

UNITED STATES PHARMACOPŒIA.

ABSTRACT OF PROPOSED CHANGES WITH NEW STANDARDS AND DESCRIPTIONS.
ELEVENTH REVISION.

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PART III—VOLATILE OILS.

The Pharmacopœial Convention of 1930 recommended that "abstracts of changes proposed for the U. S. P. XI and new standards and descriptions" be published before final adoption, that those who are not members of the Revision Committee may have an opportunity for comment and criticism.

In compliance with this recommendation, the following abstracts are submitted. The nomenclature and the exact wording does not necessarily represent that to be finally adopted. Comments should be sent to the chairman of the Revision Committee.

E. FULLERTON COOK,
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Eucalyptol.—The word "cooling" is added to the physical description of taste. The statement regarding solubility in water is omitted.

A refractive index range of 1.455 to 1.460 has been added.

Eugenol.—The specific gravity range has been changed to 1.066 to 1.070 at 25° C. A refractive index range of 1.540 to 1.542 has been added. The test for hydrocarbons now reads as follows:

"Dissolve 1 cc. of Eugenol in 20 cc. of half-normal sodium hydroxide and add 18 cc. of distilled water: an immediate clear solution results (*hydrocarbons*) which may become turbid when exposed to air."

Methylis Salicylas.—A refractive index range of 1.535 to 1.538 has been added. The test for petroleum products has been omitted as birch oil sometimes gives positive results.

The following tests have been revised or added:

"Five cc. of Methyl Salicylate when shaken with 25 cc. of freshly boiled and cooled distilled water requires not more than 0.45 cc. of tenth-normal sodium hydroxide for neutralization, phenol red T.S. being used as the indicator (limit of free acid)."

Tests for purity. A solution of one volume of Methyl Salicylate in two volumes of alcohol is neutral or slightly acid to moistened litmus paper.

Oleum Amygdalæ Amaræ.—*Assay of benzaldehyde*. Add 0.1 cc. of bromphenol blue indicator to 25 cc. of half-normal hydroxylamine hydrochloride and titrate with half-normal alcoholic potassium hydroxide to the production of a greenish blue color. Pour this mixture into a flask, fitted with a glass stopper, containing about 1 Gm. of Oil of Bitter Almond, accurately weighed. Shake well and then titrate with half-normal alcoholic potassium hydroxide until the yellow color changes to a greenish blue. Continue shaking and titrating until the greenish blue color is permanent. Multiply the number of cc. of half-normal potassium hydroxide used by 5.3 and divide the product by the weight of oil of bitter almond taken to obtain the per cent.

Oleum Anisi.—The labeling requirement has been deleted. A requirement is added whereby congealed oil should be melted and mixed before using. The refractive index range is now 1.5530–1.5600.

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Oleum Aurantii.—Change color description to read “a yellow or intense yellow or orange or deep orange liquid.” The amount of oil taken for the residue test has been reduced from 25 Gm. to 10 Gm.

Oleum Cadinum.—“Wood” has been changed to “woody portions” in the definition. The solubility test in ether has been changed to read as follows:

“Almost completely soluble in Ether with not more than a slight flocculent precipitate.”

The specific gravity range has been changed to “0.950 to 1.055 at 25° C.”

Oleum Cari.—The only change in this test is that the strength of the sodium bisulfite solution used in adjusting the neutrality has been increased from 5 per cent to 25 per cent.

Oleum Caryophylli.—The only change in this text is the substitution of normal potassium hydroxide for potassium hydroxide T.S.

Oleum Chenopodii.—The refractive index range is now 1.4723 to 1.4770 at 20° C.

Oleum Cinnamomi.—The word “steam distillation” is omitted in the definition. Changes in the assay method have been made as under *Oleum Cari*. The refractive index range is now 1.6020 to 1.6135.

Oleum Coriandri.—The optical rotation has been changed to “varies from +8° to +15° in a 100-mm. tube at 25° C.” The refractive index range is now “1.4620 to 1.4720 at 20° C.”

Oleum Eucalypti.—The solubility ratio in 70 per cent alcohol has been changed to read “The oil is soluble in 5 volumes of 70 per cent alcohol, by volume.”

