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Standard of China National Pharmaceutical Packaging Association

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# HDPE Non-woven Fabrics Active Carbon Sachet for Oral Solid Preparation

**HDPE Non-woven Fabrics Active Carbon Sachet for Oral Solid Preparation**

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# Foreword

Appendix A to this standard is an appendix to this standard.

This standard is centralized by China National Pharmaceutical Packaging Association.

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This standard is the first edition.

This standard is drafted on the basis of GB/T 1.1.

# Introduction

The HDPE non-woven fabrics desiccant sachet specified in this standard is composed of active carbon and HDPE non-woven fabrics sachet. It is suitable for oral solid preparation.

The active carbon is a kind of porous substance which is mainly used to absorb the gases in the packaging container.

HDPE non-woven fabrics made with HDPE as the main raw material crank out via the non-woven production process. They have multilayer continuous physical structure and balanced physical properties. Antistatic agent and fluorescent whitening agent must not be used. According to different requirements, it is necessary to study and evaluate the physical and chemical properties of HDPE non-woven fabrics, material specifications (mass per unit area), material cleanliness, particulate contamination, floc falling level, waterproof permeability, particle barrier, tensile strength, tear resistance, rupture resistance and surface performance etc.

The HDPE non-woven fabrics materials specified in this standard include glue-coated materials and non-glue-coated materials, which shall not release substances sufficient to cause health risks (see GB/T 16886.1 for biological evaluation and test). Where the material is coated with glue, the continuity of the coating shall be assessed. The sachets usually shall be made via the electric heating sealing process for glue-coated materials, and shall be made via the ultrasonic sealing process for non-glue-coated materials.

HDPE non-woven fabrics active carbon sachet for oral solid preparation must be produced in the environment adaptive to the production environment of corresponding pharmaceutical. Proper measures must be taken to avoid the contamination of active carbon dust to the outer surface of the HDPE non-woven fabrics active carbon sachet for oral solid preparation during the production of active carbon sachet.

# HDPE Non-woven Fabrics Active Carbon Sachet for Oral Solid Preparation

## 1 Scope

This standard stipulates the technical indicators & requirements, test methods, inspection rules and judgment rules, the technical indicators & requirements, test methods, inspection rules and judgment rules, as well as the requirements for product packaging, marking, transportation and storage of the "desiccant sachet")

## 2 Normative References

The documents cited herein are indispensable to the application of this standard. For dated references, only the dated version applies. For undated references, the latest version (including all amendments) applies. The references are as follows:

Chinese Pharmacopoeia (Version 2015)

GB/T 455 Paper and Board Determination of Tearing Resistance

GB/T 2828.1 Sampling procedures for inspection by attributes - Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection

GB/T 12496.3 Test Methods of Wooden Activated Carbon-Determination of Ash Content

GB/T 12496.4 Test Methods of Wooden Activated Carbon-Determination of Water Content

GB/T 12496.5 Test Methods of Wooden Activated Carbon-Determination of Carbon Tetrechloride Activity

GB/T 12496.6 Test Methods of Wooden Activated Carbon - Determination of Abrasion Resistance

GB/T 16886.1 Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing within a Risk Management Process

YBB00122003-2015 Test for Welding Strength

YBB00262004-2015 Test for Infrared Spectrum of Packaging Materials

YBB00312004-2015 Test for Residual Solvent of Packaging Materials

## 3 Requirement

### 3.1 Identification

The HDPE non-woven fabrics sachet material shall be determined with the fourth method in YBB00262004-2015.

### 3.2 Specification and Dimension

The specification and dimension of active carbon sachet shall be in accordance with Table 1.

