SAW PALMETTO FOR HOMOEOPATHIC PREPARATIONS

SABAL SERRULATA FOR HOMOEOPATHIC PREPARATIONS

Serenoa repens ad praeparationes homoeopathicas

The drug complies with the monograph *Sabal* (*fruit) (1848).*

STOCK

DEFINITION

Saw palmetto mother tincture complies with the requirements of the general technique for the preparation of mother tinctures (see *Homoeopathic Preparations (1038)* and French pharmacopoeia Supplement). The mother tincture is prepared with ethanol (65 per cent *V/V*), using the dried, ripe fruit of *Serenoa repens* (Bartram) Small.

Content: minimum 0.70 per cent *m/m* of total fatty acids.

CHARACTERS

Appearance: yellow liquid.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 5 mg of *β-sitosterol R* and 2 mg of *β-amyrin R* in 20 mL of *ethanol* (*96 per cent*) *R*.

Plate: *TLC silica gel plate R.*

Mobile phase: *glacial acetic acid R, ethyl acetate R, toluene R* (1:30:70 *V/V/V*).

Application: 40 µL as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with *anisaldehyde solution R* then 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

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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	
------	A blue zone ------
β-amyrin: a blue zone β-sitosterol: a blue zone	A bluish-purple zone
------	------ A slightly blue 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 0.7 per cent *m/m.*

ASSAY

Gas chromatography (*2.2.28*).

Internal standard solution. In a 100.0 mL volumetric flask, dissolve 0.47 g of *methyl pelargonate R* and 0.47 g of *methyl margarate R* in 20 mL of *dimethylformamide R* and dilute to 100.0 mL with the same solvent.

Test solution. Place 20.000 g of mother tincture into a 25.0 mL volumetric flask. Add 4.0 mL of internal standard solution and dilute to 25.0 mL with *dimethylformamide R.* To 0.4 mL of this solution, add 0.6 mL of a solution containing 18.84 g/L of *trimethylsulfonium hydroxide R* in *methanol R* and mix.

Reference stock solutions. In 10.0 mL volumetric flasks dissolve separately in *dimetylformamide R*, 32.0 mg of *caproic acid R*, 62.0 mg of *caprylic acid R*, 68.0 mg of *capric acid R*, 0.699 g of *lauric acid R*, 0.267 g of *myristic acid R*, 10.0 mg of *palmitoleic acid R*, 0.217 g of *palmitic acid R*, 0.115 g of *linoleic acid R*, 18.0 mg of *linolenic acid R*, 0.870 g of *oleic acid R* and 49.0 mg of *stearic acid R* and dilute to 10.0 mL with the same solvent.

Reference solutions. Place 1.0 mL of each fatty acid solution in a 25.0 mL volumetric flask then add 4.0 mL of internal standard solution and dilute to 25.0 mL with *dimethylformamide R*. To 0.4 mL of this solution, add 0.6 mL of a solution containing 18.84 g/L solution of *trimethylsulfonium hydroxide R* in *methanol R* and mix.

Column:
– *material*: fused silica,
– *size*: *l* = 25 m [film thickness :1 µm can be used] to 60 m [film thickness: 0.2 µm can be used], *Ø* = 0.20-0.53 mm,
– *stationary phase*: *poly(dimethyl)siloxane R.*

Carrier gas: helium for chromatography R.

Flow rate: 0.5 mL/min.

Split ratio: 1:40.

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Temperature:

	Time (min)	Temperature (°C)
Column	0-2	150
	2-7	150 →190
	7-26	190 →220
Injection port		300
Detector		300

Detection: flame ionisation

Injection: 1 µL.

With reference to the retention times determined from the chromatogram obtained with the reference solutions, locate the compounds on the chromatogram obtained with the test solution.

Use the following expression to determine the percentage content of the different fatty acids. Calculate the percentage content of caproic acid, caprylic acid, capric acid and lauric acid using methyl pelargonate as internal standard. Calculate the percentage content of myristic acid, palmitoleic acid, palmitic acid, linoleic acid, linolenic acid, oleic acid, and stearic acid using methyl margarate as internal standard. The peak area of lauric acid represents at least 20 per cent of the total area of the peaks.

$$\frac{A_1 \times A_2 \times m_2 \times p \times 0.1}{A_3 \times A_4 \times m_1}$$

A_1 = area of the peak due to the concerned, derivatised fatty acid in the chromatogram obtained with the test solution,
A_2 = area of the peak due to methyl pelargonate or methyl margarate in the chromatogram obtained with the reference solution,
A_3 = area of the peak due to methyl pelargonate or methyl margarate in the chromatogram obtained with the test solution,
A_4 = area of the peak due to the concerned derivatised fatty acid in the chromatogram obtained with the reference solution,
m_1 = mass of the mother tincture sample, in grams,
m_2 = mass of the concerned fatty acid sample, in the reference solution, in grams,
p = purity of the concerned fatty acid in the reference solution in percentage.

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