Benzyl Alcohol

1 Nonproprietary Names

BP: Benzyl Alcohol

JP: Benzyl Alcohol

PhEur: Benzyl Alcohol

USP–NF: Benzyl Alcohol

2 Synonyms

Alcohol benzylicus; bentanol; benzal alcohol; benzenecarbinol; benzenemethanol; benzoyl alcohol; α-hydroxytoluene; phenolcarbinol; phenylcarbinol; phenylmethanol; phenylmethyl alcohol; α-toluenol.

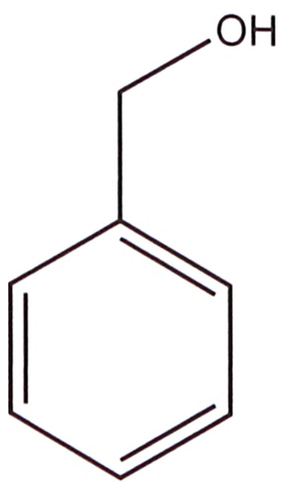
3 Chemical Name and CAS Registry Number

Benzenemethanol [100-51-6]

4 Empirical Formula and Molecular Weight

C_7H_8O 108.14

5 Structural Formula



6 Functional Category

Antimicrobial preservative; solvent.

7 Applications in Pharmaceutical Formulation or Technology

Benzyl alcohol is an antimicrobial preservative used in a wide range of pharmaceutical formulations,[1–4] including oral and parenteral preparations, at concentrations up to 2.0% v/v. The typical concentration used is 1% v/v, and it has been reported to be used in protein, peptide and small molecule products, although its frequency of use has decreased.[5] Concentrations of 5% v/v or more are employed as a solubilizer, while a 10% v/v solution is used as a disinfectant.

Although widely used as an antimicrobial preservative, benzyl alcohol has been associated with some fatal adverse reactions when administered to neonates. It is now recommended that parenteral products preserved with benzyl alcohol, or other antimicrobial preservatives, should not be used in newborn infants if at all possible; *see* Section 14.

8 Description

A clear, colorless, oily liquid with a faint aromatic odor and a sharp, burning taste.

9 Pharmacopeial Specifications

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

See Table I. *See also* Section 18.

Table I: Pharmacopeial specifications for benzyl alcohol.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification[a]	+	+	+
Characters	+	+	—
Solubility	+	+	—
Acidity	+	+	+
Clarity and color of solution[a]	+	+	+
Specific gravity	1.043–1.049	1.043–1.049	—
Refractive index	1.538–1.541	1.538–1.541	1.538–1.541
Residue on evaporation	≤5 mg	≤0.05%	≤0.05%
Related substances	+	+	+
Benzaldehyde	+	+	0.05–0.15
Peroxide value	≤5	≤5	≤5
Assay	98.0–100.5%	98.0–100.5%	98.0–100.5%

(a) These tests have not been fully harmonized at the time of publication.

10 Typical Properties

Acidity/alkalinity Aqueous solutions are neutral to litmus.

Antimicrobial activity Benzyl alcohol is bacteriostatic and is used as an antimicrobial preservative against Gram-positive bacteria, molds, fungi, and yeasts, although it possesses only modest bactericidal properties. Optimum activity occurs at pH below 5; little activity is shown above pH 8. Antimicrobial activity is reduced in the presence of nonionic surfactants, such as polysorbate 80. However, the reduction in activity is less than is the case with either hydroxybenzoate esters or quaternary ammonium compounds. The activity of benzyl alcohol may also be reduced by incompatibilities with some packaging materials, particularly polyethylene; *see* Section 12.

See Table II for reported minimum inhibitory concentrations (MICs).

Table II: Minimum inhibitory concentrations (MICs) of benzyl alcohol.[4]

Microorganism	MIC (μg/mL)
Aspergillus niger	5000
Candida albicans	2500
Escherichia coli	2000
Pseudomonas aeruginosa	2000
Staphylococcus aureus	25

Bacteria Benzyl alcohol is moderately active against most Gram-positive organisms (typical MICs are 3–5 mg/mL), although some Gram-positive bacteria are very sensitive (MICs 0.025–0.05 mg/mL). In general, benzyl alcohol is less active against Gram-negative organisms.

Fungi Benzyl alcohol is effective against molds and yeasts; typical MICs are 3–5 mg/mL.

Spores Benzyl alcohol is inactive against spores, but activity may be enhanced by heating. Benzyl alcohol 1% v/v, at pH 5–6, has been claimed to be as effective as phenylmercuric