



Form 1: Proposal for a new field of technical activity

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Proposer: SAC (China)	ISO/TS/P 259

A proposal for a new field of technical activity shall be submitted to the Central Secretariat, which will assign it a reference number and process the proposal in accordance with the ISO/IEC Directives (part 1, subclause 1.5). The proposer may be a member body of ISO, a technical committee, subcommittee or project committee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the [ISO/IEC Directives \(part 1, Annex C\)](#).

The proposal (to be completed by the proposer)

<p>Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover.)</p> <p>Pharmaceutical preparation machinery</p>
<p>Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)</p> <p>Standardization of pharmaceutical preparation machinery, including terminology, classification, requirements and test methods.</p>

Proposed initial programme of work (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subjects proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.

The subject of the committee is to develop international standards for preparation machinery, so as to meet the need of international trade of preparation machinery manufacturers in various countries. It focuses on the terms and definitions of preparation machinery, classification, requirements (including material requirements, cleaning and disinfection requirements, safety requirements and quality requirements) and test methods.

First, the committee initially plans to develop the following basic standards for preparation machinery:

- 1、 Pharmaceutical preparation machinery -Terms and definitions
- 2、 General rule of pharmaceutical preparation machinery conforming to good manufacturing practice (GMP)

Second, the committee initially plans to develop the standards for the following preparation machinery:

- 1、 Pharmaceutical preparation machinery -Roller compaction dry granulator
- 2、 Pharmaceutical preparation machinery -Rotary tablet press
- 3、 Pharmaceutical preparation machinery -Capsule filling machine

The new TC plans to propose two international standards in three years

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient.)

As shown above

A listing of relevant existing documents at the international, regional and national levels (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)

1. China national standard: GB/T 15692-2008 Terms of pharmaceutical machinery
2. China national standard: GB 28670-2012 General rule of pharmaceutical machinery conforming to good manufacturing practice
3. China national standard: GB/T 28671-2012 Guidelines for pharmaceutical machinery validation
4. China national standard: GB/T 28258-2012 Classification and code for pharmaceutical machinery products
5. China national standard: GB/T 30748-2014 Rotary tablet press
6. China national standard: GB/T 32239-2015 Chinese medicine pill making machine
7. China national standard: GB/T 32237-2015 Spray dryer for the extract of traditional Chinese medicine
8. International standard: Aseptic processing of health care products -- Part 1: General requirements, ISO 13408-1:2008, International Organization for Standardization (ISO)
9. ISO standard: Aseptic processing of health care products -- Part 2: Filtration, ISO 13408-2:2003, International Organization for Standardization (ISO)
10. ISO standard: Aseptic processing of health care products -- Part 3: Lyophilization, ISO 13408-3:2006, International Organization for Standardization (ISO)
11. ISO standard: Aseptic processing of health care products -- Part 4: Clean-in-place technologies, ISO 13408-4:2005, International Organization for Standardization (ISO)
12. ISO standard: Aseptic processing of health care products -- Part 5: Sterilization in place, ISO 13408-5:2006, International Organization for Standardization (ISO)
13. ISO standard: Aseptic processing of health care products -- Part 6: Isolator systems, ISO 13408-6:2005, International Organization for Standardization (ISO)
14. 《Good Manufacturing Practices-Medicinal products for human and veterinary use》, EU
15. 《Good Manufacturing Practice for Pharmaceutical Products》, WHO
16. 《Guide to Good Manufacturing Practice for Medicinal Products》, PIC/S
17. 《Australian Code of Good Manufacturing Practice for Medicinal Products》, TGA
18. 《Current Good Manufacturing Practice for Finished Pharmaceuticals》 Part 211, FDA
19. 《Drug Manufacturing Inspections Program 7356.002》, FDA
20. 《Drug Manufacturing Inspections Program 7356.002-56002A Sterile products manufacture》, FDA
21. 《.Guide to Inspections of Dosage Form Drug Manufacturer's - cGMP's》, FDA
22. 《Guide to Inspections of High Purity Water Systems》, FDA
23. 《Guidance for Industry Sterile Drug Products Produced by Aseptic Processing》, FDA
24. 《Guide to Inspections Validation of Cleaning Processes》, FDA
25. 《Guide to Inspections of Pharmaceutical Quality Control Laboratories》, FDA

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. (The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

There is no existing ISO/TC and IEC/TC covering pharmaceutical preparation machinery. Thus it is urgent to establish a new pharmaceutical preparation machinery TC.