The former test for phellandrene nitrite has been replaced by the following:

“Mix 2.5 cc. of oil of eucalyptus with 5 cc. of petroleum benzin, add 5 cc. of a solution of sodium nitrite made by dissolving 5 Gm. of sodium nitrite in 8 cc. of distilled water, then gradually add 5 cc. of glacial acetic acid. No crystals of phellandrene nitrite should form within ten minutes.”

The refractive index range is now “1.4580 to 1.4700 at 20° C.”

Oleum Juniperi.—The refractive index range is now “1.4780 to 1.4840 at 20° C.”

Oleum Lavandulae.—The solubility test in 70 per cent alcohol now reads: “The oil is soluble in 4 volumes of 70 per cent alcohol by volume.”

The refractive index range is now “1.4590 to 1.4700 at 20° C.”

Oleum Limonis.—The new text for oil of lemon is as follows:

OLEUM LIMONIS.

Oil of Lemon.

Ol. Limon.-Lemon Oil.

The volatile oil obtained by expression without the aid of heat from the fresh peel of the fruit of *Citrus medica* var. *Limonum* (Risso) Hooker filius (Fam. *Rutaceae*), with or without previous separation of the pulp and the peel.

Description and physical properties.—A pale yellow to deep yellow or greenish yellow liquid, having the characteristic odor and taste of the outer part of fresh lemon peel.

Tests for identity and purity. The Oil is soluble in 3 volumes of alcohol, and in all proportions in dehydrated alcohol, carbon disulfide, and in glacial acetic acid.

Specific gravity: 0.849 to 0.855 at 25° C.

Optical rotation: Varies from +57° to +65.5° in a 100-mm. tube at 25° C.

Refractive index: 1.4742 to 1.4755 at 20° C.

A solution of the recently expressed Oil in alcohol (1 in 3) is neutral or only slightly acid to moistened litmus paper.

Oil of Lemon when distilled as described under *Oleum Aurantii*, gives the following results: The angle of rotation of the first 5 cc. is not more than 5 degrees less than that of the original Oil. The refractive index of this same portion is not less than 0.0010 and not more than 0.0027 lower than that of the original Oil.

Preserve in completely filled, well-stoppered, amber-colored bottles, in a cool place, protected from light.

Oil of Lemon which has a terebinthinate odor must not be used or dispensed.

AVERAGE DOSE: Metric, 0.1 cc.—Apothecaries, 1½ minims.

Oleum Mentha Piperita.—The optical rotation range now reads: “varies between 18° and 32° in a 100-mm. tube at 25° C.”

The following test has been added:

“Mix in a dry test-tube 3 drops of Oil of Peppermint with 5 cc. of a solution of 1 volume of nitric acid in 300 volumes of glacial acetic acid, and place the tube in a beaker of boiling water. In from one to five minutes a blue color develops which, on continued heating, deepens and shows a copper-colored fluorescence, and then fades, leaving a golden-yellow solution (distinction from oil of *mentha arvensis*).”

In drying the oily layer during the assay for total menthol, anhydrous sodium sulfate has been substituted for fused calcium chloride.

Oleum Mentha Viridis.—The carvone requirement has been increased from 43 per cent to 50 per cent, with a corresponding change in the assay. The optical activity now reads “varies from -48° to -59° in a 100-mm. tube at 25° C.”

The solubility requirement now reads: “A solution of the recently distilled oil in an equal volume of 80 per cent alcohol is neutral or only slightly acid to moistened litmus paper,” and “The oil is soluble in 1 volume of 80 per cent alcohol, by volume, forming a clear solution.”

Oleum Myristica.—The optical rotation now reads: “varies from +10° to +30° in a 100-mm. tube at 25° C.” The refractive index range has been changed to “1.4740 to 1.4880 at 20° C.”

Oleum Pini Pumilionis.—The solubility test has been changed to read as follows: “The oil is soluble in 4.5 to 8 volumes of 90 per cent alcohol, by volume.” The optical rotation requirement now reads: “varies from -5° to -12° in a 100-mm. tube at 25° C. The acidity test has been eliminated. It is now required that less than 10 per cent of the oil distills below 165° C.”

