The United States Pharmacopeia

TWENTIETH REVISION

Official from July 1, 1980

The National Formulary

FIFTEENTH EDITION

Official from July 1, 1980

ienie interviewie piecker piech with a the second second

bergetaring and the file

1536 (1145-2006 [536 [69127])4 (621 (4016)

United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, Md. 20852



Find authenticated court documents without watermarks at docketalarm.com.



Official coupon Do not remove

NOTICE AND WARNING

Concerning U. S. Patent or Trademark Rights

The inclusion in the Pharmacopeia or in the National Formulary of a monograph on any drug in respect to which patent or trademark rights may exist shall not be deemed, and is not intended as, a grant of, or authority to exercise, any right or privilege protected by such patent or trademark. All such rights and privileges are vested in the patent or trademark owner, and no other person may exercise the same without express permission, authority, or license secured from such patent or trademark owner.

Concerning Use of USP or NF Text

Attention is called to the fact that USP and NF text is fully copyrighted. Authors and others wishing to use portions of the text should request permission to do so from the Secretary of the USPC Board of Trustees.

Concerning Laws of Other Countries

In establishing the Pharmacopeial and National Formulary standards, the USP Committee of Revision does not attempt to take into account the laws of countries other than the United States of America desiring to enforce these standards within their jurisdictions.

© 1979 The United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, Md. 20852

All rights reserved

OCK

ISSN 0195-7996 ISBN 0-912734-30-2 (cloth) 0-912734-31-0 (leather)

Typeset and printed by Mack Printing Company, Easton, Pa. 18042 Distributed by Mack Publishing Company, Easton, Pa. 18042

USP XX

Contents

The United States Pharmacopeia

TWENTIETH REVISION

By authority of the United States Pharmacopeial Convention, Inc., meeting at Washington, D. C., March 22, 1975. Prepared by the Committee of Revision and published by the Board of Trustees

615.1173 Un 3

Official from July 1, 1980

United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, Md. 20852



re des anteinents er der versterne statister er sicher der einen statister Ster Stehten, wie her sollten allestatiste in die statiste einstellingen

DESCRIPTION AND SOLUBILITY

Description and Relative Solubility of USP and NF Articles

The "description" and "solubility" statements pertaining to an article (formerly included in the individual monograph) are general in nature. The information is provided for those who use, prepare, and dispense drugs, solely to indicate descriptive and solubility properties of an article complying with monograph standards. The properties are not in themselves standards or tests for purity even though they may indirectly assist in the preliminary evaluation of the integrity of an article.

Only where a special, quantitative solubility test is given in the individual monograph, and is designated by a test heading, is it a test for purity.

The approximate solubilities of Pharmacopeial and National Formulary substances are indicated by the descriptive terms in the accompany table.

Descriptive Term	Parts of Solvent Required for 1 Part of Solute
Very soluble Freely soluble Soluble Sparingly soluble Slightly soluble Very slightly soluble Practically insoluble, or Insoluble	Less than 1 From 1 to 10 From 10 to 30 From 30 to 100 From 100 to 1000 From 1000 to 10,000 10,000 and over

Soluble Pharmacopeial and National Formulary articles, when brought into solution, may show traces of physical impurities, such as minute fragments of filter paper, fibers, and other particulate matter, unless limited or excluded by definite tests or other specifications in the individual monographs.