Technical Committees of ISO associated with newly established TC-PPM are: TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, TC 84 Devices for administration of medicinal products and catheters, TC150 Implants for Surgery, TC 198 Sterilization of health care products, TC 199 Safety of machinery, TC209 Cleanrooms and associated controlled environment, TC215 Health informatics, TC249 Traditional Chinese medicine. Technical Committee of IEC associated with newly established TC-PPM are TC 62 Electrical equipment in medical practice and its SCs.

TC 76 is in charge of standards on transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, which scope is: Standardization of containers (such as infusion bottles and bags, injection vials, ampoules, glass cylinders, cartridges, prefillable syringes, etc.) application systems (such as giving sets, non-electrically driven portable infusion devices, blood collection systems, etc.) and accessories for infusion, transfusion, injection and blood processing in blood banks, terms, definitions, requirements and test methods for these devices, specifications and test methods for quality and performance of their materials and components (such as elastomeric closures, caps and ports, pipettes, etc.) and quality management systems for primary packaging materials. The scope of TC 76 does not overlap with that of the newly established TC-PPM.

Scope of TC 84, Standardization of the performance of metered devices and supplies intended for administration of medicinal products, and standardization of syringes, needles and catheters, does not overlap with that of the newly established TC-PPM.

Scope of TC150, Standardization in the field of implants for surgery and their required instrumentation, covering terminology, specifications and methods of tests for all types of implants, and for the materials both basic and composite used in their manufacture and application. Objects or devices which are surgically implanted in the body either temporarily or permanently for diagnostic or therapeutic purposes. TC 150 has a few standards that deal in producing drugs and implants (ISO 14630, 12417) e.g. dealing in safety, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests. The newly established TC-PPM does not include the scope of TC150.

TC 198 is in charge of standards on Sterilization of health care products, which scope is: Standardization of processes and equipment for sterilization of health care products. The newly established TC-PPM does not include the scope of TC 198.

TC 199 is in charge of standards on Safety of machinery, which scope is: Standardization of basic concepts and general principles for safety of machinery incorporating terminology, methodology, guards and safety devices within the framework of ISO / IEC Guide 51 and in cooperation with other ISO and IEC technical committees. The newly established TC-PPM can access the documents of this TC.

TC 209 is in charge of standards on Cleanrooms and associated controlled environments, which scope is Standardization of equipment, facilities, and operational methods for cleanrooms and associated controlled environments. This includes procedural limits, operational limits and testing procedures to achieve desired attributes to minimize micro contamination. Topics of interest are non-viable particles, viable particles, surface cleanliness, room temperature and humidity profiles, airflow patterns and velocities, room vibration profiles, room light levels, room infiltration leakage, personnel procedures, personnel cleanroom clothing, equipment preparation, and any other topics related to optimizing cleanroom operations. Normally this is obligatory for pharmaceutical manufacturing, especially GMP. The newly established TC-PPM can access the documents of this TC.

TC 215 is in charge of standards on Health informatics, which scope is Standardization in the field of health informatics, to facilitate the coherent and consistent interchange and use of health-related

data, information, and knowledge to support and enable all aspects of the health system. TC 215 has a series of documents which do not describe the pharmaceutical manufacturing equipment but do describe a lot of terminology and concepts used in the pharmaceutical area with their IDMP series of documents: pharmaceutical dose form, unit of presentation, route of administration, packaging. The newly established TC-PPM can access the documents of this TC.

Scope of TC 249, Standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of standards. Both traditional and modern aspects of these systems are covered. The committee focuses on quality and safety of raw materials, manufactured products and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices & medicine, but not into the clinical practice or application of those products, does not overlap with that of the newly established TC-PPM.

Scope of IEC/TC 62 and its SCs, To prepare international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment. The newly established TC-PPM can access the documents of this TC and its SCs.

There are no ISO standards on pharmaceutical preparation machinery yet.

The new committee will work closely with related committees in order to identify standardization needs and gaps, and collaborate with other organizations to avoid duplications and overlapping standardization activities.

A listing of relevant countries where the subject of the proposal is important to their national commercial interests.

There are over 20 pharmaceutical preparation machinery producer countries, including Germany, Italy, United Kingdom, USA, France, India, South Korea, Japan, China. Main consumer markets for pharmaceutical preparation machinery are all over the world

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)

ISO/TC76, ISO/TC84, ISO/TC150, ISO/TC194, ISO/TC198, ISO/TC 199, ISO/TC209, ISO/TC215, ISO/TC249, IEC/TC62.

