ANGUSTURE VERA
FOR HOMOEOPATHIC PREPARATIONS

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Galipea cusparia ad praeparationes homoeopathicas

DEFINITION

Dried stem bark of *Galipea cusparia* St Hill.

Content: minimum 0.6 per cent of total alkaloids, expressed as chelidonine ($C_{20}H_{19}NO_5$; M_r 353.4) (dried drug).

CHARACTERS

Macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

A. More or less curved fragments with bevelled edges. Outer surface covered with a more or less thick suber, yellowish-grey to brown, marked with whitish spots. The suber slightly adheres and coming off it reveals blackish-brown cortical parenchyma of resinous aspect. The light brown inside surface is plain or slightly striated or sometimes rough and covered with pieces of wood in some places. Clear and resinous fracture.

B. Reduce Angusture vera to a powder (355). The powder is brown. Examine under a microscope, using *chloral hydrate solution R*: fragments of suber composed of several layers of superimposed polyhedral cells with outside layers presenting thickened cell-walls (“hard suber”); fragments of cortical parenchyma containing cells with calcium oxalate raphides, rare clusters of small sclerous cells with thickened and canaliculated cell-walls (< 50 µm in diameter) and cells producing essential oil, about 200 µm in diameter; liber fibres, narrow with highly thickened cell-walls and reduced lumen.

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

Test solution. To 3 g of powdered drug (355), add 30 mL of *ethanol* (65 per cent *V/V*) *R*. Heat under a reflux condenser, in a water-bath at 60 °C for 15 min. Allow to cool. Filter.

Reference solution. Dissolve 10 mg of *quinine R* and 20 mg of *brucine R* in 20 mL of *methanol (96 per cent) R*.

Plate: *TLC silica gel plate R.*

Mobile phase: *glacial acetic acid R*, *water R, butanol R* (10:10:40 *V/V/V*).

Application: 20 µL as bands.

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

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with *potassium iodobismuthate solution R* diluted 10-fold in *dilute hydrochloric acid R.* 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	
-----	Two to three orange zones

Quinine: an orange zone	Two orange zones
	An orange zone
-----	-----
Brucine: an orange zone	A large orange zone
Reference solution	**Test solution**

TESTS

Loss on drying (*2.2.32*): maximum 10.0 per cent, determined on 1.0 g of powdered drug (355).

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

ASSAY

Ultraviolet and visible absorption spectrophotometry (*2.2.25*).

Test solution. Place 5.000 g of powdered drug (355) in a round-bottomed flask. Add 200 mL of *dilute acetic acid R* and heat under a reflux condenser on a water-bath for 1 h. Cool. Filter. Transfer the whole quantity into a 250.0 mL volumetric flask. Rinse the flask with *dilute acid acetic R* and dilute to 250.0 mL with the same solvent. Filter. Discard the first 20 millilitres of filtrate. Take 5.0 mL from the remaining filtrate, add 3 mL of *ammonia R* and 100 mL of *methylene chloride R.* Shake for 1 h. Add *anhydrous sodium sulfate R* and shake until the solution becomes limpid. Filter into a round-bottomed flask. Rinse the sodium sulfate and the filter with a few millilitres of *methylene chloride R*. Combine the organic phases and evaporate them to dryness, under reduced pressure with a temperature not exceeding 40 °C. Dissolve the residue in 5.0 mL of *ethanol* (*96 per cent*) *R.* Add 20.0 mL of *dilute sulfuric acid R.* In a 25.0 mL volumetric flask, place 2.0 mL of this solution and dilute to 25.0 mL with a 10 g/L solution of *chromotropic acid sodium salt R* in *sulfuric acid R.* Close the flask and mix carefully.

Compensation liquid. Simultaneously prepare the compensation liquid in the same conditions. In a 25.0 mL volumetric flask, place 2.0 mL of *dilute sulfuric acid R* and dilute to 25.0 mL with a 10 g/L solution of *chromotropic acid sodium salt R* in *sulfuric acid R.* Close the flask and mix carefully.

Place simultaneously the test solution and the compensation liquid in a water-bath for 30 min. Cool

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and if needed, adjust to 25.0 mL with *sulfuric acid R.*

Measure the absorbance of the test solution at 570 nm, in comparison with the compensation liquid.

Calculate the percentage content of total alkaloids, expressed as chelidonine, from the expression:

$$\frac{A \times 15,625}{m \times 933}$$

*i.*e. taking the specific absorbance of chelidonine, to be 933.

A = absorbance of the test solution at 570 nm,
m = mass of the drug sample, in grams.

STOCK

DEFINITION

Angusture vera mother tincture complies with the requirements of the general technique for the preparation of the mother tincture (see *Homeopathic Preparations (1038)* and French Pharmacopoeia Supplement). The mother tincture is prepared with ethanol (65 per cent *V/V*), using the dried stem bark of *Galipea cusparia* St Hill.

Adjusted content: 0.05-0.15 per cent *m/m* of total alkaloids, expressed as chelidonine ($C_{20}H_{19}NO_5$; M_r 353.4).

CHARACTERS

Appearance: orange-brown liquid.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of *quinine R* and 20 mg of *brucine R* in 20 mL of *ethanol (96 per cent) R*.

Plate: *TLC silica gel plate R.*

Mobile phase: *glacial acetic acid* R, *water R, butanol R* (10:10:40 *V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

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

Drying: in air.

Detection: spray with *potassium iodobismuthate solution R* diluted 10-fold, in *dilute hydrochloric acid R.* 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	
-----	Two to three orange zones
Quinine: an orange zone	-----
-----	Two orange zones
Brucine: an orange zone	An orange zone

	A large orange zone
Reference solution	**Test solution**

TESTS

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

Dry residue (*2.8.16*): minimum 1.8 per cent *m/m.*

ASSAY

Ultraviolet and visible absorption spectrophotometry (*2.2.25*).

Test solution. To 1.000 g of mother tincture, add 3 mL of *ammonia R* and 100 mL of *methylene chloride R*. Shake for 1 h. Filter through *anhydrous sodium sulfate R.* Rinse the flask and the filter with a few millilitres of *methylene chloride R.* Evaporate the organic phase to dryness, under reduced pressure with a temperature not exceeding 40 °C. Dissolve the residue in 5.0 mL of *ethanol* (*96 per cent*) *R.* Add 20.0 mL of *dilute sulfuric acid R.* In a 25.0 mL volumetric flask, place 2.0 mL of this solution and dilute to 25.0 mL with a 10 g/L solution of *chromotropic acid sodium salt R* in *sulfuric acid R.* Close the flask and mix carefully.

Compensation liquid. Simultaneously prepare the compensation liquid in the same conditions. In a 25.0 mL volumetric flask, place 2.0 mL of *dilute sulfuric acid R* and dilute to 25.0 mL with a 10 g/L solution of *chromotropic acid sodium salt R* in *sulfuric acid R.* Close the flask and mix carefully.

Place simultaneously the test solution and the compensation liquid in a water-bath for 30 min. Cool and if needed, adjust to 25.0 mL with *sulfuric acid R.*

Measure the absorbance of the test solution at 570 nm, in comparison with the compensation liquid.

Calculate the percentage content *m/m* of total alkaloids, expressed as chelidonine, from the expression:

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

$$\frac{A \times 312.5}{m \times 933}$$

*i.*e. taking the specific absorbance of chelidonine, to be 933.

A = absorbance of the test solution at 570 nm,
m = mass of the mother tincture sample, in grams.

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