Table 1 Specification and Dimension

| Specification and Dimension[a] | Overall Dimension[b] (mm) | | Weight of Inclusions [c] (g) | | Test Method |
|---|---|---|---|---|---|
| | Central Value | Tolerance Range | Central Value | Tolerance Range | |
| 5g | 38×76 | ±3 | 5 | -10%/+15% | A.1 |

a: The specific indicators of other specifications and models may be determined by the seller and the buyer through consultation according to the filling requirements.

b: The indicator of overall dimension is only for reference.

c: The indicator of weight of inclusions is only for reference.

### 3.3 Appearance

The appearance defects of active carbon sachet shall comply with the provisions in Table 2.

Table 2 Appearance

| Defects | Description | Inspection Level | Acceptance Quality Limit (AQL) | Test Method |
|---|---|---|---|---|
| Sachet breaking | Breaking of HDPE non-woven fabrics sachet for various reasons, resulting in active carbon leakage | General inspection level I | 0.04 | **A.2** |
| Empty sachet | Active carbon missing | | 0.04 | |
| Dirt | The surface of active carbon sachet is contaminated, and is prone to falling off | | 0.65 | |
| Printing | The pattern of active carbon sachet is not printed or incomplete, resulting in the loss of function | | 0.65 | |
| | A part of the pattern on the active carbon sachet is blurred, causing the pattern to be illegible | | 1.0 | |
| | A part of the pattern on the active carbon sachet is blurred, but the pattern is legible | | 4.0 | |
| Printing ink | Due to printing, there are extra ink marks on the surface of the active carbon sachet which are easy to be wiped off and fall off | | 0.65 | |
| | Due to printing, there are ink marks on the surface of the active carbon sachet, which are not easy to be wiped off or fall off | | 4.0 | |
| Color difference | There exists color difference between different active carbon sachets due to packaging materials or production process | | 4.0 | |

### 3.4 Physical and chemical indicators

The physical and chemical indicators of active carbon sachet shall comply with the provisions of Table 3.

Table 3 Physical and chemical indicators

| Items | | Units | Indicators | Test Method |
|---|---|---|---|---|
| Moisture content | | % | ≤ 5.0 | **A.3** |
| Adsorption rate of carbon tetrechloride | | % | ≥40.0 | **A.4** |
| Ash content | | % | ≤ 5.0 | **A.5** |
| Strength | | % | ≥95.0 | **A.6** |
| Dropping Resistance | | — | The active carbon sachet shall not be broken and the active carbon shall not leak | **A.7** |
| Physical and Chemical Properties of HDPE Non-woven Fabrics Sachet | | | | **A.8** |
| Fluorescence of HDPE Non-woven Fabrics Sachet | | — | Shall comply with the provision | **A.8.1** |
| Decolorization test | | — | The soaking solution shall not be darker than the blank solution | **A.8.2** |
| Residue on ignition | Including opacifying agent | % | ≤ 3.0 | **A.8.3** |
| | Excluding opacifying agent | % | ≤ 0.1 | |
| Residual solvent content | Total amount | $mg/m^2$ | ≤ 5.0 | **A.8.4** |
| | Benzene | $mg/m^2$ | No content shall be detected | |
| | Benzole | $mg/m^2$ | No content shall be detected | |
| Heavy metal | | — | The content shall not exceed 1 ppm | **A.8.5** |
| Heat-sealing strength (longitudinal sealing and transverse sealing) | Non-coated | N/15mm | ≥5 | **A.8.6** |
| | Coated | N/15mm | ≥3 | |
| Tearing strength | | mN | ≥1 000 | **A.8.7** |
| **Note:** The item with mark * shall be tested by commission at least every half a year | | | | |

### 3.5 Microbial limit

The microbial limit shall comply with the provision of Table 4.

Table 4 Microbial limit

| Items | Units | Indicators | Test Method |
|---|---|---|---|
| Total number of aerobic bacteria | cfu/ sachet | ≤1 000 | A.9 |
| Total number of molds and yeasts | cfu/ sachet | ≤100 | |
| Escherichia coli | — | No content shall be detected | |

## 4 Inspection Rule

### 4.1 Lot

A lot shall be the products which are produced continuously for a period of time under the conditions of same raw material formula, same specification & variety, same technology and same equipment or otherwise agreed in the contract.

