Malic Acid

1 Nonproprietary Names

BP: Malic Acid
PhEur: Malic Acid
USP–NF: Malic Acid

2 Synonyms

Acidum malicum; apple acid; E296; 2-hydroxy-1,4-butanedioic acid; hydroxybutanedioic acid; 1-hydroxy-1,2-ethanedicarboxylic acid; hydroxysuccinic acid; 2-hydroxysuccinic acid; DL-malic acid.

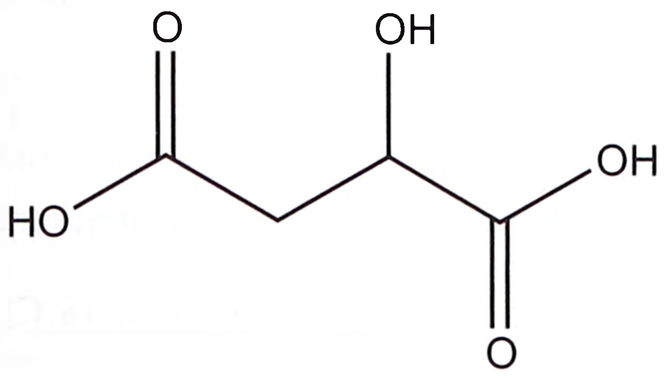
3 Chemical Name and CAS Registry Number

Hydroxybutanedioic acid [6915-15-7]
(*RS*)-(±)-Hydroxybutanedioic acid [617-48-1]

4 Empirical Formula and Molecular Weight

$C_4H_6O_5$ 134.09

5 Structural Formula



6 Functional Category

Acidulant; antioxidant; buffering agent; complexing agent; flavoring agent.

7 Applications in Pharmaceutical Formulation or Technology

Malic acid is used in pharmaceutical formulations as a general-purpose acidulant. It possesses a slight apple flavor and is used as a flavoring agent to mask bitter tastes and provide tartness. Malic acid is also used as an alternative to citric acid in effervescent powders, mouthwashes, and tooth-cleaning tablets.

In addition, malic acid has chelating and antioxidant properties.[1] It may be used with butylated hydroxytoluene as a synergist in order to retard oxidation in vegetable oils.

8 Description

White or nearly white, crystalline powder or granules having a slight odor and a strongly acidic taste. It is hygroscopic. The synthetic material produced commercially in Europe and the US is a racemic mixture, whereas the naturally occurring material found in apples and many other fruits and plants is levorotatory.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Data shown below are for the racemate. *See* Section 17 for other data for the D and L forms.

Acidity/alkalinity pH = 2.35 (1% w/v aqueous solution at 25°C)
Boiling point 150°C (with decomposition)

Table I: Pharmacopeial specifications for malic acid.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Melting point	128–132°C	–
Residue on ignition	≤0.1%	≤0.1%
Appearance of solution	+	–
Water-insoluble substances	≤0.1%	≤0.1%
Heavy metals	–	≤20 ppm
Fumaric acid	–	≤1.0%
Maleic acid	–	≤0.05%
Optical rotation	–0.10° to +0.10°	–
Related substances	+	–
Water	<2.0%	–
Assay	99.0–101.0%	99.0–100.5%

Table II: Solubility of malic acid.

Solvent	Solubility at 20°C
Acetone	1 in 5.6
Diethyl ether	1 in 119
Ethanol (95%)	1 in 2.6
Methanol	1 in 1.2
Propylene glycol	1 in 1.9
Water	1 in 1.5–2.0

Density (bulk) 0.81 g/cm^3
Density (tapped) 0.92 g/cm^3
Dissociation constant

pK_{a1} = 3.40 at 25°C;
pK_{a2} = 5.05 at 25°C.

Melting point 131–132°C
Solubility Freely soluble in ethanol (95%) and water but practically insoluble in benzene. A saturated aqueous solution contains about 56% malic acid at 20°C. *See* Table II.
Specific gravity

1.601 at 20°C;
1.250 (saturated aqueous solution at 25°C).

Spectroscopy

IR spectrum *see* Figure 1.
NIR spectrum *see* Figure 2.
Raman spectrum *see* Figure 3.

Viscosity (dynamic) 6.5 mPa s (6.5 cP) for a 50% w/v aqueous solution at 25°C.

11 Stability and Storage Conditions

Malic acid is stable at temperatures up to 150°C. At temperatures above 150°C it begins to lose water very slowly to yield fumaric acid; complete decomposition occurs at about 180°C to give fumaric acid and maleic anhydride. Conditions of high humidity and elevated temperatures should be avoided to prevent caking. The effects of grinding and humidity on malic acid have been investigated.[2] Malic acid is readily degraded by many aerobic and anaerobic microorganisms.

The bulk material should be stored in a well-closed container in a cool, dry place.