Pharmacopoeial Discussion Group

Stage 5B2

RTS C51293
78133 (94)
Nov. 13, 2006

Name: RICE STARCH

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
C	+	+	+
pH	+	+	+
Iron	+	+	+
Oxidising substances	+	+	+
Sulphur dioxide	+	+	+
Loss on drying	+	+	+
Sulphated ash	+	+	+

Legend

+ will adopt and implement ; – will not stipulate

Non-harmonised attributes

Characters, Microbial contamination, Storage

Specific local attributes

Foreign matter (EP)

Reagents and reference materials.

Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date : 25 Oct., 2006 Signatures :

A. ARTIGAS — European Pharmacopoeia

K. Jadano for T. Nakagaki — Japanese Pharmacopoeia

Oct 25, 2006 — United States Pharmacopeia
T. CECIL

STAGE 5B2
RICE STARCH

Oryzae Amylum

DEFINITION

Rice starch is obtained from the caryopsis of *Oryza sativa* L.

IDENTIFICATION

A. Examined under a microscope using a mixture of equal volumes of *glycerol R* and *water R*, it presents polyhedral, simple grains 1 µm to 10 µm, mostly 4 µm to 6 µm, in size. These simple grains often gather in ellipsoidal, compound grains 50 µm to 100 µm in diameter. The granules have a poorly visible central hilum and there are no concentric striations. Between orthogonally orientated polarising plates or prisms, the starch granules show a distinct black cross intersecting at the hilum.

B. Suspend 1 g in 50 ml of *water R*, boil for 1 min and cool. A thin, cloudy mucilage is formed.

C. To 1 ml of the mucilage obtained in identification test B add 0.05 ml of *iodine solution R1*. An orange-red to dark-blue colour is produced which disappears on heating.

TESTS

pH Shake 5.0 g with 25.0 ml of freshly boiled and cooled *water R* for 60 s. Allow to stand for 15 min. The pH of the solution is 5.0 to 8.0.

Iron (*2.4.9*). Shake 1.5 g with 15 ml of *dilute hydrochloric acid R*. Filter. The filtrate complies with the limit test for iron (10 ppm).

Loss on drying . Not more than 15.0 per cent, determined on 1.00 g by drying in an oven at 130 °C for 90 min.

Sulphated ash . Not more than 0.6 per cent, determined on 1.0 g.

Oxidising substances . Transfer 4.0 g to a glass-stoppered, 125 ml conical flask and add 50.0 ml of *water R*. Insert the stopper and swirl for 5 min. Transfer to a glass-stoppered 50 ml centrifuge tube and centrifuge. Transfer 30.0 ml of the clear supernatant liquid to a glass-stoppered 125 ml conical flask. Add 1 ml of *glacial acetic acid R* and 0.5 g to 1.0 g of *potassium iodide R*. Insert the stopper, swirl, and allow to stand for 25 min to 30 min in the dark. Add 1 ml of *starch solution R* and titrate with *0.002 M sodium thiosulphate* until the starch-

AA Oct 25, 2006 KT

iodine colour disappears. Carry out a blank determination. Not more than 1.4 ml of *0.002 M sodium thiosulphate* is required (0.002 per cent, calculated as H_2O_2).

1 ml of *0.002 M sodium thiosulphate* is equivalent to 34 µg of oxidising substances, calculated as hydrogen peroxide.

Starch solution. Triturate 1.0 g of soluble starch R with 5 ml of water R and whilst stirring pour the mixture into 100 ml of boiling water R containing 10 mg of mercuric iodide R.

Carry out the test for sensitivity each time the reagent is used.

Test for sensitivity. To a mixture of 1 ml of the starch solution and 20 ml of water R, add about 50 mg of potassium iodide R and 0.05 ml of iodine solution R1; the solution is blue.

Sulphur dioxide . Not more than 50 ppm.

Introduce 150 ml of *water R* into the flask (*A*) (see Figure —) and pass *carbon dioxide R* through the whole system for 15 min at a rate of 100 ml/min. To 10 ml of *dilute hydrogen peroxide solution R* add 0.15 ml of a 1 g/l solution of *bromophenol blue R* in *alcohol (20 per cent V/V) R. Add 0.1 M sodium hydroxide* until a violet-blue colour is obtained, without exceeding the end-point. Place the solution in the test-tube (*D*). Without interrupting the stream of carbon dioxide, remove the funnel (*B*) and introduce through the opening into the flask (*A*) 25.0 g (*m* g) of the substance to be examined with the aid of 100 ml of *water R*. Add through the funnel 80 ml of *dilute hydrochloric acid R* and boil for 1 h. Open the tap of the funnel and stop the flow of carbon dioxide and also the heating and the cooling water. Transfer the contents of the test-tube with the aid of a little *water R* to a 200 ml wide-necked, conical flask. Heat on a water-bath for 15 min and allow to cool. Add 0.1 ml of 1 g/l solution of *bromophenol blue R* in *alcohol (20 per cent V/V) R* and titrate with *0.1 M sodium hydroxide* until the colour changes from yellow to violet-blue (V_1 ml). Carry out a blank titration (V_2 ml). Calculate the content of sulphur dioxide in parts per million from the expression:

$$32030 \times (V_1 - V_2) \times n/m$$

n = molarity of the sodium hydroxide solution used as titrant

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Oct 25, 2006

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