# NEW JERSEY TEA, DRIED FOR HOMOEOPATHIC PREPARATIONS CEANOTHUS AMERICANUS SICCUM FOR HOMOEOPATHIC PREPARATIONS

Ceanothus americanus siccum ad praeparationes homoeopathicas Other Latin name used in homoeopathy: Ceanothus

## DEFINITION

Dried leaves of Ceanothus americanus L.

Content: minimum 2.3 per cent of total flavonoids, expressed as rutin  $(C_{27}H_{30}O_{16}, 3H_2O; M_r, 665)$ .

#### IDENTIFICATION

- A. Simple, entire leaf, oval to oblong-oval, borne on a short petiole, sometimes curved or rolled on itself, 3-9 cm long and 1-3 cm large. Cordiform base or slightly rounded; obtuse apex, acute or acuminate. The margins of the lamina are slightly dentate. Glossy, green upper side of the leaf, underside pubescent near the veins. Three veins emerge from the petiole to become almost parallel; secondary veins emerge from the central vein in the upper half of the leaf and terminate at the apex, both lateral veins terminate in the upper three-quarters of the lamina.
- B. Reduce New Jersey tea, dried to a powder (355). The powder is yellowish-brown. Examine under a microscope, using *chloral hydrate solution R*. The powder contains the following elements: numerous fragments of lamina; between the veins upper epidermis consisting of polyhedral cells and rounded cells of palisade parenchyma; lower epidermis with polyhedral cells showing numerous anomocytic stomata (2.8.3); at the level of the veins epidermises with rectangular cells bearing uni or multicellular covering trichomes with thick, sclerified, canaliculate base, and tapered tip; spiraled or annular xylem vessels; calcium oxalate closters.
- C. Thin-layer chromatography (2.2.27).

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

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

Reference solution. Dissolve 10 mg of quercitrin R and 10 mg of rutin R in 10 ml methanol R.

Plate: TLC silica gel plate R.

Mobile phase: anhydrous formic acid R, water R, ethyl acetate R (10:10:80 V/V/V).

Application: 20 µl, as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: first spray with a 10 g/l solution of diphenylboric acid aminoethyl ester R in methanol R then with a 50 g/l solution of macrogol 400 R in methanol R. Allow the plate to dry in air for about 30 min. Examine in ultraviolet light at 365 nm.

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

Top of the plate	
Quercitrin: an orange zone	A greenish-yellow zone An orange zone
	A green zone more or less merged with a yellow zone above One-two more or less merged yellow zones
Rutin: an orange zone	An orange zone A yellow zone
Reference solution	Test solution

### **TESTS**

Foreign matter (2.8.2): maximum 5 per cent.

**Loss on drying** (2.2.32): maximum 12.0 per cent, determined on 1.0 g of powdered drug (355), by drying in an oven at 100-105 °C for 2 h.

**Total ash** (2.4.16): maximum 7.0 per cent, determined on 1.0 g of powdered drug (355).

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#### ASSAY

Ultraviolet and visible absorption spectrophotometry (2.2.25).

Stock solution. In a 100 ml flask, place 1.000 g of powered drug (355). Add 40 ml of ethanol (60 per cent V/V) R and heat under a reflux condenser on a water-bath at 80 °C for 1 h. Allow to decant and filter the supernatant liquid. Dissolve the residue in 40 ml of ethanol (60 per cent V/V) R. Heat again under a reflux condenser on a water-bath at 80 °C for 1 h. Filter. Rinse the flask and the filter with ethanol (60 per cent V/V) R. In a 100.0 ml volumetric flask mix the supernatant liquid and the washings and dilute to 100.0 ml with ethanol (60 per cent V/V) R. Evaporate 5.0 ml of this solution to dryness under reduced pressure. Dilute the residue in 25.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R.

Test solution. To 10.0 ml of stock solution, add 10.0 ml of a solution of 25.0 g/l of boric acid R and 20.0 g/l of oxalic acid R in anhydrous formic acid R then dilute to 25.0 ml with glacial acetic acid R.

Compensation liquid. To 10.0 ml of stock solution, add 10.0 ml of anhydrous formic acid R and dilute to 25.0 ml with glacial acetic acid R.

Reference stock solution. Dissolve 10.0 mg of rutin CRS in a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R and dilute to 50.0 ml with the same mixture. To 10 ml of this solution add a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R and dilute to 25.0 ml with the same mixture.

