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Acacia, Dried Dispersion

General Notices

Spray-dried Acacia

(Ph. Eur. monograph 0308)

Ph Eur

DEFINITION

Powder obtained from a dispersion of *Acacia (0307)* after a drying process.

CHARACTERS

It dissolves completely, after about 20 min, in twice its mass of water. The liquid obtained is colourless or yellowish, dense, viscous, adhesive, translucent and weakly acid to blue litmus paper. It is practically insoluble in ethanol (96 per cent).

IDENTIFICATION

A. Examine under a microscope using *ethanol (96 per cent) R* as the mounting medium. The preparation to be examined consists of predominantly spheroidal or irregular and angular particles varying in size (4-500 µm), with 1 or more rounded cavities containing 1 or several air bubbles; a few flat fragments are also present. Only traces of starch granules are visible and no plant tissue is observed.
B. Examine the chromatograms obtained in the test for glucose and fructose.

Results See below the sequence of zones present in the chromatograms obtained with reference solution (a) and the test solution.

Top of the plate	
	3 blue zones, very faint
Rhamnose: a greenish-brown zone	A greenish-brown zone, very faint to equivalent (rhamnose)
Xylose: a brownish-grey zone	
Arabinose: a brownish-grey zone	A brownish-grey zone, intense (arabinose)

Top of the plate	
Glucose: a greyish-blue zone Galactose: a greyish-blue zone	A greyish-blue zone, intense (galactose)
_____	1 or 2 brownish-grey zones, very faint to equivalent 1 or 2 blue zones, faint to equivalent _____
Reference solution (a)	**Test solution**

C. Dissolve 1 g of the preparation to be examined in 2 mL of *water R* by stirring frequently for 20 min. Add 2 mL of *ethanol (96 per cent) R*. After shaking, a white gelatinous mucilage is formed that becomes fluid upon addition of 10 mL of *water R*.

TESTS

Solution S

Dissolve 3.0 g of the preparation to be examined in 25 mL of *water R* by stirring for 10 min. Allow to stand for 20 min and dilute to 30 mL with *water R*.

Glucose and fructose

High-performance thin-layer chromatography (*2.8.25*)

Test solution To 0.1 g in a thick-walled centrifuge tube add 2 mL of a 100 g/L solution of *trifluoroacetic acid R* and shake vigorously. Stopper the tube and heat the mixture at 120 °C for 1 h. Centrifuge, transfer 1 mL of the clear supernatant into a 10 mL flask and add 5 mL of *methanol R*.

Reference solution (a) Dissolve 5 mg of *arabinose R*, 5 mg of *galactose R*, 5 mg of *glucose R*, 5 mg of *rhamnose R* and 5 mg of *xylose R* in 1 mL of *water R* and dilute to 10.0 mL with *methanol R*.

Reference solution (b) Dilute 2.5 mL of reference solution (a) to 10.0 mL with *methanol R*.

Reference solution (c) Dissolve 5 mg of *galactose R* and 5 mg of *glucose R* in 1 mL of *water R* and dilute to 10 mL with *methanol R*.

Intensity marker Galactose.

Plate *TLC silica gel F_{254} plate R* (2-10 µm).

Mobile phase *water R*, *acetonitrile R* (15:85 *V/V*).

Application 4 µL of the test solution and reference solutions (a) and (b), and 2 µL of reference solution (c), as bands of 8 mm.

Development A 70 mm from the lower edge of the plate, in an unsaturated tank.

Drying A In air.

Development B 70 mm from the lower edge of the plate, in an unsaturated tank, using freshly prepared mobile phase.

Drying B In air.

Detection Treat with a solution prepared as follows: dissolve 4 g of *diphenylamine R* and 4 mL of *aniline R* in 160 mL of *acetone R* and add *phosphoric acid R* until the precipitate formed dissolves again (about 30 mL). Heat at 120 °C for 5-10 min and examine in daylight.

System suitability Reference solution (c):

— the chromatogram shows in the middle third 2 distinct zones, which may be touching; the lower zone (galactose) and the upper zone (glucose) are greyish-blue.

Results The chromatogram obtained with the test solution shows no greyish-blue zone and no reddish zone between the zones due to galactose and arabinose in the chromatogram obtained with reference solution (a).

Starch, dextrin and agar

To 10 mL of solution S, previously boiled and cooled, add 0.1 mL of *0.05 M iodine*. No blue or reddish-brown colour develops.

Sterculia gum

A. Place 0.2 g in a 10 mL ground-glass-stoppered cylinder graduated in 0.1 mL. Add 10 mL of *ethanol (60 per cent V/V) R* and shake. Any gel formed occupies not more than 1.5 mL.
B. To 1.0 g add 100 mL of *water R* and shake. Add 0.1 mL of *methyl red solution R*. Not more than 5.0 mL of *0.01 M sodium hydroxide* is required to change the colour of the indicator.

Tannins

To 10 mL of solution S add 0.1 mL of *ferric chloride solution R1*. A gelatinous precipitate is formed, but neither the precipitate nor the liquid is dark blue.

Tragacanth

Examine the chromatograms obtained in the test for glucose and fructose.

Results The chromatogram obtained with the test solution shows no faint to intense brownish-grey zone corresponding to the zone due to xylose in the chromatogram obtained with reference solution (a).

Loss on drying (*2.2.32*)

Maximum 10.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Total ash (*2.4.16*)

Maximum 4.0 per cent.

Microbial contamination

TAMC: acceptance criterion 10^4 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

Absence of *Salmonella* (*2.6.13*).

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is

included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristic may be relevant for acacia dried dispersion used as a viscosity-increasing agent and/or suspending agent in aqueous preparations.

Apparent viscosity

Determine the dynamic viscosity using a capillary viscometer (*2.2.9*) or a rotating viscometer (*2.2.10*) on a 100 g/L solution of acacia, dried dispersion (dried substance).

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