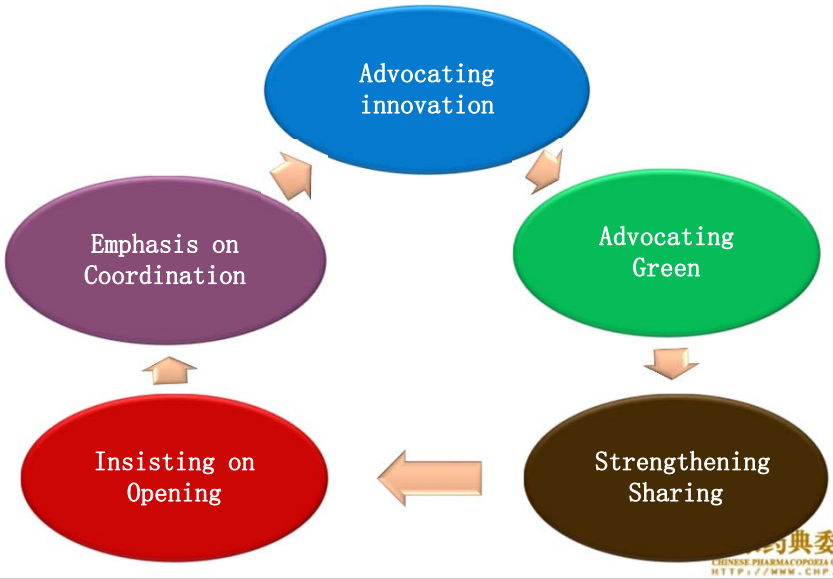
Previous versions of Chinese Pharmacopoeia, ten versions in all

1953 1963 1977 1985 1990 1995 2000 2005 2010 2015

Preparation Outline of Chinese Pharmacopoeia 2020- Guiding Ideology



Preparation Outline of Chinese Pharmacopoeia 2020-Guiding Ideology

Standard procedure

Scientific and rational

Precise process → Precise method → Precise limit → Precise implement action

Advanced and practical

Strict and self-conscious

Progress in Pharmacopeia

- Volume I for TCM
- Volume II for chemical products
- Volume III for biological products
- Volume IV for general chapters, pharmaceutical excipients and drug packaging materials

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Volume I (TCM)

- ✓ **218** medicinal Materia Medica monographs to be revised
- ✓ Added general requirements for heavy metal harmful substances and pesticide residues to more than 500 plant-based medicinal materials
- ✓ Revised 7 vegetable oil and extract standards
- ✓ 117 new monographs and 160 revised monographs in Traditional Chinese Patent Medicines

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Volume I (TCM)

- ✓ In safety control, putting forward the requirement for effective control of the impact of exogenous pollutants and endogenous toxic ingredients on TCM safety
- ✓ In effectiveness control, putting forward the requirement for strengthening the specificity and integrality of standard, and especially carrying out the study of biological assessment and determination method based on the clinical efficacy of TCM

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II. Volume II (Chemical products)

- **117** varieties to be increased and **2385** varieties to be revised
- Safety control

① Further improve the analysis method of impurities and relevant substances

② Promote the application of advanced testing techniques.

③ Especially strengthen the control of toxic and harmful impurities (especially genotoxic impurity) .

④ Strengthen the study of drug safety control items and limit standard.

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II. Volume II (Chemical products)

- Effectiveness control

Reflect the achievement of drug quality and efficacy compliance evaluation in the improvement of quality standard of relevant preparations, and have further improved the dissolution and releasing rate testing method of conventional solid preparations.

III. Volume III (Biological Products)

- ✓ **23** newly increased monographs, **126** revised monographs
- ✓ **4** newly increased and **4** revised general chapters
- ✓ **2** newly increased monographs and **8** revised monographs in the general technical requirements for biological products
- ✓ **14** new general rules for testing methods and **4** revised

III. Volume III (Biological Products)

- ✓Further improve the whole process quality control requirement of biological products.
- ✓Supplement and improve the biological detection technology, method and relevant technical guidelines.

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IV. Volume IV

(General Rules, Excipients and Packaging Materials)

- ✓ 36 general requirements for preparations revised
- ✓ Updated about 15 testing methods and revised 30 methods
- ✓ 10 newly increased guidelines and 11 revised guidelines
- ✓ 65 newly increased standards for pharmaceutical excipients and 212 revised methods

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IV. Volume IV

(General Rules, Excipients and Packaging Materials)

- ✓ 4 newly increased and revised general technical requirements
- ✓ Having increased indicators in functional properties and safety
- ✓ Having updated 16 general testing methods for drug packaging materials

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Harmonization of Chinese Pharmacopoeia and International Standards(ICH)

- ✓ The purpose of ICH coordination is to ensure the safety, effectiveness, quality and international coordination of medicines.
- ✓ The Chinese Pharmacopoeia refers to the relevant requirements of the other Pharmacopoeias in the formulation and revision of the standards.
- ✓ Fully understand the ICH Q4B standard coordination and standard implementation, and achieve a balance of personalization and commonality.
- ✓ Further improve the comprehensive evaluation of the Chinese Pharmacopoeia and ICH Q4B.