The committee will not pursue subjects within the scope of other TCs including but not limited to ISO/TC76, ISO/TC84, ISO/TC150, ISO/TC194, ISO/TC198, ISO/TC 199, ISO/TC209, ISO/TC215, ISO/TC249, IEC/TC62.

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).

Stakeholders of pharmaceutical preparation machinery refer to producers and consumers that will be affected or may be affected by implementation of pharmaceutical preparation machinery standards. International standards of pharmaceutical preparation machinery will bring the following benefits and impacts to the above stakeholders: consumers will gain access to pharmaceutical preparation machinery with reliable quality and security; the interests of consumers will also be safeguarded.

For producers, these standards will help manufacturing enterprises and small and medium enterprises to improve the technical level of product, so as to make them produce preparation machinery which meets the requirements of international standards and increase exports.

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

If the proposal succeeds, China is willing to undertake the work of secretariat of new TC. The proposer will provide office space, necessary office facilities and staff to the Committee Secretariat and will provide necessary funding to support the activities of the committee.

Purpose and justification for the proposal. (The purpose and justification for the creation of a new technical committee shall be made clear and the need for standardization in this field shall be justified. Clause C.4.13.3 of Annex C of the ISO/IEC Directives, Part 1 contains a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)

With the rapid development of pharmaceutical industry in the world and the continuous emergence of innovative drugs, the volume of international trade of pharmaceutical preparation machinery has increased sharply. Currently, there are more than 20 main producers for pharmaceutical machinery such as Germany, Italy, the United Kingdom (UK), the United States (US), Japan, Korea, India, etc. Consumers of pharmaceutical preparation machinery are almost all over the world. The total global trade volume of pharmaceutical preparation machinery is very huge. However, lack of unified standards has hindered the development of international trade on pharmaceutical preparation machinery.

Quality of pharmaceutical production is directly related to human life and health. Preparation machinery, as the primary machinery for drug production, directly affects the safety and quality of pharmaceutical production. So various countries and regions have strict laws, regulations and Good Manufacturing Practices (referred to GMP), and also have the corresponding requirements for pharmaceutical manufacturing machinery (such as the US CGMP, European EUGMP and GMP promulgated in various countries).

But because of the differences in the level of science and technology and industry, there are different requirements for the safety and quality of pharmaceutical preparation machinery in various countries and region. The pharmaceutical preparation machinery manufacturers must provide products according to their requirements. It increases their costs of production and is harmful to international trade, thus proposes more pressing needs for unifying international standards to ensure the quality of pharmaceutical production, eliminate trade barriers, and reduce cost of international trade.

The new committee will develop relevant international standards and unify the requirements of materials, cleaning and disinfection for pharmaceutical preparation machinery in various countries and regions, so as to ensure the health and safety requirements for producing pharmaceuticals. It will encourage manufacturers to adopt the new technology (such as servo technology, computer control technology, digital technology), so as to improve the technical requirements, such as technological level of products, environmental protection and personnel safety etc. It will meet the requirements of regulatory and manufacturing practices for pharmaceutical preparation machinery in various countries and regions, which will help manufacturing enterprises and SMEs in developing countries to improve the technical level of products, so as to make them produce pharmaceutical preparation machinery which meets the requirements of international trade, and to increase exports.

Signature of the proposer
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Further information to assist with understanding the requirements for the items above can be found [in the Directives, Part 1, Annex C.](#)

Proposal to Establish ISO Technical Committee for Pharmaceutical Preparation Machinery

Since there is no technical committee of standardization (TC or PC) directly related to pharmaceutical preparation machinery in ISO and IEC. China proposes to establish Technical Committee for Pharmaceutical Preparation Machinery (TC-PPM), ISO, as follows:

I. Purpose of Establishing a New TC

A. To meet the needs of international trade

With the rapid development of pharmaceutical industry in the world and the continuous emergence of innovative drugs, the volume of international trade of pharmaceutical preparation machinery has increased sharply. Currently, there are more than 20 main producers for pharmaceutical machinery such as Germany, Italy, the United Kingdom (UK), the United States (US), Japan, Korea, India, etc. Consumers of pharmaceutical preparation machinery are almost all over the world. The total global trade volume of pharmaceutical preparation machinery is very huge. However, lack of unified standards has hindered the development of international trade on pharmaceutical preparation machinery.

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and regions have strict laws, regulations and Good Manufacturing Practices (referred to GMP), and also have the corresponding requirements for pharmaceutical manufacturing machinery (such as the US CGMP, European EUGMP and GMP promulgated in various countries).

