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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 1790-2012

Replacing GB 1790-2003

Medicinal vaseline

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(English Translation)

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Foreword

The standard Chapter 6, Chapter 7 (except for test methods) are mandatory, the rest are recommended.

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

This standard replaces GB 1790-2003 "medicine Vaseline." The main differences between this standard and GB 1790-2003 are as follows.

--- Added "Terms and Definitions", "characteristics" and "recognition" chapter (see 5 and 6);

--- Increasing the "look" technical requirements (see 7);

--- Remove the "characters", "UV absorbance," "heterosexual organic" technical requirements (see the 2003 edition 4);

--- On the "dropping point", "penetration" and "sulfated ash" quality index has been modified (see 7, 2003 edition 4).

This standard uses redrafted law revision by the British Pharmacopoeia BP-2008 in the "white petrolatum", "yellow Vaseline" (in English) prepared. test Into account China's national conditions, when employing BP-2008, made some changes in this standard. This standard BP-2008 version of the main differences.

--- Increase the "scope", "normative references", "sample", "packaging, labeling, storage and delivery acceptance" and chapter;

--- The standard reference standard using our corresponding national standards and

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industry standards;

--- To increase the operability of the British Pharmacopoeia BP-2008 were refined, the British Pharmacopoeia BP-2008 version of "color" and "acid Alkalinity "test method as an appendix to this standard.

This standard by the National Standardization Technical Committee on Petroleum Products and Lubricants made.

This standard by the National Petroleum Products and Lubricants Standardization Technical Committee petroleum wax products Technical Committee (SAC/TC280 /SC3) centralized.

This standard was drafted. China Petroleum & Chemical Co., Ltd. Fushun Research Institute of Petroleum, Nanjing Chang Jiang Jiangyu petrochemical limited liability any company.

1 Scope

This standard specifies the definition of medicine Vaseline, classification, characteristics, identification, technical requirements and test methods, sampling, packaging, labeling, storage and Delivery and acceptance.

This standard applies to the petroleum fractions, refined obtained medicine Vaseline. This standard is applicable to the preparation of pharmaceutical products owned ointment and skin protection ointment.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 269 Lubricating grease and petrolatum Determination of cone penetration method (GB/T 269-1991, eqvISO 2137. 1985) GB/T 6040 General rules for infrared spectroscopy SH/T 0131 Petroleum waxes and petroleum grease sulphate - Determination of ash SH0164 petroleum product packaging, storage and delivery acceptance rules SH/T 0229 semi-solid and solid petroleum products - sampling method SH/T 0655 Test Method Vaseline polycyclic aromatic hydrocarbons SH/T 0678 Determination of dropping point Vaseline

3 Terms and Definitions

The following terms and definitions apply to this document.

White petrolatum whitesoftparaffin, whitepetroleumjely Semi-solid mixture is obtained from petroleum refining white more hydrocarbons. It can contain an appropriate antioxidant, this

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product does not fit for oral administration.

Yellow Vaseline yelowsoftparaffin, yelowpetroleumjely Semisolid mixture of hydrocarbons obtained from refined petroleum. It can contain an appropriate antioxidant, this product is not suitable for oral administration.

4 Products

The standard depth of their products by refining into white petrolatum and petrolatum two kinds of yellow.

5 Features

Table 1. Characteristics of medicine Vaseline.

Table 1 Characteristics of medicine Vaseline

Yellow Vaseline white petrolatum project Traits White or off-white, translucent, oleaginous ointments, after melting Sunlight showed a slight fluorescence Yellow, translucent, oily ointments, after melting showed a slight fluorescence daylight Solubility almost insoluble in water, ethanol and glycerol, slightly soluble in dichloromethane

6 Recognition

The primary identification. A, B, D;

Secondary identification. A, C, D.

A. Dropping Point

White petrolatum dropping point 35 °C ~ 70 °C, the label indicating the difference between the drop point is not more than 5 °C. Determination and installed according to SH/T 0678 Method Fill grease cup amended as follows. The test sample is heated to no more than 80 °C, stirring to ensure uniformity. The metal cup is heated to no greater than in the oven 80 °C.

Yellow Vaseline dropping point 40 °C ~ 60 °C, the label indicating the difference between the drop point is not more than 5 °C. Press SH/T 0678 Method Determination.

B. according to GB/T 6040 infrared spectra, and Vaseline typical infrared light absorption spectrum (see Appendix A) compared to its main Peak position and intensity of the infrared light absorption spectrum similar.

C. Take 2g sample was heated and melted, when a homogeneous mobile phase, and distilled water was added 2mL 0.2mL0.05mol/L iodine (iodine Preparation of solution. dissolve 13g of water with a small amount of iodine and potassium iodide 20g, add water to 1000mL, shake), shaken after cooling, the upper layer is a solid purple Pink (or light brown).

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D. meet the technical requirements (see Table 2) the appearance requirements.

7 Technical requirements and test methods

Pharmaceutical Vaseline technical requirements and test methods are shown in Table 2.

2 medicine Vaseline technical requirements and test methods for tables project Quality Index Yellow Vaseline white petrolatum experiment method Exterior White, the color of melted not deeper than the reference solution A Yellow, the color of melted not deeper than the reference solution B Appendix B PH No Appendix C Dropping point/°C 35 ~ 70 40 ~ 60 SH/T 0678 Polycyclic aromatic hydrocarbons through by SH/T 0655 Penetration (150g, 25 °C) /0.1mm 60 ~ 300 100 ~ 300 GB/T 269 Sulfate ash (mass fraction) /% no greater than

0.05 SH/T 0131

8 Sampling

Sampling by SH/T 0229 carried 2.5kg taken as a test sample and stay with.

9 Packaging, labeling, storage and delivery acceptance

The product packaging, labeling, storage and delivery acceptance by SH0164 be stored away from light and marked drop point, use, add the oxidation Agent name and content.

Appendix A

(Normative)

Vaseline typical infrared spectrum Typical white, yellow Vaseline infrared light absorption spectra are shown in Figure A.1 and A.2.

Figure A.1 Typical white petrolatum infrared light absorption spectrum

Figure A.2 Typical yellow Vaseline infrared light absorption spectrum

Appendix B

(Normative)

Color Test Method

B.1 Scope

This appendix provides pharmaceutical vaseline color test.

This appendix applies to medicine Vaseline.

B.2 Method Summary

Load sample volume in flat-bottomed test tube, placed in a water bath to melt. Color samples were observed and compared with the reference liquid ratio.

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