

# Hydrochloric Acid

## 1 Nonproprietary Names

BP: Hydrochloric acid  
JP: Hydrochloric acid  
PhEur: Acidum hydrochloricum concentratum  
USPNF: Hydrochloric acid

## 2 Synonyms

Chlorohydric acid; concentrated hydrochloric acid; E507.

## 3 Chemical Name and CAS Registry Number

Hydrochloric acid [7647-01-0]

## 4 Empirical Formula      Molecular Weight

HCl                                      36.46

## 5 Structural Formula

HCl

## 6 Functional Category

Acidifying agent.

## 7 Applications in Pharmaceutical Formulation or Technology

ACis widely used as an acidifying agent, in a variety of pharmaceutical and food preparations (*see* Section 16). It may also be used to prepare dilute hydrochloric acid, which in addition to its use as an excipient has some therapeutic use, intravenously in the management of metabolic alkalosis, and orally for the treatment of achlorhydria. *See* Section 17.

## 8 Description

Hydrochloric acid occurs as a clear, colorless, fuming aqueous solution of hydrogen chloride, with a pungent odor.

The JP 2001 specifies that hydrochloric acid contains 35.0–38.0% w/w of HCl; the PhEur 2002 specifies that hydrochloric acid contains 35.0–39.0% w/w of HCl; and the USPNF 20 specifies that hydrochloric acid contains 36.5–38.0% w/w of HCl. *See also* Section 9.

## 9 Pharmacopeial Specifications

*See* Table I.

**Table I:** Pharmacopeial specifications for hydrochloric acid.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	+	+	+
Appearance of solution	—	+	—
Residue on ignition	+	—	≤0.008%
Residue on evaporation	—	≤0.01%	—
Bromide or iodide	+	—	+
Free bromine	+	—	+
Free chlorine	+	≤4 ppm	+
Sulfate	+	≤20 ppm	+
Sulfite	+	—	+
Arsenic	≤1 ppm	—	—
Heavy metals	≤5 ppm	≤2 ppm	≤5 ppm
Mercury	≤0.04 ppm	—	—
Assay (of HCl)	35.0–38.0%	35.0–39.0%	36.5–38.0%

## 10 Typical Properties

**Acidity/alkalinity:** pH = 0.1 (10% v/v aqueous solution)

**Boiling point:** 110 °C (constant boiling mixture of 20.24% w/w HCl)

**Density:** ≈ 1.18 g/cm<sup>3</sup> at 20 °C

**Freezing point:** ≈ –24 °C

**Refractive index:**  $n_D^{20}$  = 1.342 (10% v/v aqueous solution)

**Solubility:** miscible with water; soluble in diethyl ether, ethanol, and methanol.

## 11 Stability and Storage Conditions

Hydrochloric acid should be stored in a well-closed, glass or other inert container at a temperature below 30 °C. Storage in close proximity to concentrated alkalis, metals, and cyanides should be avoided.

## 12 Incompatibilities

Hydrochloric acid reacts violently with alkalis, with the evolution of a large amount of heat. Hydrochloric acid also reacts with many metals, liberating hydrogen.

## 13 Method of Manufacture

Hydrochloric acid is an aqueous solution of hydrogen chloride gas produced by a number of methods including: from the reaction of sodium chloride and sulfuric acid; from the constituent elements; as a by-product from the electrolysis of sodium hydroxide; or as a by-product during the chlorination of hydrocarbons.

## 14 Safety

When used diluted, at low concentration, hydrochloric acid is not usually associated with any adverse effects. However, the concentrated solution is corrosive and can cause severe damage on contact with the eyes and skin, or if ingested.

LD<sub>50</sub> (mouse, IP): 1.4 g/kg<sup>(1)</sup>

LD<sub>50</sub> (rabbit, oral): 0.9 g/kg

## 15 Handling Precautions

Caution should be exercised when handling hydrochloric acid and suitable protection against inhalation and spillage should be taken. Eye protection, gloves, face mask, apron, and respirator are recommended, depending on the circumstances and quantity of hydrochloric acid handled. Spillages should be diluted with copious amounts of water and run to waste. Splashes on the skin and eyes should be treated by immediate and prolonged washing with large amounts of water and medical attention should be sought. Fumes can cause irritation to the eyes, nose, and respiratory system; prolonged exposure to fumes may damage the lungs. In the UK, the recommended short-term exposure limit for hydrogen chloride gas and aerosol mists is  $8 \text{ mg/m}^3$  (5 ppm). The long-term exposure limit (8-hour TWA) is  $2 \text{ mg/m}^3$  (1 ppm).<sup>(2)</sup>

## 16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (IM, IV, and SC injections, inhalations, ophthalmic preparations, oral solutions, otic, rectal, and topical preparations). Included in parenteral and nonparenteral medicines licensed in the UK.

## 17 Related Substances

Dilute hydrochloric acid.

### Dilute hydrochloric acid

**Synonyms:** acidum hydrochloricum dilutum; diluted hydrochloric acid.

**Density:**  $\approx 1.05 \text{ g/cm}^3$  at  $20^\circ\text{C}$

**Comments:** the JP 2001 and PhEur 2002 specify that dilute hydrochloric acid contains 9.5–10.5% w/w of HCl and is

prepared by mixing 274 g of hydrochloric acid with 726 g of water. The USPNF 20 specifies 9.5–10.5% w/v of HCl, prepared by mixing 226 mL of hydrochloric acid with sufficient water to make 1000 mL.

## 18 Comments

In pharmaceutical formulations, dilute hydrochloric acid is usually used as an acidifying agent in preference to hydrochloric acid. Hydrochloric acid is also used therapeutically as an escharotic.<sup>(3)</sup>

The EINECS number for hydrochloric acid is 231-595-7.

## 19 Specific References

- 1 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000; 1988–1989.
- 2 Health and Safety Executive. *EH40/2002: Occupational Exposure Limits 2002*. Sudbury: Health and Safety Executive, 2002.
- 3 Sweetman S, ed. *Martindale: The Complete Drug Reference*, 33rd edn. London: Pharmaceutical Press, 2002: 1621.

## 20 General References

Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients Directory 1996*. Tokyo: Yakuji Nippo, 1996: 228.

## 21 Author

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## 22 Date of Revision

27 June 2002.