### 4.2 Sampling

After the external packaging is inspected, a certain number of packages shall be randomly selected from the same lot of products according to Table 5 for sampling.

Table 5 Quantity of packages sampled

| Quantity of packages sampled from each lot of products | Quantity of packages sampled |
|---|---|
| 2 ~15 pieces | 2 |
| 16 ~ 50 pieces | 3 |
| 51 ~ 150 pieces | 5 |
| 151 ~ 500 pieces | 8 |
| > 500 | 13 |

Then answer, the above packages shall be sampled for inspection according to Sampling Procedures for Inspection by Attributes- Part 1: Sampling Schemes Indexes by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection (GB/T 2828.1).

### 4.3 Inspection

The dropping resistance inspection items, inspection level and acceptance quality limit (AQL) shall comply with the provisions of Table 6.

Table 6 Inspection

| Inspection Items | Inspection Level | Acceptance Quality Limit |
|---|---|---|
| Dropping Resistance | Special Inspection Level S-3 | 4.0 |

## 5 Acceptance Rule

If any technical indicator cannot reach the requirement when the receiving party carries out acceptance inspection, it shall conduct the joint inspection for the defective item together with the manufacturer; the joint inspection result shall be based to judge the compliance.

## 6 Packaging and shelf life, marking, transportation, storage

### 6.1 Packaging and shelf life

The packaging form and material of active carbon sachet will directly affect the shelf life of active carbon sachet. For example: For the active carbon sachet packaged in the double-layer medicinal low density polyethylene sachet, the shelf life will 2 years as of the production date under the premise that it is unopened. For other packaging forms and materials, the shelf life shall be determined by both parties through negotiation.

### 6.2 Marking

The product marking shall comply with the relevant requirements of applicable national laws and regulations.

### 6.3 Transportation

The products shall be protected from pressure, sunshine and moisture in the transportation process. Products must not be shipped along with toxic or spoiled materials

### 6.4 Storage

The product must be sealed and stored in a room temperature, dark, clean, dry and ventilated warehouse.

# Appendix A

# (Normative)

# Test Method

## A.1 Specification and Dimension

### A.1.1 Overall Dimension

Use the vernier caliper with accuracy of 0.01mm to measure the length.

### A.1.2 Weight of Inclusions

Use the analytical balance with accuracy of 0.1mg to measure the weight.

## A.2 Appearance

Take appropriate amount of this product, place in the bright place with natural light and conduct visual inspection.

## A.3 Moisture content

In an environment with relative humidity not more than 75%, take out the active carbonsachet quickly from the enclosed packaging bag (2 sachets for the specification below 3g, and 1 sachet for the specification of 3g and above), remove the HDPE non-woven fabrics sachet and determine in accordance with GB/T 12496.4.

## A.4 Adsorption rate of carbon tetrechloride

In an environment with relative humidity not more than 75%, take out the active carbonsachet quickly from the enclosed packaging bag, take out the active carbon (a little more) from the active carbonsachet, dry at 105-110℃ to constant weight, put in the dryer and determine in accordance with GB/T 12496.5.

## A.5 Ash content

In an environment with relative humidity not more than 75%, take out the active carbonsachet quickly from the enclosed packaging bag, take 1g active carbon with HDPE non-woven fabrics sachet removed and determine in accordance with GB/T 12496.3.

## A.6 Strength

In an environment with relative humidity not more than 75%, take out the active carbonsachet quickly from the enclosed packaging bag, take 100g active carbon with HDPE non-woven fabrics sachet removed and determine in accordance with GB/T 12496.6.

## A.7 Dropping Resistance

Take appropriate amount of the product, and drop onto the horizontal, rigid and smooth surface freely from the height of 1.2m.

