01/2008:0070

BEESWAX, YELLOW

Cera flava

DEFINITION

Wax obtained by melting the walls of the honeycomb made by the honey-bee, *Apis mellifera* L., with hot water and removing foreign matter.

CHARACTERS

Appearance: yellow or light brown pieces or plates with a fine-grained, matt and non-crystalline fracture; when warmed in the hand they become soft and malleable.

It has a faint odour, characteristic of honey. It is tasteless and does not stick to the teeth.

Solubility: practically insoluble in water, partially soluble in hot ethanol (90 per cent *V/V*) and completely soluble in fatty and essential oils.

Relative density: about 0.960.

TESTS

Drop point (*2.2.17*): 61 °C to 66 °C.

Melt the beeswax by heating on a water-bath, pour onto a glass plate and allow to cool to a semi-solid mass. Fill the metal cup by inserting the wider end into the beeswax and repeating the procedure until beeswax extrudes from the narrow opening. Remove the excess with a spatula and insert the thermometer immediately. Remove the beeswax displaced. Allow to stand at room temperature for at least 12 h before determining the drop point.

Acid value: 17.0 to 22.0.

To 2.00 g (*m* g), in a 250 ml conical flask fitted with a reflux condenser, add 40 ml of *xylene R* and a few glass beads. Heat until the substance is dissolved. Add 20 ml of *ethanol (96 per cent) R* and 0.5 ml of *phenolphthalein solution R1* and titrate the hot solution with *0.5 M alcoholic potassium hydroxide* until a red colour persists for at least 10 s (n_1 ml). Carry out a blank test (n_2 ml).

$$\text{Acid value} = \frac{28.05\,(n_1 - n_2)}{m}$$

Ester value (*2.5.2*): 70 to 80.

Saponification value: 87 to 102.

To 2.00 g (*m* g), in a 250 ml conical flask fitted with a reflux condenser, add 30 ml of a mixture of equal volumes of *ethanol (96 per cent) R* and *xylene R* and a few glass beads. Heat until the substance is dissolved. Add 25.0 ml of *0.5 M alcoholic potassium hydroxide* and heat under a reflux condenser for 3 h. Titrate the hot solution immediately with *0.5 M hydrochloric acid*, using 1 ml of *phenolphthalein solution R1* as indicator (n_1 ml). Reheat the solution to boiling several times during the course of the titration. Carry out a blank test (n_2 ml).

$$\text{Saponification value} = \frac{28.05\,(n_2 - n_1)}{m}$$

Ceresin, paraffins and certain other waxes. To 3.0 g, in a 100 ml round-bottomed flask, add 30 ml of a 40 g/l solution of *potassium hydroxide R* in *aldehyde-free alcohol R* and boil gently under a reflux condenser for 2 h. Remove the condenser and immediately insert a thermometer. Place the flask in a water-bath at 80 °C and allow to cool, swirling the solution continuously. No precipitate is formed until 65 °C, although the solution may be slightly opalescent. Beginning at 65 °C, the solution may become cloudy and precipitates may be formed. At 59 °C, the solution is cloudy.

Glycerol and other polyols: maximum 0.5 per cent *m/m*, calculated as glycerol.

To 0.20 g add 10 ml of *alcoholic potassium hydroxide solution R* and heat on a water-bath under a reflux condenser for 30 min. Add 50 ml of *dilute sulphuric acid R*, cool and filter. Rinse the flask and the filter with *dilute sulphuric acid R*. Combine the filtrate and washings and dilute to 100.0 ml with *dilute sulphuric acid R*. Place 1.0 ml of the solution in a test-tube, add 0.5 ml of a 10.7 g/l solution of *sodium periodate R*, mix and allow to stand for 5 min. Add 1.0 ml of *decolorised fuchsin solution R* and mix. Any precipitate disappears. Place the tube in a beaker containing water at 40 °C. During cooling observe for 10-15 min. Any violet-blue colour in the solution is not more intense than that in a standard prepared at the same time and in the same manner using 1.0 ml of a 10 mg/l solution of *glycerol R* in *dilute sulphuric acid R*.

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corrected 6.0

BELLADONNA LEAF

Belladonnae folium

DEFINITION

Dried leaf or dried leaf and flowering, and occasionally fruit-bearing tops of *Atropa belladonna* L.

Content: minimum 0.30 per cent of total alkaloids, expressed as hyoscyamine ($C_{17}H_{23}NO_3$; M_r 289.4) (dried drug). The alkaloids consist mainly of hyoscyamine together with small quantities of hyoscine (scopolamine).

CHARACTERS

Slightly nauseous odour.

IDENTIFICATION

A. The leaves are green or brownish-green, slightly darker on the upper surface, often crumpled and rolled and partly matted together in the drug. The leaf is petiolate and the base of the lamina is acute and decurrent and the margin entire. The flowering stems are flattened and bear at each node a pair of leaves unequal in size, in the axils of which occur singly the flowers or occasionally fruits. The flowers have a gamosepalous calyx and campanulate corolla. The fruits are globular berries, green or brownish-black and surrounded by the persistent calyx with widely spread lobes.

B. Reduce to a powder (355) (*2.9.12*). The powder is dark green. Examine under a microscope, using *chloral hydrate solution R*. The powder shows the following diagnostic characters: fragments of leaf lamina showing sinuous-walled epidermal cells, a striated cuticle; stomata more frequent on the lower epidermis (anisocytic and also some anomocytic) (*2.8.3*); multicellular uniseriate covering trichomes with smooth cuticle, glandular trichomes with unicellular heads and multicellular, uniseriate stalks or with multicellular heads and unicellular stalks; parenchyma cells including rounded cells containing microsphenoidal crystals of calcium oxalate; annular and spirally thickened vessels. The powdered drug may also show: fibres and reticulately thickened vessels from the stems; subspherical pollen grains, 40-50 µm in diameter, with 3 germinal pores, 3 furrows and an extensively pitted exine; fragments