FOXGLOVE
FOR HOMOEOPATHIC PREPARATIONS

DIGITALIS PURPUREA
FOR HOMOEOPATHIC PREPARATIONS

Digitalis purpurea (folium) ad praeparationes homoeopathicas

Other Latin name used in homoeopathy: **Digitalis**

DEFINITION

Fresh, two years old leaf of *Digitalis purpurea* L., harvested just before flowering.

CHARACTERS

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

IDENTIFICATION

A. The leaves of foxglove are variable in size: 10-40 cm long and 4-15 cm wide. They are simple, entire, lanceolate, oblong, with a sub-acute tip. The margins are crenelate or sharply dentate. They are thick, with a velvety or rough texture. The lamina is decurrent and attenuated along the median vein which forms a winged, triangular petiole with purple-pink marks at the base. The venation is pinnate. The lateral veins form a 45° angle with the median vein and they anastomose towards the edge of the lamina forming a festoon; they are linked by a network of small, tertiary veins. The upper surface of the leaf is grey-green, pubescent, but sometimes almost glabrous. The veins are grooved and form depressions between which the lamina bubbles. The underside of the leaf is paler and highly tomentose. The whitish veins are highly prominent and give the surface a waffle-like appearance.

B. Take a sample of epidermis from the underside of the leaf. Examine under a microscope, using *chloral hydrate solution R*. The leaf has a smooth cuticle and epidermal cells up to 30-75 µm long, with straight anticlinal walls or slightly sinuous on the upper surface and markedly sinuous on the lower surface. Two types of trichomes are present: covering uniseriate trichomes, often articulated, right-angled, generally comprising 3-5 cells, whose terminal cell is covered with a cuticle sometimes smooth but most often finely verrucous or striated and globular trichomes with a unicellular or sometimes multicellular, uniseriate base and bi cellular or unicellular tip. Anomocytic stomata (*2.8.3*) are frequent.

TESTS

Foreign matter (*2.8.2*): maximum 5 per cent.

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

Loss on drying (*2.2.32*): minimum 70.0 per cent, determined on 5.0 g of finely cut drug, by drying in an oven at 105 °C for 2 h.

***Digitalis lanata* Ehrh**. The presence of narrow, oval lanceolate leaves with an entire margin, or dentate only near the tip, the existence of secretory trichomes and cells with walls displaying highly characteristic regular bead like thickenings, and the absence of covering trichomes may indicate adulteration by *Digitalis lanata* Ehrh.

***Digitalis lutea* L**. The presence of sessile, lanceolate, denticulate, almost glabrous leaves and the scarcity of smooth covering trichomes may indicate adulteration by *Digitalis lutea* L.

***Digitalis grandiflora* All**. The presence of oblong to oval leaves, with a saw like dentate margin, non-reticulate venation, carrying only a few, large, covering trichomes with very large dots on the vein, may indicate adulteration by *Digitalis grandiflora* All.

***Digitalis thlapsi* L**. The presence of numerous secretory trichomes with unicellular tip and multi cellular base, and pericyclic fibres may indicate adulteration by *Digitalis thlapsi* L.

STOCK

DEFINITION

Foxglove mother tincture complies with the requirements of the general technique for the preparation of mother tinctures (see *Homoeopathic Preparations (1038)* and French Pharmacopoeia Authority Supplement). The mother tincture is prepared with ethanol (65 per cent *V/V*), using the fresh, two-year old leaf of *Digitalis purpurea* L., harvested just before flowering.

Content, adjusted value: minimum 0.020 per cent *m/m* and maximum 0.040 per cent *m/m* of cardenolic heterosides, expressed as digitoxin ($C_{41}H_{64}O_{13}$; M_r 765).

CHARACTERS

Appearance: brown liquid.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. To 10 mL of mother tincture, add 10 mL of *lead acetate solution R*. Boil for 2 min, allow to cool, then centrifuge. Shake the supernatant liquid with 2 quantities, each of 15 mL, of *methylene chloride R* and separate the 2 layers (by centrifuging, if necessary). Dry the organic layer over *anhydrous sodium sulfate R* and filter.

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

Evaporate 10 mL of the solution to dryness on a water-bath. Dissolve the residue in 1 mL of a mixture of equal volumes of *methylene chloride R* and *methanol R*.