## A.8 Physical and Chemical Indicators of HDPE Non-woven Fabrics Sachet

### A.8.1 Fluorescence of HDPE Non-woven Fabrics Sachet

Take 10 sachets of the product, cut off the heat-sealed part, take out the active carbon, clean the surface of HDPE non-woven fabrics sachet, place the surface of sachet in contact with the pharmaceutical under the UV lamp with the wavelength of 365nm and 254nm for inspection; there shall be no flake fluorescent.

### A.8.2 Decolorization test

(Apply to the active carbon sachet with painting), Take 5 bags of product, remove the active carbon, add 50ml water respectively, soak (60℃±2℃, 2h) and select the solvent from same lot as the blank solution for comparison.

### A.8.3 Residue on ignition

Take appropriate amount of the product, remove the active carbon, weigh 2g HDPE non-woven fabrics sachet and determine in accordance with the General Rules0841 of Part IV, Chinese Pharmacopoeia 2015.

### A.8.4 Residual solvent content

(Apply to the active carbon sachet with painting) Take several HDPE non-woven fabrics sachets with active carbon removed (internal area is about 0.02$m^2$), and determine in accordance with the method I in YBB00312004-

2015.

### A.8.5 Heavy metal

#### A.8.5.1 Preparation of leaching solution

Take appropriate amount of the product, remove the active carbon, take 600cm$^2$ (internal surface area) of HDPE non-woven fabrics sachet (cut into small pieces with length of 5cm and width of 0.3cm), put them in conical flask with cover, add appropriate amount of water, shake to wash the small pieces, discard the water and repeat the operations twice. Soak in (70℃±2℃) 200ml water for 24h after drying at 30℃-40℃, then take out and cool down to room temperature, supplement to the original volume with the aqueous solution for test from the same lot as the leaching solution and use the water from the same lot as the blank solution.

#### A.8.5.2 Detection of heavy metal

Measure out 20ml leaching solution precisely, add acetate buffer (pH3.5), and determine in accordance with the method I in General Rules 0821 of Part IV, Chinese Pharmacopoeia 2015.

### A.8.6 Heat-sealing strength

Take appropriate amount of HDPE non-woven fabrics sachets with active carbon removed, and determine according to YBB00122003-2015.

### A.8.7 Tearing strength

Take appropriate amount of materials for HDPE non-woven fabrics sachets, and determine according to GB/T 455.

## A.9 Microbial limit

Take 10 sachets of the product, put them in conical flask, add 100ml sodium chloride injection-peptone buffered solution (pH7.0), and shake out by 1min to obtain 1:10 solution for testing product. Determine according to the General Rules 1105 and 1106 of Part IV, Chinese Pharmacopoeia 2015.

# Standard of HDPE Non-woven Fabrics Active Carbon Sachet for Oral Solid Preparation

## Drafting Instruction

## I. Overview

There has not been a complete standard in line with the development of modern pharmaceuticals for the active carbon manufacturers and users. Pharmacopoeia of the People's Republic of China (hereinafter referred to as “Chinese Pharmacopoeia”) stipulates some items focusing on the personal safety of from the perspective of drug use safety; although Test Methods of Wooden Activated Carbon(GB/T 12496) has made relatively detailed settings for inspection items of active carbon, but there are many restrictions merely on the raw materials but there are no definite provisions for the active carbon sachets, which obviously has been unable to meet the development needs of medical active carbon. At present, the dominant active carbon sachets are packaged with HDPE non-woven fabrics in Europe and America. For the active carbon sachet, the part that comes into direct contact with the pharmaceutical is the HDPE non-woven fabrics sachet whose materials and characteristics will directly affect the quality of the pharmaceutical, thus causing harm to the pharmaceutical users.

