Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2024
Document Type: NF Monographs
DocId: GUID-FF2D8691-5EE7-40FC-82B6-8B7474A449CB_4_en-US
DOI: https://doi.org/10.31003/USPNF_M62480_04_01
DOI Ref: l4bt1

Peppermint Oil

DEFINITION

Peppermint Oil is the volatile oil distilled with steam from the fresh overground parts of the flowering plant of *Mentha piperita* L. (Fam. Labiatae), rectified by distillation and neither partially nor wholly dementholized. It yields NLT 5.0% of esters, calculated as menthyl acetate ($C_{12}H_{22}O_2$), and NLT 50.0% of total menthol ($C_{10}H_{20}O$), free and as esters.

IDENTIFICATION

• **A.**

Sample: 6 drops of Oil

Analysis: Place the *Sample* in a dry test tube and mix with 5 mL of a 1-in-300 solution of nitric acid in glacial acetic acid, and place the tube in a beaker of boiling water.

Acceptance criteria: Within 5 min the liquid develops a blue color that, on continued heating, deepens and shows a copper-colored fluorescence and then fades, leaving a golden-yellow solution.

ASSAY

Change to read:

• **Total Esters**

Sample: 10 g of Oil

Analysis: Place the *Sample* in a 250-mL conical flask, add 10 mL of neutralized alcohol and 2 drops of phenolphthalein TS, then add, dropwise, 0.1 N sodium hydroxide until a faint pink color appears. Add 25.0 mL of 0.5 N alcoholic potassium hydroxide VS, connect the flask to a reflux condenser, and heat on a boiling water bath for 1 h. Allow the mixture to cool, add 20 mL of water, and add phenolphthalein TS.

Titrate the excess alkali with 0.5 N hydrochloric acid VS. Perform a blank determination, disregarding the 0.1 N sodium hydroxide (see ▲*Titrimetry ⟨541⟩*▲ (CN 1-Aug-2024)). Each mL of 0.5 N alcoholic potassium hydroxide consumed in the saponification is equivalent to 99.15 mg of total esters calculated as $C_{12}H_{22}O_2$.

Acceptance criteria: NLT 5.0% of esters, calculated as $C_{12}H_{22}O_2$

Change to read:

• **Total Menthol**

Sample: 10 mL of Oil

Analysis: Place the *Sample* in an acetylation flask of 100-mL capacity, and add 10 mL of acetic anhydride and 1 g of anhydrous sodium acetate. Boil the mixture gently for 1 h, accurately timed, cool, disconnect the flask from the condenser, transfer the mixture to a small separator, rinsing the acetylation flask with three 5-mL portions of warm water, and add the rinsings to the separator. When the liquids have completely separated, discard the water layer, and wash the remaining oil with successive portions of sodium carbonate TS, diluted with an equal volume of water, until the last washing is alkaline to phenolphthalein TS. Dry the resulting oil with anhydrous sodium sulfate, and filter. Transfer 5 mL of the dry acetylated oil to a tared, 100-mL conical flask, and weigh. Add 50.0 mL of 0.5 N alcoholic potassium hydroxide VS, connect the flask to a reflux condenser, and boil the mixture on a steam bath for 1 h, accurately timed. Allow the mixture to cool, and add 10 drops of phenolphthalein TS.

Titrate the excess alkali with 0.5 N hydrochloric acid VS. Perform a blank determination (see ▲*Titrimetry ⟨541⟩, Types of Titrations, Blank Corrections*▲ (CN 1-Aug-2024)).

Calculate the percentage of total menthol in the Oil tested:

$$\text{Result} = 7.813 \times A \times (1 - 0.0021 \times E)/(W - 0.021 \times A)$$

A = result obtained by subtracting the number of mL of 0.5 N hydrochloric acid required in the above titration from the number of mL of 0.5 N hydrochloric acid required in the residual titration blank

E = percentage of esters calculated as menthyl acetate ($C_{12}H_{22}O_2$)

W = weight of acetylated Oil taken (g)

Acceptance criteria: NLT 50.0% of $C_{10}H_{20}O$, free and as esters

IMPURITIES

• **Limit of Dimethyl Sulfide**

Analysis: Distill 1 mL from 25 mL of Oil, and carefully superimpose the distillate on 5 mL of mercuric chloride TS in a test tube.

Acceptance criteria: A white film does not form at the zone of contact within 1 min.

SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 0.896–0.908

• **Optical Rotation, *Angular Rotation* ⟨781A⟩:** −18° to −32°

• **Refractive Index ⟨831⟩:** 1.459–1.465 at 20°

• **Solubility in 70% Alcohol:** One volume dissolves in 3 volumes of 70% alcohol, with NMT slight opalescence.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and prevent exposure to excessive heat.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PEPPERMINT OIL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-FF2D8691-5EE7-40FC-82B6-8B7474A449CB_4_en-US

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