Reference solution. To 5.0 ml of reference stock solution, add 5.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R and 10.0 ml of a solution of 25.0 g/l of boric acid R and 20.0 g/l of oxalic acid R in anhydrous formic acid R then dilute to 25.0 ml with glacial acetic acid R.

Reference compensation liquid. To 5.0 ml of reference stock solution, add 5.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R. Then add 10.0 ml of anhydrous formic acid R and dilute to 25.0 ml with glacial acetic acid R.

Thirty min after the addition of the last reagent, measure the absorbance of the test solution and of the reference solution at 420 nm, in comparison with the compensation liquids.

Calculate the percentage content of total flavonoids, expressed as rutin, from the expression:

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$$\frac{A_1 \times m_2 \times 2 \times p}{A_2 \times m_1}$$

absorbance of the test solution,

 $A_2$  = absorbance of the reference solution,  $m_1$  = mass of the drug sample in the stock solution, in grams,  $m_2$  = mass of rutin sample in the reference stock solution, in grams,

= percentage content of rutin in rutin CRS.

#### STOCK

## DESCRIPTION

New Jersey tea, dried mother tincture is prepared with ethanol (65 per cent V/V), using the dried leaf of Ceanothus americanus L.

Content: minimum 0.20 per cent m/m of total flavonoids, expressed as rutin  $(C_{27}H_{30}O_{16}, 3 H_2O; M_r 665).$ 

## **PRODUCTION**

Method 4c (2371). Fragmented drug. Maceration time: about 3 weeks.

#### CHARACTERS

Brown liquid.

## **IDENTIFICATION**

Thin-layer chromatography (2.2.27).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of quercitrin R and 10 mg of rutin R in 10 ml of methanol R.

Plate: TLC silica gel plate R.

Mobile phase: anhydrous formic acid R, water R, ethyl acetate R (10:10:80 V/V/V).

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Application: 20 μl, as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: first spray with a 10 g/l solution of diphenylboric acid aminoethyl ester R in methanol R then with a 50 g/l solution of macrogol 400 R in methanol R. Allow the plate to dry in air for about 30 min. Examine in ultraviolet light at 365 nm.

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

Top of the plate	
Quercitrin: an orange zone	A greenish-yellow zone An orange zone
	A green zone more or less merged, topped by a yellow zone One-two more or less merged yellow zones
Rutin: an orange zone	An orange zone A yellow zone
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 1.2 per cent m/m.

## **ASSAY**

Ultraviolet and visible absorption spectrophotometry (2.2.25).

Stock solution. Evaporate 1.000 g of mother tincture to dryness under reduced pressure. Dilute the residue in 25.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial formic acid R.

Test solution. To 5.0 ml of stock solution, add 5.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R then 10.0 ml of a solution of 25.0 g/l of boric acid R and 20.0 g/l of oxalic acid R in anhydrous formic acid R and dilute to 25.0 ml with glacial acetic acid R.

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Compensation liquid. To 5.0 ml of stock solution, add 5.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R then 10.0 ml of anhydrous formic acid R and dilute to 25.0 ml with glacial acetic acid R.

Reference stock solution. Dissolve 10.0 mg of rutin CRS in a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R and dilute to 50.0 ml with the same mixture. To 10.0 ml of this solution, add a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R and dilute to 25.0 ml with the same mixture.

Reference solution. To 5.0 ml of reference stock solution, add 5.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R then 10.0 ml of a solution of 25.0 g/l of boric acid R and 20.0 g/l of oxalic acid R in anhydrous formic acid R and dilute to 25.0 ml with glacial acetic acid R.

Reference compensation liquid. To 5.0 ml of reference stock solution, add 5.0 ml of a mixture of 10 volumes of methanol R and 100 volumes of glacial acetic acid R then dilute to 25.0 ml with glacial acetic acid R.

Thirty min after the addition of the last reagent, measure the absorbance of the test solution and of the reference solution at 420 nm, in comparison with the compensation liquids.

Calculate the percentage content m/m of total flavonoids, expressed as rutin, from the expression:

$$\frac{A_1 \times m_2 \times 0.2 \times p}{A_2 \times m_1}$$

 $A_1$  = absorbance of the test solution,

 $A_2$  = absorbance of the reference solution,

 $m_1 = \text{mass of the mother tincture sample in the stock solution, in grams,}$ 

 $m_2$  = mass of rutin sample in the reference stock solution, in grams,

p = percentage content of rutin in rutin CRS.

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