As the raw material for pharmaceutical packaging material, the high density polyethylene (HDPE) has been widely applied both at home and abroad. It is non-toxic, tasteless, odorless, high in crystallinity and relatively high in density; relative molecular weight is often several hundred thousand to hundreds of thousands; the range of melt flow rate is narrow; it has relatively high rigidity and toughness, excellent mechanical strength and heat resistance, and good solvent resistance. The excellent performance of high density polyethylene provides favorable conditions for the production of active carbon sachets; for example, the melt index is moderate, the processing temperature is not high, it has the performance satisfying the pharmaceutical packaging requirement including non-toxicity, tastelessness, odorlessness, good toughness and surface hardness, tensile strength, stiffness and other mechanical strength etc., and complies with the requirement of the FDA and the European Union.

This standard is formulated for the purpose of effectively strengthening the quality control of active carbon sachet, ensuring the quality of pharmaceutical, and facilitating pharmaceutical enterprises to use active carbon sachet more confidently.

## II. Description of standard project establishment and requirements

1. Name According to the preparation requirements of standard, the standards for pharmaceutical packaging materials shall be classified as per the materials, wherein one standard shall be prepared for each (variety) material and each purpose; the standard name shall follow the sequential format of administration route, pharmaceutical form, application and material. Therefore, the name of this standard is proposed as “HDPE non-woven Fabrics Active Carbon Sachet for Oral Solid Preparation”.

2. Appearance The appearance, which shall be described according to the production requirements of the product and in combination with the actual situation of the sample, can reflect the external quality of the product directly and comprehensively.

3. Moisture content The moisture content of active carbon will affect the actual content of active carbon in the packaging bag, thus influencing the adsorption capacity of active carbon. This standard specifies “moisture content” to control the active carbon.

4. Adsorption rate of carbon tetrechloride The adsorption capacity of active carbon is usually determined by the adsorption rate of carbon tetrachloride. This standard specifies “adsorption rate of carbon tetrechloride” to control the active carbon.

5. Ash content The purity of active carbon will affect the loading capacity of active carbon, thus influencing the adsorption capacity of active carbon. This standard specifies“ ash content” to control the active carbon.

6. Strength In the production process of active carbon sachets, the raw material of active carbon will be squeezed and hit, which is very easy to produce active carbon dust, thus affecting the production environment and product quality. This standard specifies “strength” to control the active carbon.

7. Dropping resistance The active carbon sachets are placed in the packaging of oral solid pharmaceutical preparations when they are used. If they drop during transportation, storage and use, the active carbon sachets without certain fastness will be damaged and the active carbon will leak out, causing contamination to the pharmaceuticals. This standard specifies a "dropping resistance" item to evaluate the product endurance.

8. “Fluorescence of HDPE non-woven fabrics sachet”, “residue on ignition” and “heavy metal” In this

standard, HDPE non-woven fabrics are used as the raw material for packaging bag of active carbon sachets. This standard specifies three items, namely, “fluorescence of HDPE non-woven fabrics sachet”, “residue on ignition” and “heavy metal”, to test the performance of HDPE non-woven fabrics material.

9. “Heat-sealing strength” and “tearing strength” In order to prevent the contamination to the oral solid preparations caused by active carbon leakage, this standard specifies two items “heat-sealing strength” and “tearing strength” to test the performance of HDPE non-woven fabrics sachet materials.

10. “Residual solvent content” and “decolorization test” Considering that the wording “请勿食用” and “DO NOT EAT” are printed on the outside of the active carbon sachet, this standard specifies two items “residual solvent content” and “decolorization test” to test the performance of HDPE non-woven fabrics sachet materials.

11. Microbial limit In order to ensure that the active carbon sachet will not contaminate the oral solid preparations, this standard adopts the method specified in the Chinese Pharmacopoeia to test the microbial limit of the active carbon sachet. The total number of aerobic bacteria shall not exceed 1,000cfu/sachet; the total number of molds and yeasts shall not exceed 100cfu/sachet; no escherichia coli shall be detected in each bag.

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