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S Mujumdar.

22 Date of Revision

4 May 2017.

Ethanol

1 Nonproprietary Names

BP: Ethanol (96 per cent)
JP: Ethanol
PhEur: Ethanol (96 per cent)
USP–NF: Alcohol

Note that in the *Handbook of Pharmaceutical Excipients*, the term 'ethanol' is used for either ethanol 95% v/v or ethanol 96% v/v.

2 Synonyms

Alcohol; ethanolum (96 per centum); ethyl alcohol; ethyl alcohol, undenatured; ethyl hydrate; ethyl hydroxide; grain alcohol; methylcarbinol.

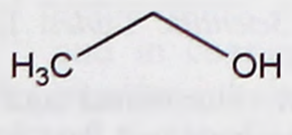
3 Chemical Name and CAS Registry Number

Ethanol [64-17-5]

4 Empirical Formula and Molecular Weight

C_2H_6O 46.07

5 Structural Formula



6 Functional Category

Antimicrobial preservative; penetration enhancer; solvent.

7 Applications in Pharmaceutical Formulation or Technology

Ethanol and aqueous ethanol solutions of various concentrations (*see* Sections 9 and 17) are widely used in pharmaceutical formulations and cosmetics; *see* Table I. Although ethanol is primarily used as a solvent, for example in solid dosage formulation,[1] it is also employed as a disinfectant, and in solutions as an antimicrobial preservative.[2,3] Topical ethanol solutions are used in the development of transdermal drug delivery systems as penetration enhancers.[4–9] Ethanol has also been used in the development of transdermal preparations as a co-surfactant.[10–12]

8 Description

Ethanol is a clear, colorless, mobile, and volatile liquid with a slight, characteristic odor and burning taste.

Table I: Uses of alcohol.

Use	Concentration (% v/v)
Antimicrobial preservative	≥10
Disinfectant	60–90
Extracting solvent in galenical manufacture	Up to 85
Solvent in film coating	Variable
Solvent in injectable solutions	Variable
Solvent in oral liquids	Variable
Solvent in topical products	60–90

9 Pharmacopeial Specifications

In the BP 2017, the term 'ethanol' used without other qualification refers to ethanol containing ≥99.5% v/v of C_2H_6O. The term 'alcohol', without other qualification, refers to ethanol 95.1–96.9% v/v. Where other strengths are intended, the term 'alcohol' or 'ethanol' is used, followed by the statement of the strength.

In the PhEur 9.2, the term ethanol (96%) is used to describe the material containing water and 95.1–96.9% v/v of C_2H_6O at 20°C. The PhEur 9.2 also includes a monograph for anhydrous ethanol, in which it states that anhydrous ethanol contains not less than 99.5% v/v of C_2H_6O at 20°C.

In the USP 40–NF 35 S1, the term 'dehydrated alcohol' refers to ethanol ≥99.5% v/v. The term 'alcohol' without other qualification refers to ethanol 94.9–96.0% v/v.

In the JP XVII, ethanol (alcohol) contains 95.1–96.9% v/v (by specific gravity) of C_2H_6O at 15°C.

The pharmacopeial specifications for ethanol have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table II. *See also* Sections 17 and 18.

10 Typical Properties

Antimicrobial activity Ethanol is bactericidal in aqueous mixtures at concentrations between 60% and 95% v/v; the optimum concentration is generally considered to be 70% v/v. Antimicrobial activity is enhanced in the presence of edetic acid or edetate salts.[2] Ethanol is inactivated in the presence of nonionic surfactants and is ineffective against bacterial spores.

Autoignition temperature 362°C

Boiling point 78.5°C

Flammability Readily flammable, burning with a blue, smokeless flame.

Flash point 13°C (closed cup)

Freezing point −117.3°C