Edition: BP 2025 (Ph. Eur. 11.6 update)

Acacia

General Notices

(Ph. Eur. monograph 0307)

Action and use

Bulk-forming laxative; excipient.

When Powdered Acacia is prescribed or demanded, material complying with the requirements below with the exception of Identification test A shall be dispensed or supplied.

Ph Eur

DEFINITION

Air-hardened, gummy exudate flowing naturally from or obtained by incision of the trunk and branches of *Acacia senegal* L. Willd. (syn. *Senegalia senegal* (L.) Britton), other species of *Acacia* of African origin and *Acacia seyal* Delile.

CHARACTERS

It is almost completely but very slowly soluble, after about 2 h, in twice its mass of water leaving only a very small residue of vegetable particles; 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. It occurs as yellowish-white, yellow or pale amber, sometimes with a pinkish tint, friable, opaque, spheroidal, oval or reniform pieces (tears) of a diameter from about 1-3 cm, frequently with a cracked surface, easily broken into irregular, whitish or slightly yellowish angular fragments with a conchoidal fracture and a glassy and transparent appearance. In the centre of an unbroken tear there is sometimes a small cavity.
B. Microscopic examination (*2.8.23*). The powder is white or yellowish-white. Examine under a microscope using *ethanol (96 per cent) R*. The powder shows the following diagnostic characters: angular, irregular, colourless, transparent fragments. Only traces of starch or plant tissues are visible. No stratified membrane is apparent.
C. 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)

Top of the plate	
Xylose: a brownish-grey zone	
_____	_____
Arabinose: a brownish-grey zone	A brownish-grey zone, intense (arabinose)
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**

D. Dissolve 1 g of the powdered herbal drug (355) (2.9.12) in 2 mL of *water R* by stirring frequently for 2 h. 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 powdered herbal drug (355) (2.9.12) in 25 mL of *water R* by stirring for 30 min. Allow to stand for 30 min and dilute to 30 mL with *water R*.

Insoluble matter

Maximum 0.5 per cent.

To 5.0 g of the powdered herbal drug (355) (2.9.12) add 100 mL of *water R* and 14 mL of *dilute hydrochloric acid R*, boil gently for 15 min, shaking frequently and filter while hot through a tared sintered-glass filter (2.1.2). Wash with hot *water R* and dry at 100-105 °C. The residue weighs a maximum of 25 mg.

Glucose and fructose

High-performance thin-layer chromatography (2.8.25).

Test solution To 0.1 g of the powdered herbal drug (355) (2.9.12) 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 of the powdered herbal drug (355) (*2.9.12*) 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 a maximum of 1.5 mL.
B. To 1.0 g of the powdered herbal drug (355) (*2.9.12*) 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 15.0 per cent, determined on 1.000 g of the powdered herbal drug (355) (*2.9.12*) 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 10^4 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 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 substance).