

GENERAL NOTICES

1. This is English version of the Japanese Pharmacopoeia Fourteenth Edition, which may be abbreviated as JPXIV or JP 14.

2. Drugs of the Japanese Pharmacopoeia are those specified in the monographs. The official names in the Pharmacopoeia are the title names and the commonly used names adopted in the monographs, provided that in the case of a drug in fine granules which is recognized as powder in the General Rules for Preparations, "powder" may read "fine granules". In the monographs, the titles are accompanied with chemical names or Latin names as occasion demands.

3. Drugs are to be tested according to the provisions given in the pertinent monographs, General Notices, General Rules for Crude Drugs, General Rules for Preparations, and the provisions of General Tests, Processes and Apparatus for their conformity to the Japanese Pharmacopoeia. However, the odor (excepting Crude Drugs), taste (excepting Crude Drugs), crystal form, solubility, acidity or alkalinity, stability, absorbance, congealing point, refractive index, congealing point of fatty acid, optical rotation, viscosity, specific gravity, boiling point, melting point under Description, and storage under the Containers and storage in the monographs on preparations are given for information, and should not be taken as indicating standards for conformity.

When an assurance that a product is of the Pharmacopoeia quality is obtained consistently from data derived from the manufacturing process validation studies, and from the records of appropriate manufacturing process control and of the test results of the quality control, some of the test items in the monograph being performed for the release of a product may be omitted as occasion demands.

4. In the English version, the names of drugs specified in the Japanese Pharmacopoeia begin with a capital letter.

5. The names of drugs or chemicals followed by molecular formulas or constitution formulas in parentheses () designate chemically pure substances. Atomic masses adopted in the Japanese Pharmacopoeia conform to the table of "Standard Atomic Weights 1999". Molecular masses are indicated to two decimal places rounded from three decimals.

6. The following abbreviations are used for the main units.

meter	m
centimeter	cm
millimeter	mm
micrometer	μm
nanometer	nm
kilogram	kg
gram	g
milligram	mg
microgram	μg
nanogram	ng
picogram	pg
Celsius degree	$^{\circ}\text{C}$
square centimeter	cm^2
liter	L
milliliter	mL
microliter	μL
megahertz	MHz
per centimeter	cm^{-1}
newton	N
kilopascal	kPa
mole per liter	mol/L
millipascal second	mPa·s
square millimeter second	mm^2/s
mass per cent	%
mass parts per million	ppm
mass parts per billion	ppb
mass per volume per cent	w/v%
volume per cent	vol%
volume parts per million	vol ppm
hydrogen ion concentration	pH
Endotoxin unit	EU

Note: "ppm" used in the Nuclear Magnetic Resonance Spectroscopy (^1H) indicates the chemical shift, and "w/v%" is used in the formula or composition of preparations.

7. The unit used for expressing the potency of medicine is recognized as the quantity of medicine. Usually, it is expressed by a definite quantity of a definite standard substance which shows a definite biological activity, and differs according to each drug. The units are determined, in principle, by comparison with each reference standard by means of biological methods. The word "Unit" used for the articles of this book indicates the unit defined in the Japanese Pharmacopoeia.

8. Standard temperature, ordinary temperature,

room temperature, and lukewarm are defined as 20°C, 15 – 25°C, 1 – 30°C, and 30 – 40°C, respectively. A cold place, unless otherwise specified, shall be a place having a temperature not exceeding 15°C.

The temperatures of cold water, lukewarm water, warm water, and hot water are defined as not exceeding 10°C, 30 – 40°C, 60 – 70°C, and about 100°C, respectively.

The term “heated solvent” or “hot solvent” means a solvent heated almost to the boiling point of the solvent, and the term “warmed solvent” or “warm solvent” usually means a solvent heated to a temperature between 60°C and 70°C. The term “heat on or in a water bath” indicates, unless otherwise specified, heating with a boiling water bath or a steam bath at about 100°C.

Cold extraction and warm extraction are usually performed at temperatures of 15 – 25°C and 35 – 45°C, respectively.

9. To measure the number of drops, a dropping device which delivers 20 drops of Purified Water weighing 0.90 – 1.10 g at 20°C shall be used.

10. The term “in vacuum” indicates, unless otherwise specified, a pressure not exceeding 2.0 kPa.

11. The acidity or alkalinity of a solution, unless otherwise specified, is determined by blue or red litmus paper. To indicate these properties more precisely, pH values are used.

12. The terms in Table 1 are used to express the degree of coarseness or fineness of a powdered medicine.

Table 1

Sieve No.	4	6.5	8.6	18	50	100	200
Nominal designation of sieve	4750 μm	2800 μm	2000 μm	850 μm	300 μm	150 μm	75 μm
Names of the powders which pass through the respective sieves	Coarse cutting	Medium cutting	Fine cutting	Coarse powder	Medium powder	Fine powder	Very fine powder

13. The water to be used in the tests of drugs shall be Purified Water.

14. The name of a solute followed by the word “solution” without indication of the name of the solvent means aqueous solution.

15. The concentration of solution expressed as (1 in 3), (1 in 10) or (1 in 100) means the ratio whereby 1 g of a solid or 1 mL of a liquid chemical dissolved in the solvent will make the total volume into 3 mL, 10 mL or 100 mL, respectively. The liquid mixture indicated as (10:1) or (5:3:1) denotes the mixture of 10 and 1

volumes of liquids, or the mixture 5, 3 and 1 volumes of liquids, respectively.

16. The term “weigh accurately” means to weigh down to the degree of 0.1 mg, 0.01 mg or 0.001 mg according to the sensitivity in the balance to be used, and the term “weigh exactly” means to weigh to the given decimal places.

17. A value of n figures in a test of a drug shall be obtained by rounding from a value of $(n + 1)$ figures.

18. Unless otherwise specified, all tests of the drugs shall be performed at ordinary temperature and observations of the results shall follow immediately after the operations. However, the judgment for a test which is affected by temperature should be based on the conditions at standard temperature.

19. The terms “immediately” and “at once” used in test of a drug mean that the procedure is to be performed within 30 seconds after the preceding procedure.

20. In the section under the heading Description, the term “white” is used to indicate white or practically white, and “colorless” denotes colorless or practically colorless. Unless otherwise specified, the test of color is carried out by placing 1 g of the solid drug on a sheet of white paper or in a watch glass placed on white paper. Liquid drug is put into a colorless test tube of 15-mm inside diameter and is observed in front of a white background through a layer of 30 mm. For the test of clarity of a liquid drugs the same procedure is applied with either a black or white background. For the observation of fluorescence of a liquid drug, only a black background shall be used.

21. In the section under the heading Description, the term “odorless” is used to indicate odorless or practically odorless. Unless otherwise specified, the test of odor shall be carried out by placing 1 g of the solid drug or 1 mL of the liquid drug in a beaker.

22. In the section under the heading Description, solubilities are expressed in the terms in Table 2. Unless otherwise directed, solubility means the degree of dissolution of drug, previously powdered in the case of a solid, within 30 minutes in a solvent at $20 \pm 5^\circ\text{C}$, by vigorous shaking for 30 seconds each time at 5-minute intervals.

Table 2

Descriptive term	Solvent required for 1 g or 1 mL of solute
Very soluble	Less than 1 mL
Freely soluble	From 1 mL to 10 mL
Soluble	From 10 mL to 30 mL
Sparingly soluble	From 30 mL to 100 mL
Slightly soluble	From 100 mL to 1000 mL
Very slightly soluble	From 1000 mL to 10,000 mL
Practically insoluble or insoluble	10,000 mL and over

23. In the test of drug, the description "dissolve" or "miscible" indicates that it dissolves in, or mixes with, in arbitrary proportion, the solvent to form a clear solution or mixture, and the presence of fibers etc. is not permitted unless in extremely minute quantities.

24. Identification is the test necessary to identify the drug or the main ingredients of the drug based upon a specific property.

25. Purity is for detecting contaminants in drugs, and it, as well as other requirements in each monograph, specifies the purity of the drug usually by limiting the kind and quantity of the contaminants. The contaminants which are considered to be the subject of the test are those supposed to contaminate the drug during the course of the manufacturing process or storage, and hazardous contaminants such as heavy metals, arsenic, etc. If substitution by foreign substances or addition of such materials is expected, the corresponding tests are necessary.

26. The term "constant mass" in drying or ignition, unless otherwise specified, means that the mass difference after an additional 1 hour of drying or ignition is not more than 0.10% of the preceding mass of the dried substance or ignited residue. In crude drugs, the difference is not more than 0.25%. However, when the difference does not exceed 0.5 mg in a chemical balance, 0.05 mg in a semi-microbalance, and 0.005 mg in a microbalance, it is considered that the difference is negligible and constant mass has been attained.

27. Assay is the test to determine the composition, the content of the ingredients, and the potency unit of medicine by physical, chemical or biological procedures.

28. The sample quantity for assay indicated with the word "about" means that the weighed quantity of sample may deviate within $\pm 10\%$ of the described amount. The word "dry" in respect of the sample indicates drying under the same conditions, as described in Loss on drying in the monograph.

29. If it is stated that "the tests are specified separately" and no detailed description is given in the monographs, this means that the tests will be specified when the drugs are granted approval based on the Pharmaceutical Affairs Law.

30. In monographs, if the content of an ingredient

determined by Assay is expressed simply as not less than a certain percentage without indicating its upper limit, 101.0% is understood as the upper limit.

31. The test methods of the Japanese Pharmacopoeia can be replaced by alternative methods which give better accuracy and precision. However, where a difference is suspected, only the result obtained by the procedure given in this Pharmacopoeia is effective for the final judgment.

32. The details of the biological test methods may be changed insofar as they do not affect the essential qualities of the test.

33. The container is the device which holds drugs. The concept of a container also includes constituent parts such as the stopper or cap.

34. A well-closed container protects the contents from the invasion of extraneous solids and from loss of the drug under ordinary or customary conditions of handling and storage.

Where a well-closed container is specified, it may be replaced by a tight container.

35. A tight container protects the contents from contamination by extraneous liquids, solids or moisture, from loss of the contents, and from efflorescence, deliquescence, or evaporation under ordinary or customary conditions of handling and storage.

Where a tight container is specified, it may be replaced by a hermetic container.

36. A hermetic container is impervious to any gas and any microbe under ordinary or customary conditions of handling and storage.

37. The term "light-resistant" means that it can prevent transmittance of light affecting in the specified description and quality of the contents and protect the contained medicament from the light under ordinary or customary conditions of handling, transport, and storage.

38. In the drugs of the Japanese Pharmacopoeia, when the contents or potency in terms of units of the active ingredient(s), or the expiration date is specified in the monographs, these statements should be shown on the immediate container or wrapping. When labeling of items such as the origin or numerical value is indicated in particular, these items should be labeled definitely on them.