Oleum Rosæ.—This is a new text as follows:

OLEUM ROSÆ

Oil of Rose

The volatile oil distilled from the fresh flowers of *Rosa gallica* L. and *Rosa damascena* Miller, and varieties of these species (Fam. *Compositæ*).

Description and physical properties. A colorless or yellow liquid having the characteristic odor and taste of rose.

Tests for identity and purity. Oil of Rose at 25° C. is a viscous liquid. Upon gradual cooling it changes to a translucent crystalline mass, which may be easily liquefied by warming.

Specific gravity: 0.848 to 0.863 at 30° C. compared with water at 15° C.

Optical rotation: varies from -1° to -4° in a 100-mm. tube at 25° C.

Refractive index: 1.457 to 1.463 at 30° C.

One cc. of Oil of Rose mixes with 1 cc. of chloroform without turbidity. Upon adding 20 cc. of 90 per cent alcohol by volume to this solution, the resulting liquid is neutral or faintly acid to moistened litmus paper and deposits a crystalline residue upon standing.

Storage.—Preserve Oil of Rose in well-stoppered, completely filled containers in a cool place and protected from light.

Oleum Rosmarini.—The optical rotation requirement now reads: “varies from -5° to +10° in a 100-mm. tube at 25° C.” The refractive index range is now “1.4640 to 1.4760 at 20° C.”

Oleum Santali.—The refractive index range is now “1.5000 to 1.5100 at 20° C., in a 100-mm. tube at 25° C.”

Oleum Sassafras.—The optical rotation requirement now reads: “varies from +2° to +4° in a 100-mm. tube at 25° C.”

Oleum Sinapis Volatile.—The following tests have been added:

“To 3 Gm. of the oil, gradually add 6 Gm. of sulphuric acid, meanwhile keeping the liquid cool. Upon subsequent agitation the mixture will evolve sulfur dioxide, but will remain of a light yellow color, while the pungent odor of the oil will entirely disappear.”

“To 3 Gm. of the oil add 3 Gm. of alcohol in a small flask, and then add 6 Gm. of ammonia water. Upon warming to 50° C., the liquid will at first become clear and will then subsequently deposit crystals of thiosinamine.”

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PART IV—EXTRACTS, FLUIDEXTRACTS AND TINCTURES—SOLUTIONS, SPIRITS AND SYRUPS—
CERATES, OINTMENTS AND MISCELLANEOUS GALENICALS.

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Distilled Water.—Distilled water is now used in the Pharmacopœia in all formulas where water was formerly directed.

EXTRACTS, FLUIDEXTRACTS AND TINCTURES.

Only formulas and directions are considered here. Assays are reported elsewhere.

Extracta.—General chapter rewritten—extracts to be evaporated at not over 60° C.

Extractum Belladonnæ.—Maceration of drug for 16 instead of 48 hours. Evaporation under reduced pressure at not over 60° C.

Extractum Fellis Bovis.—Oxgall evaporated to 200 cc., 500 cc. alcohol added, stand 24 hours, decant, mix residue with 250 cc. alcohol, filter, wash filter with 250 cc. alcohol. Evaporate alcoholic liquids to dryness at 80° C.; add starch to make the extract weigh one-eighth the weight of the original Oxgall.

Extractum Glycyrrhizæ Purum.—Percolate is evaporated to one-half its volume by boiling under atmospheric pressure and final evaporation conducted on a water-bath.

Extractum Hyoscyami.—Same as for Extractum Belladonnæ.

Extractum Nucis Vomica.—First menstruum consists of 750 cc. alcohol, 10 cc. acetic acid, 240 cc. water. Second menstruum consists of alcohol 3 and water 1. Maceration 24 instead of 48 hours. Evaporated at not over 100° C.

Extractum Stramonii.—Same as for Extractum Belladonnæ.

Fluidextracta.—General chapter rewritten—evaporation to be made at not over 60° C. Dampened drug allowed to stand for 15 minutes instead of 6 hours.

Fluidextractum Belladonnæ Radicis.—Menstruum—alcohol 4, water 1.

Fluidextractum Cascara Sagrada Aromaticum.—Formula changed to the following:

Cascara Sagrada.....	1000	Gm.
Magnesium Oxide.....	120	Gm.

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