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Harmonization of Chinese Pharmacopoeia and International Standards

No.	Testing Methods	Harmonization Situation	Main Differences	Harmonizable
1	Residue on Ignition/Sulphated Ash	Basically the same	sulfuric acid addition, ignition temperature, and conditions at the end of the experiment	●
2	Test for Particulate Contamination: Sub-Visible Particles	Basically the same	method for measuring water for particle inspection, sampling method, and determination result of 100ml labeled amount	○
3	Microbiological Examination of Non-Sterile Products: Microbial Enumerations Tests	Basically the same	the test amount is slightly different, and the method suitability test and fungal counting medium are slightly supplemented	√
4	Microbiological Examination of Non-Sterile Products:Test for Specified Micro-Oganisms	Basically the same	the source of the strains and bile salt-resistant Gram-negative bacteria have different pre-cultivation times, and ChP adds biochemical tests for some control bacteria	√
5	Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use	Basically the same	ChP also includes microbial limit standards for traditional Chinese medicine preparations, traditional Chinese medicine extracts, and some traditional Chinese medicine decoction pieces.	√
6	Disintegration Test	Basically the same	control the temperature, the number of times the basket is lifted, the relevant test parameters, and the results judged	●
7	Uniformity of Dosage Units	the same overall structure	method, determination	●
8	Sterility Test	Basically the same	Strains, test numbers, and flushing amounts are slightly different, which slightly complements the sterility method for biological products	√

Harmonization of Chinese Pharmacopoeia and International Standards

No.	Testing Methods	Harmonization Situation	Main Differences	Harmonizable
9	Tablet Friability	Basically the same	instruments and special dosage forms	○
10	Analytical Sieving	Basically the same	ChP still retains the manual sieving method. ICH makes more detailed regulations on different specifications of sieve types, how to choose a suitable sieve according to the size of the sample, and the weight of the sample	○
11	Bacterial Endotoxins Test	Basically the same	slightly different in method representation	√
12	Dissolution Test	Partially consistent	method, determination. flow cell method not included	●√
13	Test for Extractable Volume of Parenteral Preparations	Basically the same	different sampling methods and specific operations	○
14	Polyacrylamide Gel Electrophoresis	Basically the same	ICH method is more flexible and detailed	○
15	Capillary Electrophoresis	Basically the same	ChP is more explicit (separation mode, equipment)	○
16	Bulk Density and Tapped Density of Powders	Not included		√

Based on experimental research, verification and research work, try to be harmonized with international standards

ChP International Cooperation

Globalization of pharmaceutical circulation --- harmonization of pharmacopoeia standards globally (promoting import and export trade and eliminating technical barriers)

Globalization of pharmaceutical production --- cGMP

Globalization of Drug R & D --- ICH Guidelines

Global synchronization of drug registration declarations

Drug Regulatory Cooperation Globalization --- Information Sharing, mutual recognition of standards

ChP International Cooperation

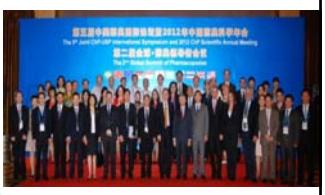
Over the past ten years, we have established good cooperation relationships with pharmacopoeial institutions in various countries or regions

- Signed bilateral memorandums of cooperation to gradually promote the international coordination of drug standards with EDQM,USP,BP,JP, SPRK...
- Chinese medicinal materials, auxiliary materials, packaging materials and biological products standards are being jointly formulated or planned
- FHH (China, Japan, Korea, Singapore, Vietnam, Australia, Hong Kong 6 + 1 International Herbal Forum) Group I: Pharmacopoeia Standard Discussion

ChP International Cooperation -With WHO

ChP International Cooperation -With EDQM

ChP International Cooperation -With USP



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ChP International Cooperation -With BP




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ChP International Cooperation -With JP

ChP International Cooperation -With SPRK

Other international cooperation on pharmacopoeia standards

2019 International Drug Standards Development and Standards Certification was held in Xuzhou City, Jiangsu Province.

Workshop on the Development History of Pharmacopoeias was held in Shandong Province.

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Welcome to the Pharmacopoeia Museum

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Thanks for your attention!

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