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PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国轻工行业标准

QB 2354–2005
Replace QB 2354–1998

Pharmaceutical Gelatino

药用明胶

Issued on Jul 26, 2005 **Implemented on Jan 01, 2006**

Issued by the National Development and Reform Commission (NDRC)

Contents

Foreword

All the technical contents in this standard are mandatory.

This standard is the revision for QB 2354—1998 *Pharmaceutical Gelatin*.

Comparing with QB 2354—1998, this standard is modified as follow:

- Some technical index of pharmaceutical gelatin was adjusted.
- Water content of sample itself was no longer considered for testing.
- Jelly strength was renamed as congelation strength, and transparency was changed to transmittance. The measurement for superoxide, cadmium, staphylococcus aureus were added, and measurement for moisture, congelation strength, ash content, sulfur dioxide, water insoluble, chromium, arsenic, heavy metals, total bacterial count, coli and salmonella were modified;
- The inspection rules, mark, package, transportation and storage were modified .
- Annex A of this standard may be regarded as informative annex.

This standard is proposed by China National Light Industry Council.

This standard is under the jurisdiction by Gelatin Branch of China Daily Chemical Industry Association.

This standard is drafted by China Quality Supervision & Inspection Center for Gelatin and Gelatin Used Product (Beijing), Rousselot (Guangdong) Gelatin Co., Ltd., Qinghai Gelatin Company Limited, Jilin Daan Gelatin Co., LTD., Wenzhou Sanhesheng Gelatin Co., LTD., Sanming Food Additives Factory in Pingyang county of Zhejiang Province, Zhejiang Feipeng Rubber Industry Co., LTD., ShenYu Gelatin Co., LTD in Haian County of Jiangsu, participated in drafting.

This standard was first issued in 1998 and this is the first revision.

Since implementation of this standard, the primary light industry standard QB 2354—1998 *Pharmaceutical Gelatin* is abolished

Pharmaceutical Gelatin

1. Scope

This standard specifies classification, requirements, test method inspection rules and mark, packing, transportation, storage of pharmaceutical gelatin.

This standard is applicable to pharmaceutical gelatin made of animal skin and bone.

2. Normative Reference

The following provisions contain provisions which, through reference in this text, constitute provisions of this standard. For dated reference, subsequent amendments to, or revisions of (excluding corrigendum contents), or Revised Edition do not apply. However, it is encouraged that every part of this standard to research the latest edition of these documents. For undated references, the latest edition of the normative document referred to applies

3. Classifications

Pharmaceutical gelatin is divided into A type, B type (A type is acid gelatin, and B type is alkali gelatin.) and bone kind, skin kind. Each kind is divided into congelation strength of 200 and congelation strength of 100.

4. Requirements

4.1. Raw Material Requirements

4.1.1 It should come from non-epidemic region.

4.1.2 It should come from healthy animals inspected by related departments.

4.1.3 It should not come from factories conducted by noxious substance.

4.1.4 Organic solvent such as benzene should not be used for degreasing.

4.2 Production Process Requirements

Any poisonous and harmful chemicals should not be added in production process.

4.3 Sensory Requirements

4.3.1 Product is light yellow or yellow grain, should keep dry, clean and even, without inclusion.

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