LEVANT WORMSEED FOR HOMOEOPATHIC PREPARATIONS CINA FOR HOMOEOPATHIC PREPARATIONS

Artemisia cina ad praeparationes homoeopathicas

DEFINITION

Dried, non-blooming capitulum of *Artemisia cina* Berg.

Content : minimum 3.0 per cent of santonin ($C_{15}H_{18}O_3$; M_r 246.3) (dried drug).

CHARACTERS

Strong, aromatic smell, slightly remembering camphor.

IDENTIFICATION

A. Ovoid capitulum, elongated, non-blooming about 3 mm long and 1 mm in diameter ; greenish-yellow when fresh, turning brown as time passes, often accompanied with fragments of leaves and very small peduncles. Involucre composed of about 16 bracts much smaller at the base of the capitulum than at its top, keeled on the back and covered with a light, cobweb-like down. Three to five flowers per capitulum, tubular with a divided corolla, 5 short teeth at the apex and a constricted tube.

B. Reduce levant wormseed to a powder (355). The powder is greenish-yellow. Examine under a microscope, using *chloral hydrate solution R* : pollen grains isolated or in clusters, dark yellow, 16-20 μm in diameter with a smooth cuticle disrupted by 3 pores ; covering trichomes usually with unicellular foot bearing a much elongated, flexuous, lozenge-shaped cell ; fragments of epidermis from bracts comprising numerous stomata ; fragments of petals with elongated thinly cuticle-covered cells and straight cell-walls, bearing biseriate, sessile secretory trichomes, with a short head composed of 3 or 4 layers of cells covered with a vesicular cuticle.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

C. Thin-layer chromatography (*2.2.27*).

Test solution. Add 30 ml of *ethanol* (65 per cent *V/V*) *R* to 3 g of powdered drug (355). Cover. Heat on a water-bath at 60 °C for 15 min. Allow to cool. Filter.

Reference solution. Dissolve 2.5 mg of *santonin R* and 20 mg of *cineole R* in 10 ml of *ethanol* (*96 per cent*) *R*.

Plate : TLC silica gel plate R.

Mobile phase : acetone R, methylene chloride R (5:95 *V/V*).

Application : 20 µl as bands.

Development : over a path of 10 cm.

Drying : in air.

Detection : spray with *phosphomolybdic acid solution R*. Heat at 100-105 °C for 10 min. Examine in daylight.

Results : see below the sequence of zones present in the chromatograms obtained with the reference solution and the test solution. Furthermore other faint zones may be present in the chromatogram obtained with the test solution.

Top of the plate	
Cineole : a bluish-grey zone	A bluish-grey zone (cineole)
Santonin : a bluish-grey zone	A bluish-grey zone (santonin)
	Four to six bluish-grey zones
Reference solution	**Test solution**

TESTS

Foreign matter (*2.8.2*) : maximum 5.0 per cent, among which maximum 3 per cent of peduncle fragments.

Loss on drying (*2.2.32*) : maximum 10.0 per cent, determined on 1.0 g of powdered drug (355) by drying in an oven at 105 °C for 2 h.

Total ash (*2.4.16*) : maximum 10.0 per cent, determined on 1.0 g of powdered drug (355).

Artemisia herba alba. The presence of very small capitula, closed, rounded and often gathered by an abundant down shows adulteration by *Artemisia herba alba* Asso.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

ASSAY

Liquid chromatography (*2.2.29*).

Test solution. Place 1.00 g of powdered drug (355) into a flask and add 90 ml of *methanol R*. Shake for 2 h. Filter. Rinse the filter with *methanol R*. In a 100.0 ml volumetric flask combine the filtrate and the washings and dilute to 100.0 ml with *methanol R*.

Reference solution. In a 100.0 ml volumetric flask, dissolve 0.035 g of *santonin R* in *methanol R* and dilute to 100.0 ml with the same solvent.

Column :

— *size : l* = 0.125 m, Ø = 4 mm,
— *stationary phase : octadecylsilyl silica gel for chromatography R* (5 μm),
— *temperature :* 25 °C.