Reference solution. Dissolve 2 mg of *gitoxin R*, 2 mg of *purpureaglucoside B CRS*, 5 mg of *purpureaglucoside A CRS* and 5 mg of *digitoxin R* in a mixture of equal volumes of *methylene chloride R* and *methanol R*, and dilute to 10 mL with the same mixture of solvents.

Plate: TLC *silica gel plate R.*

Mobile phase: *water R, methanol R, ethyl acetate R* (7.5:10:75 *V/V/V*).

Application: 20 µL, as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with a mixture of 2 mL of a 10 g/L solution of *chloramine R* and 8 mL of a 250 g/L solution of *trichloroacetic acid R* in *ethanol (96 per cent) R*. Heat for 10 min at 100-105 °C. Examine in ultraviolet light at 365 nm.

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

Top of the plate	
Digitoxin: a brown-yellow zone Gitoxin: a light blue zone Purpureaglucoside A: a brown-yellow zone Purpureaglucoside B: a light blue zone	A brown-yellow zone (digitoxin) A light blue zone (gitoxin) A faint brown-yellow zone (purpurea glucoside A) A faint light blue zone (purpurea glucoside B)
Reference solution	**Test solution**

TESTS

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

Dry residue: minimum 1.8 per cent *m/m* (see French Pharmacopoeia Authority Supplement).

ASSAY

Visible absorption spectrophotometry (*2.2.25*).

Test solution. Accurately weigh 2.5 g of mother tincture. Dilute to 50.0 mL with *water R*. Add 5.0 mL of a 150 g/L solution of *lead acetate R*. Shake for a few min. Add 7.5 mL of a 40 g/L solution of *disodium phosphate R*. Filter through pleated filter paper. To 50.0 mL of filtrate,

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add 5 mL of a 150 g/L solution of *hydrochloric acid R* and heat for 1 h on a water-bath under a reflux condenser. Transfer to a separating funnel, rinse the flask with 2 quantities, each of 5 mL of *water R* and shake with 3 quantities, each of 25 mL of *methylene chloride R*. Combine the organic phases, dry over *anhydrous sodium sulfate R* and dilute to 100.0 mL with *methylene chloride R*. Evaporate 40.0 mL of the organic solution to dryness. Dissolve the residue in 7 mL of *ethanol R* (50 per cent *V/V*), then add 2 mL of *dinitro benzoic acid R* and 1 mL of *1 M sodium hydroxide*.

Reference solution. Prepare the test and reference solutions simultaneously. Dissolve precisely 50.0 mg of *digitoxin SCR* in 50.0 mL of *ethanol (96 per cent) R*. Dilute 5.0 mL of this solution to 50.0 mL with *ethanol (96 per cent) R*. To 5.0 mL of this solution, add 25 mL of *water R* and 3 mL of a 150 g/L solution of *hydrochloric acid R*. Heat for 1 h on a water-bath under a reflux condenser. Transfer to a separating funnel. Rinse the flask with 2 quantities, each of 5 mL of *water R* and shake with 3 quantities, each of 25 mL of *methylene chloride R*. Combine the organic phases, dry over *anhydrous sodium sulfate R* and dilute to 100.0 mL with *methylene chloride R*. Evaporate 40.0 mL of the organic solution to dryness. Dissolve the residue in 7 mL of *ethanol R* (50 per cent *V/V*), then add 2 mL of *dinitrobenzoic acid solution R* and 1 mL of *1 M sodium hydroxide*.

Compensation liquid. Mix 1 mL of *1 M sodium hydroxide*, 2 mL of *dinitrobenzoic acid R* and 7 mL of *ethanol R* (50 per cent *V/V*).

Measure the absorbance of the solutions several times at 540 nm during the first 12 min, until the maximum is attained, in comparison with the compensation liquid.

Calculate the percentage content *m/m* of cardenolic heterosides, expressed as digitoxin, from the expression:

$$\frac{A_1 \times m_2 \times 1.25}{A_2 \times m_1}$$

A_1 = absorbance of the test solution,
A_2 = absorbance of the reference solution,
m_1 = mass of the mother tincture sample in grams,
m_2 = mass of digitoxin in the reference solution in grams.