

European Pharmacopoeia Essential Oils for Change Optical Rotation Measurements

Changes to the European Pharmacopoeia Essential Oils regarding Optical Rotation Measurements / Polarimeter Measurements

In April 2022 there is a change coming to the European Pharmacopoeia regarding the measurement of essential oils such as Sweet Orange Oil. The revised monograph requires that samples now need to be measured in a 0.1 dm (10mm) length cell instead of the standard 100mm polarimeter cell.

Example of essential oil that is required to be tested in a 0.1 dm (10mm) length cell.

Measuring Sweet Orange Oil

Aurantii dulcis aetheroleum

TESTS

Relative Density (2.2.5) : 0.842 to 0.850.

Refractive Index (2.2.6) : 1.470 to 1.476.

Optical Rotation (2.2.7) : +9.4° to +9.9°

(measured in a 0.1 dm tube).

The Solution to meeting new European Pharmacopoeia requirements

Compliance with the new European Pharmacopoeia requirements can be achieved with the purchase of a Rudolph .1dm/10mm length Polarimeter cell for use with Rudolph's TempTrol® heating and cooling system. These cells are being made available by Rudolph throughout the world.

Regardless of origin, essential oils in products made or destined for the European Market will need to comply with this new requirement beginning in April of 2022.

Excerpt from the European Pharmacopoeia for Sweet Orange Oil.

Essential Oils in the European Pharmacopoeia: anise, bitter fennel, caraway, cassia, cinnamon bark, citronella, clove, coriander, eucalyptus, juniper, lavender, lemon, matricaria, neroli, peppermint, pine needle, pumilio pine, rosemary, thyme, turpentine, dementholized mint, nutmeg, sweet orange, cinnamon leaf, clary sage, mandarin, star anise, and tea tree).



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SWEET ORANGE OIL

Aurantii dulcis aetheroleum

DEFINITION
Essential oil obtained without heating, by suitable mechanical treatment from the fresh peel of the fruit of *Citrus × sinensis* (L.) Osbeck. A suitable antioxidant may be added.

CHARACTERS
Appearance: clear, pale yellow or orange, mobile liquid, which may become cloudy when chilled.

IDENTIFICATION
First identification: B.
Second identification: A.
A. Thin-layer chromatography (2.2.27).
Examine the chromatograms obtained in the test for bergapten.
Results A: see below the sequence of zones present in the chromatograms obtained with the reference solution and the test solution.

Top of the plate	
Bergapten: a greenish-yellow fluorescent zone	Many blue fluorescent zones
Reference solution	Test solution

Results B: see below the sequence of zones present in the chromatograms obtained with the reference solution and the test solution.

Reference solution

Test solution

B. It complies with the limits of the test for chromatographic profile.

TESTS
Relative density (2.2.5): 0.842 to 0.850.
Refractive index (2.2.6): 1.470 to 1.476.
Optical rotation (2.2.7): + 9.4° to + 9.9° (measured in a 0.1 dm tube).
Peroxide value (2.5.5, *Method B*): maximum 20.
Fatty oils and resinsoluble essential oils (2.8.7). It complies with the test.
Bergapten. Thin-layer chromatography (2.2.27).
Test solution. Dilute 0.2 mL of the substance to be examined in 1 mL of ethanol (96 per cent) R.
Reference solution. Dissolve 2 mg of bergapten R, 10 µL of limonene R and 20 µL of limonene acetate R in 1 mL of ethanol (96 per cent) R.
Plate: TLC silica gel plate R.
Mobile phase: ethyl acetate R, toluene R (15:85 V/V).
Application: 10 µL as bands.
Development: over a path of 15 cm.
Drying: in air.
Detection A: examine in ultraviolet light at 365 nm.
Results A: the chromatogram obtained with the test solution shows no greenish-yellow fluorescent zone corresponding to that of bergapten in the chromatogram obtained with the reference solution.
Detection B: spray with *anisaldehyde solution* R and heat at 100–105 °C for 10 min; examine the plate in ultraviolet light at 365 nm.
Chromatographic profile. Gas chromatography (2.2.28): use the normalisation procedure.
Test solution. Dilute 200 µL of the substance to be examined to 10.0 mL with heptane R.
Reference solution (a). Dilute 5 µL of *α-pinene* R, 5 µL of *sabinene* R, 5 µL of *β-pinene* R, 5 µL of *β-myrcene* R, 5 µL of *octanal* R, 70 µL of *limonene* R, 5 µL of *limonene* R, 5 µL of *decanal* R, 10 µL of *citral* R (composed of *neral* and *geranial*) and 5 µL of *valencene* R to 5.0 mL with heptane R.
Reference solution (b). Dilute 5 µL of *limonene* R to 50.0 mL with heptane R. Dilute 0.1 mL of the solution to 5.0 mL with heptane R.
Column:
– *material*: fused silica;
– *size*: $l = 60$ m, $\varnothing = 0.25$ mm;
– *stationary phase*: phenyl(5)methyl(95)polystyloxane R (film thickness 0.25 µm).
Carrier gas: helium for chromatography R.

General Notices (1) apply to all monographs and other texts

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Rudolph Research Analytical is available to assist you in remaining in compliance of the United States FDA, US 21CFR Part 11, the European Pharmacopoeia and other regulatory agencies around the world.

Now may be the time to upgrade to the latest generation of 21 CFR Part 11 software with a new Rudolph Polarimeter.

Contact us to see our current line up of instruments;
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