Mobile phase : water R, methanol R (50:50 *V*/*V*).

Flow rate : 1.0 ml/min.

Detection : spectrophotometer at 236 nm.

Injection : 10 μl.

Retention time : santonin = about 4 min.

System suitability : reference solution

The number of theoretical plates determined from the peak corresponding to santonin in the chromatogram obtained with the reference solution is not inferior to 8,000.

Calculate the percentage content of santonin, from the expression :

$$\frac{m_2 \times A_1 \times p}{m_1 \times A_2}$$

A_1 = area of the peak due to santonin in the chromatogram obtained with the test solution,

A_2 = area of the peak due to santonin in the chromatogram obtained with the reference solution,

m_1 = mass of the drug sample in the test solution, in grams,

m_2 = mass of santonin sample in the reference solution, in grams,

p = percentage content of santonin in *santonin R*.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

STOCK

DEFINITION

Levant wormseed mother tincture is prepared with ethanol (65 per cent *V*/*V*), using the dried non-blooming capitulum of *Artemisia cina* Berg.

Content : minimum 0.30 per cent *m*/*m* of santonin ($C_{15}H_{18}O_3$; M_r 246.3).

PRODUCTION

Method 4c (2371). Whole drug. Maceration time : 3-5 weeks.

CHARACTERS

Brown liquid.

Resinous odour.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 2.5 mg of *santonin R* and 20 mg of *cineole R* in 10 ml of *ethanol* (*96 per cent*) *R*.

Plate : TLC silica gel plate R.

Mobile phase : acetone R, methylene chloride R (5:95 *V*/*V*).

Application : 20 µl as bands.

Development : over a path of 10 cm.

Drying : in air.

Detection : spray with *phosphomolybdic acid solution R*. Heat at 100-105 °C for 10 min. Examine in daylight.

Results : see below the sequence of zones present in the chromatograms obtained with the reference solution and the test solution. Furthermore other faint zones may be present in the chromatogram obtained with the test solution.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

Top of the plate	
Cineole : a bluish-grey zone Santonin : a bluish-grey zone	A bluish-grey zone (cineole) A bluish-grey zone (santonin) Four to six bluish-grey zones
Reference solution	**Test solution**

TESTS

Ethanol content (*2.9.10*) : 60 per cent *V*/*V* to 70 per cent *V*/*V*.

Dry residue (*2.8.16*) : minimum 3.5 per cent *m*/*m*.

ASSAY

Liquid chromatography (*2.2.29*).

Test solution. In a 100.0 ml volumetric flask, weigh accurately 10.0 g of mother tincture and dilute to 100.0 ml with a mixture of 50 volumes of *methanol R* and 50 volumes of *water R*.

Reference solution. In a 100.0 ml volumetric flask, dissolve 0.035 g of *santonin R* in *methanol R* and dilute to 100.0 ml with the same solvent.

Column :

— *size : l* = 0.125 m, Ø = 4 mm,
— *stationary phase : octadecylsilyl silica gel for chromatography R* (5 μm),
— *temperature :* 25 °C.

Mobile phase : water R, *methanol R* (50:50 *V*/*V*).

Flow rate : 1.0 ml/min.

Detection : spectrophotometer at 236 nm.

Injection : 10 μl.

Retention time : santonin = about 4 min.

System suitability : reference solution

The number of theoretical plates determined from the peak corresponding to santonin in the chromatogram obtained with the reference solution is not inferior to 8,000.

Calculate the percentage content of santonin, from the expression :

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

$$\frac{m_2 \times A_1 \times p}{m_1 \times A_2}$$

A_1 = area of the peak due to santonin in the chromatogram obtained with the test solution,

A_2 = area of the peak due to santonin in the chromatogram obtained with the reference solution,

m_1 = mass of the mother tincture sample in the test solution, in grams,

m_2 = mass of santonin sample in the reference solution, in grams,

p = percentage content of santonin in *santonin R*.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.