- Acacia: Is practically odorless and produces a mucilaginous sensation on the tongue. Insoluble in alcohol.
- Acetaminophen: White, odorless, crystalline powder, having a slightly bitter taste. Soluble in boiling water and in 1 N sodium hydroxide; freely soluble in alcohol.
- Acetazolamide: White to faintly yellowish white, crystalline, odorless powder. Very slightly soluble in water; sparingly soluble in practically boiling water; slightly soluble in alcohol.
- Sterile Acetazolamide Sodium: White solid, having the characteristic appearance of freeze-dried products.
- Acetic Acid: Clear, colorless liquid, having a strong, characteristic odor, and a sharply acid taste. Specific gravity is about 1.045. Miscible with water, with alcohol, and with glycerin.
- Diluted Acetic Acid: Clear, colorless liquid, having a characteristic odor and a sharply acid taste. Specific gravity is about 1.008. Miscible with water, with alcohol, and with glycerin.
- Glacial Acetic Acid: Clear, colorless liquid, having a pungent, characteristic odor and, when well diluted with water, an acid taste. Boils at about 118°. Specific gravity is about 1.05. Miscible with water, with alcohol, and with glycerin.
- Acetohexamide: White, crystalline, practically odorless powder. Practically insoluble in water and in ether; soluble in pyridine and in dilute solutions of alkali hydroxides; slightly soluble in alcohol and in chloroform.

Acetone: Transparent, colorless, mobile, volatile liquid, having

Acetophenazine Maleate: Fine, yellow powder. Melts at about 165°, with decomposition. Soluble in water; slightly soluble in acetone and in alcohol.

- Acetylcysteine: White, crystalline powder, having a slight acetic odor. Freely soluble in water and in alcohol; practically insoluble in chloroform and in ether.
- Acrisorcin: Yellow, odorless powder. Melts at about 190°, with decomposition (see (741)). Very slightly soluble in water and in ether; soluble in alcohol; slightly soluble in chloroform.
- Agar: Odorless or has a slight odor, and produces a mucilaginous sensation on the tongue. Insoluble in cold water; soluble in boiling water.
- Alanine: White, odorless crystals or crystalline powder, having a slightly sweet taste. Freely soluble in water; slightly soluble in 80% alcohol; insoluble in ether.
- Albumin Human: Practically odorless, moderately viscous, clear, brownish fluid.
- Alcohol: Clear, colorless, mobile, volatile liquid. Has a characteristic odor and produces a burning sensation on the tongue. Is readily volatilized even at low temperatures, and boils at about 78°. Is flammable. Miscible with water and with practically all organic solvents.
- **Dehydrated Alcohol:** Clear, colorless, mobile, volatile liquid. Has a characteristic odor and produces a burning sensation on the tongue. Is readily volatilized even at low temperatures, and boils at about 78°. Is flammable. Miscible with water and with practically all organic solvents.
- **Diluted Alcohol:** Clear, colorless, mobile liquid, having a characteristic odor and producing a burning sensation on the tongue.
- **Rubbing Alcohol:** Transparent, colorless, or colored as desired, mobile, volatile liquid. Has an extremely bitter taste and, in the absence of added odorous constituents, a characteristic odor. Is flammable.
- Alginic Acid: White to yellowish white, fibrous powder. Is odorless, or practically odorless, and is tasteless. Insoluble in water and in organic solvents; soluble in alkaline solutions.
- Allopurinol: Fluffy white to off-white powder, having only a slight odor. Very slightly soluble in water and in alcohol; soluble in solutions of potassium and sodium hydroxides; practically insoluble in chloroform and in ether.
- Almond Oil: Clear, pale straw-colored or colorless, oily liquid, having a bland taste. Remains clear at -10° , and does not congeal until cooled to almost -20° . Slightly soluble in alcohol; miscible with ether, with chloroform, with benzene, and with solvent hexane.
- Aloe: Has a characteristic, somewhat sour and disagreeable, odor.
- Alphaprodine Hydrochloride: White, crystalline powder, having a slight odor. Freely soluble in water, in alcohol, and in chloroform; insoluble in ether.
- Alum: Large, colorless crystals, crystalline fragments, or white powder. Is odorless, and has a sweetish, strongly astringent taste. Its solutions are acid to litmus. Freely soluble in water; very soluble in boiling water; freely but slowly soluble in glycerin; insoluble in alcohol.

Aluminum Apotata Tanical Solution Clear colorless liquid baving