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Preparation and Pharmacodynamic Analysis of Granules

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Abstract

Granule refers to a dry granular preparation made of drugs and appropriate excipients, which is divided into soluble granules, suspension granules and effervescent granules. Compared with powder, granule has small dispersibility, adhesion, and hygroscopicity, and is convenient to take, and suitable adjuvants, aromatic agent, and correctant can be added. You can see that by experiment: (1)Particle size:unless otherwise specified, the total number of granules that fail to pass through No.1 sieve and that pass through No.5 sieve determined by particle size and particle size distribution method shall not exceed 15%. (2)Water:otherwise specified, granules of chemical and biological products are determined according to loss on drying method and dried at 105 C .(3) heating water 200ml, stirring for 5 minutes, immediately observed, soluble particles should be all dissolved or slightly cloudy.

Keywords

Granules; Particle Size; Solubility; Pharmacodynamic.

1. Introduction

Granule refers to a dry granular preparation made of drugs and appropriate excipients, which is divided into soluble granules, suspension granules and effervescent granules. Compared with powder, granule has small dispersibility, adhesion, and hygroscopicity, and is convenient to take, and suitable adjuvants, aromatic agent, and correctant can be added. The excipients used for soluble granules should be soluble[1]. The mixture of citric acid, tartaric acid and sodium bicarbonate is usually used as effervescent agent. The granules can also be coated to achieve the purposes of taste correction, stability, enteric coating and sustained release. The preparation process of soluble granules generally included extraction of medicinal materials → concentration → refining → making soft materials → granulating → drying → granulating → quality inspection → packaging. The commonly used adjuvants of granule include sugar powder, dextrin and effervescent disintegrant[2].

The amount of adjuvant adde for granulating dry extract pow is generally not more than 2 times of extract powder, and that amount of adjuvant added for granulate soft extract is generally not more than 5 times of fluid extract amount. The appropriate degree of making soft wood was "kneading with the hand, and dispersing immediately after gentle pressure". If the degree of soft wood was not appropriate, appropriate concentration of ethanol could be added to adjust the dry humidity[3-4]. Granulation methods include extrusion granulation, wet blending granulation, and spray drying granulation. Dry immediately after wet granulation. When drying temperature should rise gradually, general control in 60℃~80℃ advisable. The effervescent granule utilize that action of organic acid and weak base and water to produce carbon dioxide gas so as to make the medicinal liquid produce bubble so as to form effervescent state, and can make the granules loose and split so as to obtain quick solubility. However, carbon dioxide, after being dissolved in water, is sour, which can stimulate the taste buds and has the effect of taste correction[5]. With the addition of a proper amount of aromatic and sweetening agents, a beverage-like flavor can be obtained[6].

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2. Materials and Production Methods

Main instruments and equipment: ordinary balance, mortar, medicine screen (100 mesh), nylon screen (16 mesh), alcohol meter, hydrometer, plastic bag, analytical balance, etc.

Materials: Vitamin C, dextrin, sugar powder, tartaric acid, 50% ethanol.

2.1 Preparation of Vitamin C Granules

vitamin C 1.0g.

dextrin 10.0g.

powdered sugar 9.0g.

tartaric acid 0.1g.

50% ethanol of appropriate amount.

Make into 10 packs.

2.2 Preparation of Vitamin C Granules

① Grinding: Sucrose, dextrin and vitamin C were respectively pulverized and sieved by a 100-mesh sieve.

② mixing: vitamin c, sugar powder and dextrin were added in equal amounts and mixed evenly to obtain mixed powder.

③ soft wood preparation: tartaric acid was dissolve in an appropriate amount of 70% ethanol, added into that mix powder, and mixed to make a soft wood.

④ Wet granulation: the soft materials were extruded through a 12-mesh sieve to obtain wet granulation.

⑤ Drying: The wet particles were put into an oven for drying at 50–60 C for about 40min.

⑥ Granulation: The above dry granules were sieved by 10-mesh and 30-mesh sieves for granulation. The granules were packed in plastic bags containing 2g of vitamin C100mg.

2.3 Use of Vitamin C Granules

Figure 1. The vitamin C granule

This product is a vitamin medicine, used for preventing and treating scurvy and other diseases caused by vitamin C deficiency.

Summary and discussion:Vitamin C dosage is small, so when mixing should use equal volume increasing with research method, to ensure that the mixed evenly.Vitamin C easily oxidative decomposition discoloration, granulating time should be shortened as far as possible, and dilute

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ethanol as a wetting agent granulating, drying at a lower temperature, and should avoid contact with metal utensils, add tartaric acid (or use citric acid instead of) as a metal ion chelating agent.

The prepared vitamin C granules were white in appearance, and the granules in this test were less, because the soft materials were softer due to insufficient drying time after the soft materials were prepared, and most of the soft materials could not be obtained after being left in the sieve holes and the stainless steel plates.

The vitamin C granule prepared in this test was 8.3g after weighing.

3. Results and Analysis

3.1 Quality Inspection of Granules

Particle size :unless otherwise specified, the total number of granules that fail to pass through No.1 sieve and that pass through No.5 sieve determined by particle size and particle size distribution method shall not exceed 15%. Specific operations: About 10g of test article was taken, accurately weighed, and placed in a drug sieve for 3min to calculate the percentages of the coarse powder that failed to pass through the No.1 sieve and the fine powder that passed through the No.5 sieve in the total weight.

Water:otherwise specified, granules of chemical and biological products are determined according to loss on drying method and dried at 105 C (sugar-containing granules shall be dried under reduced pressure at 80C) to constant weight with loss reduction no more than%. Specific operations: About 1g of test article was placed in a flat weighing bottle, which had been dried to a constant weight, covered with a precision weighing, and then dried at 105 C to a constant weight. Calculate the loss weight.

Solubility:unless otherwise specified, the granules were examined as described below and the solubility was in accordance with the regulations. Soluble particle inspection method to take 10g of test article (chinese medicine single dose packaging to take a bag), heating water 200ml, stirring for 5 minutes, immediately observed, soluble particles should be all dissolved or slightly cloudy.

3.2 Quality Test Results

Appearance: dry, consistent color, not caking.Identification experiment: 2g of each test article was dissolved in 5ml of water, followed by the addition of AgNO3 solution and 2,6-dichloro-indophenol sodium solution, to observe the phenomenon. TLC identification. The AgNO3 solution produced a black precipitate and the sodium 2,6-dichloroindophenol solution changed from blue to colorless.

Solution clarity: All dissolved, slightly cloudy, but no other foreign bodies.

4. Conclusion

(1)Particle size:unless otherwise specified, the total number of granules that fail to pass through No.1 sieve and that pass through No.5 sieve determined by particle size and particle size distribution method shall not exceed 15%.

(2)Water:otherwise specified, granules of chemical and biological products are determined according to loss on drying method and dried at 105 C.

(3) heating water 200ml, stirring for 5 minutes, immediately observed, soluble particles should be all dissolved or slightly cloudy.

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