A Acetone

1 Nonproprietary Names

BP: Acetone

PhEur: Acetone

USP–NF: Acetone

2 Synonyms

Acetonum; dimethylformaldehyde; dimethyl ketone; β-ketopropane; pyroacetic ether.

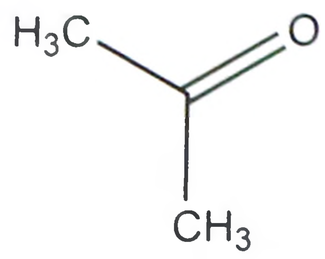
3 Chemical Name and CAS Registry Number

2-Propanone [67-64-1]

4 Empirical Formula and Molecular Weight

C_3H_6O 58.08

5 Structural Formula



6 Functional Category

Solvent.

7 Applications in Pharmaceutical Formulation or Technology

Acetone is used as a solvent or cosolvent in topical preparations up to a concentration of 13%, and as an aid in wet granulation.[1,2] It has also been used when formulating tablets with water-sensitive active ingredients, or to solvate poorly water-soluble binders in a wet granulation process.

Acetone has also been used in the formulation of microspheres[3] and polymeric nanoparticles[4] to enhance drug release.

8 Description

Acetone is a colorless volatile, flammable, transparent liquid, with a sweetish odor and pungent sweetish taste.

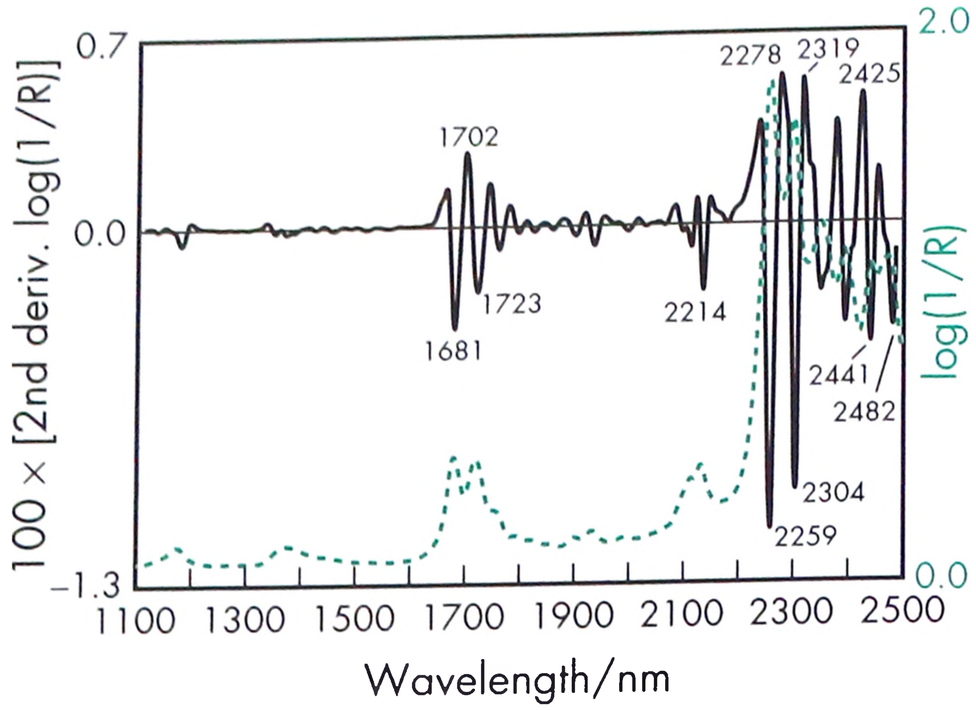


Figure 1: Near-infrared spectrum of acetone measured by transflectance (1 mm path-length).

9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

10 Typical Properties

Boiling point 56.2°C
Flash point −20°C
Melting point 94.3°C
Refractive index $n_D^{20} = 1.359$
Solubility Soluble in water; freely soluble in ethanol (95%).
Spectroscopy

NIR spectrum *see* Figure 1.

Vapor pressure 185 mmHg at 20°C

11 Stability and Storage Conditions

Acetone should be stored in a cool, dry, well-ventilated place out of direct sunlight.

12 Incompatibilities

Acetone reacts violently with oxidizing agents, chlorinated solvents, and alkali mixtures. It reacts vigorously with sulfur dichloride, potassium *t*-butoxide, and hexachloromelamine. Acetone should not be used as a solvent for iodine, as it forms a volatile compound that is extremely irritating to the eyes.[5]

Table I: Pharmacopeial specifications for acetone.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Appearance of solution	+	–
Acidity or alkalinity	+	–
Relative density	0.790–0.793	≤0.789
Related substances	+	–
Matter insoluble in water	+	–
Reducing substances	+	+
Residue on evaporation	≤50 ppm	≤0.004%
Water	≤3 g/L	+
Assay	–	≥99.0%

13 Method of Manufacture

Acetone is obtained by fermentation as a by-product of *n*-butyl alcohol manufacture, or by chemical synthesis from isopropyl alcohol; from cumene as a by-product in phenol manufacture; or from propane as a by-product of oxidation-cracking.

14 Safety

Acetone is considered moderately toxic, and is a skin irritant and severe eye irritant. It is important to remove it completely from the finished dosage if it was used as a solvent during manufacture. Skin irritation has been reported due to its defatting action, and prolonged inhalation may result in headaches. Inhalation of acetone can produce systemic effects such as conjunctival irritation, respiratory system effects, nausea, and vomiting.[6]