

# **Quality standards**

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

# **Shellac**

**General Notices** 

(Ph. Eur. monograph 1149)

Action and use

Excipient.

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#### **DEFINITION**

Purified material obtained from the resinous secretion of the female insect *Kerria lacca* (Kerr) Lindinger (*Laccifer lacca* Kerr). There are 4 types of shellac depending on the nature of the treatment of crude secretion (seedlac): wax-containing shellac, bleached shellac, dewaxed shellac and bleached, dewaxed shellac.

Wax-containing shellac is obtained from seedlac: it is purified by filtration of the molten substance and/or by hot extraction using a suitable solvent.

Bleached shellac is obtained from seedlac by treatment with sodium hypochlorite after dissolution in a suitable alkaline solution, precipitation by dilute acid and drying.

Dewaxed shellac is obtained from wax-containing shellac or seedlac by treatment with a suitable solvent and removal of the insoluble wax by filtering.

Bleached, dewaxed shellac is obtained from wax-containing shellac or seedlac by treatment with sodium hypochlorite after dissolution in a suitable alkaline solution; the insoluble wax is removed by filtration. It is precipitated by dilute acid and dried.

#### **CHARACTERS**

#### **Appearance**

Brownish-orange or yellow, shining, translucent, hard or brittle, more or less thin flakes (wax-containing shellac and dewaxed shellac), or a creamy white or brownish-yellow powder (bleached shellac and bleached, dewaxed shellac).

#### Solubility

Practically insoluble in water, gives a more or less opalescent solution (wax containing shellac and bleached shellac) or a clear solution (dewaxed shellac and bleached, dewaxed shellac) in anhydrous ethanol. When warmed it is sparingly soluble or soluble in alkaline solutions.

#### **IDENTIFICATION**

A. Thin-layer chromatography (2.2.27).

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Test solution Heat 0.25 g of the powdered substance (500) (2.9.12) on a water-bath with 2 mL of <u>dilute sodium hydroxide</u> <u>solution R</u> for 5 min. Cool, add 5 mL of <u>ethyl acetate R</u> and slowly, with stirring, 2 mL of <u>dilute acetic acid R</u>. Shake and filter the upper layer through <u>anhydrous sodium sulfate R</u>.

Reference solution Dissolve 6.0 mg of aleuritic acid R in 1.0 mL of methanol R, heating slightly if necessary.

Plate <u>TLC silica gel F<sub>254</sub> plate R</u>.

Mobile phase acetic acid R, methanol R, methylene chloride R, ethyl acetate R (1:8:32:60 V/V/V/V).

Application 10 μL, as bands.

Development Twice over a path of 15 cm.

Drying In air.

Detection Spray with anisaldehyde solution R, heat at 100-105 °C for 5-10 min and examine in daylight.

Results The chromatogram obtained with the test solution shows several coloured zones, one of which is similar in position and colour to the zone in the chromatogram obtained with the reference solution. Above this zone the chromatogram obtained with the test solution shows a pink zone and below it several violet zones. Below the zone due to aleuritic acid, there is a light blue zone (shellolic acid) accompanied by zones of the same colour but of lower intensity. Other faint grey and violet zones may be visible.

B. Examine the chromatograms obtained in the test for colophony.

Results For wax-containing shellac, in the chromatogram obtained with the test solution, a more or less strong bluish-grey zone is visible, just above the zone due to thymolphthalein in the chromatogram obtained with the reference solution; for dewaxed shellac, no such zone is visible just above the zone due to thymolphthalein in the chromatogram obtained with the reference solution.

## **TESTS**

#### **Acid value** (2.5.1)

65 to 95 (dried substance).

Examine 1.00 g of the coarsely ground substance. Determine the end-point potentiometrically (2.2.20).

## **Colophony**

Thin-layer chromatography (2.2.27) as described under identification test A with the following modifications.

Test solution Dissolve 50 mg of the powdered substance (500) ( $\underline{2.9.12}$ ), with heating, in a mixture of 0.5 mL of  $\underline{methylene}$  chloride R and 0.5 mL of  $\underline{methanol}$  R.

Reference solution Dissolve 2.0 mg of thymolphthalein R in 1.0 mL of methanol R.

Detection Examine in ultraviolet light at 254 nm; mark the quenching zones in the chromatogram obtained with the test solution that have similar  $R_F$  values to that of the quenching zone due to thymolphthalein in the chromatogram obtained with the reference solution; spray with <u>anisaldehyde solution R</u>, heat at 100-105 °C for 5-10 min and examine in daylight.

Results The chromatogram obtained with the reference solution shows a principal zone with a reddish-violet colour (thymolphthalein). None of the quenching zones in the chromatogram obtained with the test solution that have an  $R_F$  value similar to the zone due to thymolphthalein in the reference solution show a more or less strong violet or brownish colour (colophony). Disregard any faint violet zone at this level that does not show quenching before spraying and heating.

#### Arsenic (2.4.2, Method A)

Maximum 3 ppm.

Introduce 0.33 g of the substance to be examined and 5 mL of <u>sulfuric acid R</u> into a combustion flask. Carefully add a few millilitres of <u>strong hydrogen peroxide solution R</u> and heat to boiling until a clear, colourless solution is obtained. Continue heating to eliminate the water and as much sulfuric acid as possible and dilute to 25 mL with <u>water R</u>.

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# Loss on drying (2.2.32)

Maximum 2.0 per cent for unbleached shellac and maximum 6.0 per cent for bleached shellac, determined on 1.000 g of the powdered substance (500) (2.9.12) by drying in an oven at 40-45 °C for 24 h.

# **STORAGE**

Protected from light. Store bleached shellac and bleached, dewaxed shellac at a temperature not exceeding 15 °C.

# **LABELLING**

The label indicates the type of shellac.

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