But because of the differences in the level of science and technology and industry, there are different requirements for the safety and quality of pharmaceutical preparation machinery in various countries and region. The pharmaceutical preparation machinery manufacturers must provide products according to their requirements. It increases their costs of production and is harmful to international trade, thus proposes more pressing needs for unifying international standards to ensure the quality of pharmaceutical production, eliminate trade barriers, and reduce cost of international trade.

B. To promote technological development in developing countries and SMEs and to increase exports

The new committee will develop relevant international standards and unify the requirements of materials, cleaning and disinfection for pharmaceutical preparation machinery in various countries and regions, so as to ensure the health and safety requirements for producing pharmaceuticals. It will encourage manufacturers to adopt the new technology (such as servo technology, computer control technology, digital technology), so as to improve the technical requirements, such as technological level of products, environmental protection

and personnel safety etc. It will meet the requirements of regulatory and manufacturing practices for pharmaceutical preparation machinery in various countries and regions, which will help manufacturing enterprises and SMEs in developing countries to improve the technical level of products, so as to make them produce pharmaceutical preparation machinery which meets the requirements of international trade, and to increase exports.

II. Relations and differences with relevant existing ISO/TCs

There is no existing ISO/TC covering pharmaceutical preparation machinery. Thus it is urgent to establish a new pharmaceutical preparation machinery TC.

Technical Committees of ISO associated with newly established TC-PPM are: TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, TC 84 Devices for administration of medicinal products and catheters, TC 198 Sterilization of health care products, TC 199 Safety of machinery.

TC 76 is in charge of standards on transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use, which scope is: Standardization of containers (such as infusion bottles and bags, injection vials, ampoules, glass cylinders, cartridges, prefillable syringes, etc.) application systems (such as giving sets, non-electrically driven portable infusion devices, blood collection systems, etc.) and accessories for infusion, transfusion, injection and blood processing in blood banks, terms, definitions, requirements and test

methods for these devices, specifications and test methods for quality and performance of their materials and components (such as elastomeric closures, caps and ports, pipettes, etc.) and quality management systems for primary packaging materials. The scope of TC 76 does not overlap with that of the newly established TC-PPM.

Scope of TC 84, Standardization of the performance of metered devices and supplies intended for administration of medicinal products, and standardization of syringes, needles and catheters, does not overlap with that of the newly established TC-PPM.

TC 198 is in charge of standards on Sterilization of health care products, which scope is: Standardization of processes and equipment for sterilization of health care products. The newly established TC-PPM does not include the scope of TC 198.

TC 199 is in charge of standards on Safety of machinery, which scope is: Standardization of basic concepts and general principles for safety of machinery incorporating terminology, methodology, guards and safety devices within the framework of ISO / IEC Guide 51 and in cooperation with other ISO and IEC technical committees. The newly established TC-PPM can access the documents of this TC.

Scope of TC 249, Standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of

standards. Both traditional and modern aspects of these systems are covered. The committee focuses on quality and safety of raw materials, manufactured products and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices & medicine, but not into the clinical practice or application of those products, does not overlap with that of the newly established TC-PPM.

There are no ISO standards on pharmaceutical preparation machinery yet.

III. Work Plan of the New TC

The subject of the proposed TC-PPM is to develop international standards for pharmaceutical preparation machinery, so as to meet international trade need of pharmaceutical preparation machinery manufacturers in various countries. It focuses of the terms and definitions of pharmaceutical preparation machinery, classification, requirements (including material requirements, cleaning and disinfection requirements, safety requirements and quality requirements) and test methods.

First, the committee initially plans to develop the following basic standards for preparation machinery:

- 1、 Pharmaceutical preparation machinery-Terms and definitions
- 2、 General rule of pharmaceutical preparation machinery conforming to good manufacturing practice (GMP)

Second, the committee initially plans to develop the standards for the following preparation machinery:

- 1、 Pharmaceutical preparation machinery-Dry Granulator
- 2、 Pharmaceutical preparation machinery-Rotary Tablet Press
- 3、 Pharmaceutical preparation machinery-Capsule Filling Machine

IV. Strengthening Global Cooperation

As global pharmaceutical industry rapidly develops, an increasing number of countries and regions join in the production, consumption and trade of pharmaceutical preparation machinery, thus generating a promising international market. The newly established TC-PPM will work with producers, consumers, related ISO/TCs, etc. to strengthen cooperation, develop international standards related to pharmaceutical preparation machinery, and promote global trade.