

ICS 11.120.30

CCS C 90



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 15692-2024

Replacing GB/T 15692-2008

Pharmaceutical machinery - Terms

制药机械 术语

Issued on: May 28, 2024

Implemented on: December 1, 2024

**Issued by: State Administration for Market Regulation;
Standardization Administration of China**

Table of Contents

1 Scope	1
2 Normative references	1
12 Sterilization equipment	21
13 Pharmaceutical film machinery	38
3 Grinding machinery	40
4 Medicinal material drying machinery	44
2 Gas (steam) equipment for pharmaceutical processes	46
9 Pharmaceutical packaging machinery	47
10 Drug testing equipment	50
57 Index	58

Foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting: This document replaces GB/T 15692-2008 "Pharmaceutical Machinery Terminology": Compared with GB/T 15692-2008, except for the structural adjustment and compilation In addition to logical changes, the main technical changes are as follows:

- Deleted the new product design confirmation, design confirmation, verification, installation confirmation, operation confirmation, performance confirmation, and standards for pharmaceutical machinery (equipment) 7 terms in operating procedures (see 2:2 to 2:8 of the:2008 edition);
- Deleted in-situ detection, fully automatic machine, semi-automatic machine, multi-function machine, integrated machine, linkage line, medicine, pharmaceutical excipients, lump materials, medicine 12 terms for packaging, pharmaceutical packaging, and filling (see 2:11 to 2:22 of the:2008 edition);
- Deleted the five terms of sealing, bundling, printing, processing and mothering (see 2:25 to 2:29 of the:2008 edition);
- Fluidized bed reactors, tower reactors, membrane reactors, tubular reactors, microtubular reactors, microchannel reactors and cell 7 terms for culture bioreactors (see 4:1:5 to 4:1:11);
- Added three terms: bottle transfer machine, oscillator, and fermenter (see 4:1:12:2 to 4:1:12:4);

- Deleted mechanical self-priming fermentation tank (see 3:1:5:4 of the:2008 edition);
- Added fermentation system (see 4:1:12:5);
- Deleted the terms immobilized cell fluidized bed fermenter and culture tank (see 3:1:5:11 and 3:1:5:12 of the:2008 edition);
- Added two terms: packed tower and alcohol recovery tower (see 4:2:6, 4:2:7);
- Deleted the terms random packed tower and structured packed tower (see 3:2:5 and 3:2:6 of the:2008 edition);
- The internal circulation crystallizer has been changed (see 4:3:1:5, 3:3:1:4 of the:2008 edition);
- Added centrifuge (see 4:4:1);
- Deleted three-column centrifuge, upper unloading three-column centrifuge, lower automatic unloading three-column centrifuge, direct-connected three-column centrifuge 4 terms for machine (see:2008 edition, 3:4:1:1, 3:4:1:1:1~3:4:1:1:3);

1 Scope

China's national vocabulary for pharmaceutical machinery and equipment - the machines used to make an active ingredient and then to turn it into a dosage form. It defines the terms and the definitions for pharmaceutical machinery and equipment, and it applies to their design, manufacture, distribution, use and supervisory inspection. The document is built in two halves. The first covers the machinery of the active pharmaceutical ingredient plant: the reaction vessels, the columns, the crystallisers, the separation machinery, the extraction and the extraction-and-concentration equipment, the evaporators and concentrators, the distillation equipment, the heat exchangers, the dryers, the storage vessels and the sterilising equipment. The second covers preparation machinery, arranged by dosage form, and it is the longer half: granulating machinery, tablet machinery, capsule machinery, powder injection machinery, small-volume and large-volume injection lines, pill machinery, suppository machinery, ointment machinery, oral liquid machinery, aerosol and spray machinery, ophthalmic preparation machinery and pharmaceutical film machinery. A vocabulary matters more here than in most machine sectors because pharmaceutical equipment is bought against a validation protocol and inspected against GMP, and both the protocol and the inspection are written in words. If the manufacturer, the buyer and the inspector do not mean the same thing by a term, the qualification documents do not demonstrate what they claim to demonstrate. Issued on 28 May 2024 and in force since 1 December 2024, it replaces GB/T 15692-2008.

This document defines the terms and definitions for pharmaceutical machinery and equipment: This document applies to the design, manufacture, circulation, use and supervisory inspection of pharmaceutical machinery and equipment:

2 Normative references

This document has no normative references:

3 General terms

1 Production machinery and equipment used to complete and assist in the completion of pharmaceutical processes: 3:1:

1 Use physical and chemical methods to biologically or chemically transform animals, plants or minerals or change their shapes and properties to produce raw materials machinery and equipment: 3:1:1:

1 Reaction equipmentreactionequipment Under certain conditions, a device that uses biological and chemical methods to achieve transformation between substances and generate new substances: 3:1:1:

2 Tower equipment columnreactor Under certain conditions, the unit operation process of distillation, absorption, desorption, extraction, medium cooling, gas purification, drying, humidification, etc: Tower equipment: 3:1:1:3 A device that allows solutes to precipitate and crystallize by cooling or evaporating a saturated solution to form a supersaturated solution: 3:1:1:

4 Machinery and equipment for classifying and separating suspensions, emulsions, aerosols and solid particle sizes: 3:1:1:

5 Extraction equipmentextractingequipment Equipment that uses the different solubility of different substances in the same solvent to separate the effective components in the material: 3:1:1:

6 Equipment that has both extraction and concentration functions: