NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Standard for fundamental terms of pharmaceutical engineering

医药工程基本术语标准

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1 General provisions

1.0.1 The standard was drawn up in order to unify the fundamental terms of pharmaceutical engineering and their definitions, to standardise the professional vocabulary, to help technical exchange in pharmaceutical engineering and to advance pharmaceutical engineering technology.

1.0.2 The standard applies to the planning, design, construction, acceptance, quality inspection and qualification of newly built, rebuilt and extended pharmaceutical works.

1.0.3 Besides the provisions of this standard, the fundamental terms of pharmaceutical engineering shall also meet the relevant current national standards.

2.1 Production

The clause is divided into five groups, printed with the headings I active pharmaceutical ingredient production, II preparation production, III traditional Chinese medicine production, IV biological fermentation and V others.

2.1.1 Active pharmaceutical ingredient (API): any substance or mixture of substances used

in the manufacture of a medicinal product which, when so used, becomes an active ingredient of that product; such a substance has pharmacological activity or another direct effect in the diagnosis, treatment, relief of symptoms, handling or prevention of disease, or can affect the function or structure of the body.

2.1.2 Bulk pharmaceutical chemicals (BPC): a pharmacologically active ingredient produced by a one step or multi step chemical reaction route.

2.1.3 API intermediates: chemical raw materials or chemical products used during the synthesis of a medicinal product in order to carry the process forward, so as to reach the final synthesised drug, that is intermediate products.

2.1.4 API starting materials: a raw material, intermediate or active pharmaceutical ingredient used in the production of a given active pharmaceutical ingredient and becoming an important structural part of it; the starting material may be an article of commerce, bought from one or several suppliers under contract or commercial agreement, or made in house, and it normally has a well defined chemical nature and structure.

2.1.5 Critical steps: the one or more steps at which failure of the process or contamination would make it impossible to obtain a drug active ingredient of the intended properties and impurity content, or to obtain the intended therapeutic effect.

2.1.6 Dedicated facility: a facility used solely for the production of one active pharmaceutical ingredient or one intermediate.

2.1.7 Multi-use facility: a facility usable for the production of several active pharmaceutical ingredients or intermediates, in which each drug or intermediate is nevertheless handled on a defined production equipment line.

2.1.8 Multi-purpose facility: a facility holding several non dedicated production lines for active pharmaceutical ingredients, on which several products can be made at the same time or in turn.

2.1.9 Dangerous chemicals: highly toxic chemicals and other chemicals that are poisonous, corrosive, explosive, combustible or combustion supporting and are harmful to people, installations and the environment.

2.1.10 Major hazardous resources for dangerous chemicals: a unit, including its site and its facilities, in which dangerous chemicals are produced, stored, used or transported and in which the quantity of dangerous chemicals equals or exceeds the threshold quantity.

2.1.11 Dangerous chemicals production: the production of final products or intermediates listed in the Catalogue of Dangerous Chemicals.

2.1.12 Mother liquid: the residual liquid left after crystallisation or separation.

2.1.13 Preparation, formulation: a medicinal form of the stated specification made from an active pharmaceutical ingredient by a defined preparation process, according to the

pharmacopoeia, a drug standard or another suitable prescription.

2.1.14 Liquid preparation: a liquid medicinal form for internal or external use, made by dispersing the drug in a liquid medium.

2.1.15 Oral solid dosage, solid preparation: a solid medicinal form obtained from the active ingredient by a defined preparation process, such as tablets, capsules, granules, pills and films.

2.1.16 Oral dosage: a medicinal form given by mouth and absorbed through the digestive tract to produce its therapeutic effect.

2.1.17 External preparation: a drug preparation applied to the body surface so as to produce a local or a systemic effect.

2.1.18 Injection, parenteral dosage: a sterile preparation made of the drug with a suitable solvent or dispersing medium, as a solution, emulsion or suspension for injection into the body, or as a powder or concentrated solution to be made up or diluted into a solution or suspension before use; it covers injection solutions, sterile powders for injection and concentrated solutions for injection.

2.1.19 Large volume parenterals (LVPs): injections with a volume equal to or greater than 50 mL, also called large volume infusions.

2.1.21 Small volume parenterals (SVPs): injections with a volume of less than 50 mL.

2.1.23 Aseptic powder for injection: a sterile powder or sterile block made from the drug, to be made up before clinical use with a suitable sterile solution into a clear solution or an even suspension; it may be obtained by solvent crystallisation, spray drying or freeze drying.

2.1.25 Sustained release preparation: a preparation that releases the drug slowly and at a non constant rate in the stated release medium as required, whose dosing frequency is halved or otherwise reduced compared with the corresponding ordinary preparation and which markedly improves patient compliance.

2.1.26 Controlled release preparation: a preparation that releases the drug slowly and at a constant rate in the stated release medium as required, whose dosing frequency is halved or otherwise reduced compared with the corresponding ordinary preparation, whose blood concentration is steadier than that of a sustained release preparation and which markedly improves patient compliance.

2.1.30 Soft capsule, soft gelatin capsule: a capsule in which a measured quantity of liquid drug is sealed directly, or in which a solid drug is dissolved or dispersed in a suitable vehicle to form a solution, suspension, emulsion or semi solid, sealed in a spherical or oval soft capsule shell.

2.1.34 Paste: a semi solid external preparation in which a large quantity of solid powder,

generally more than 25 %, is evenly dispersed in a suitable base.

2.1.73 Herbal medicine granules: a series of pure traditional Chinese medicine products made from traditional Chinese medicine decoction pieces as raw material by modern pharmaceutical techniques of extraction, concentration, separation, drying, granulation and packing; they carry the full therapeutic effect of the original decoction pieces, need no decoction, are safe and hygienic and are convenient to carry and to take.

2.1.81 Medium: an artificially prepared nutrient for the growth and maintenance of micro organisms and of plant and animal tissue, generally containing carbohydrates, nitrogenous substances, inorganic salts including trace elements, growth factors and water.

2.1.83 Biological products: preparations made from micro organisms, cells, animal or human tissue and body fluids as raw material by traditional or modern biotechnology, used for the prevention, treatment and diagnosis of human disease; biological products for human use include bacterial vaccines containing toxoids, viral vaccines, antitoxins and antisera, blood products, cytokines, growth factors, enzymes, in vivo and in vitro diagnostic preparations and other active biological preparations such as toxins, antigens, allergens, monoclonal antibodies, antigen antibody complexes, immunomodulators and micro ecological preparations.

2.1.87 Medicinal gas: a gas or gas mixture given to a patient for the purpose of treating, diagnosing or preventing disease through its pharmacological action, and supplied as a medicinal product.

2.1.88 Oxygen for medical use: oxygen for clinical use meeting the quality standard of the Chinese Pharmacopoeia.

2.2 Process

2.2.1 Inoculation: the process of transferring the target micro organism into the culture medium under aseptic technique requirements.

2.2.2 Cultivation: the process of multiplying animal and plant cells by means of a culture medium.

2.2.3 Fermentation: the process in which organic matter is oxidised and broken down by an organism into oxidation products with release of energy.

2.2.4 Separation: the process of grading and parting a two component or multi component solute or solvent, a liquid solid, gas solid or gas liquid system, or solid particles by size.

2.2.5 Crystallization: the process by which the solute comes out of a supersaturated solution and forms crystals.

2.2.6 Centrifugation: a method that uses differences in density and similar properties, the centrifugal force produced by rotation causing particles or solute to settle, so that they are