Sodium Bicarbonate

1 Nonproprietary Names

BP: Sodium Bicarbonate

JP: Sodium Bicarbonate

PhEur: Sodium Hydrogen Carbonate

USP–NF: Sodium Bicarbonate

2 Synonyms

Baking soda; E500; *Effer-Soda*; monosodium carbonate; natrii hydrogenocarbonas; Sal de Vichy; sodium acid carbonate; sodium hydrogen carbonate.

3 Chemical Name and CAS Registry Number

Carbonic acid monosodium salt [144-55-8]

4 Empirical Formula and Molecular Weight

$NaHCO_3$ 84.01

5 Structural Formula

See Section 4.

6 Functional Category

Alkalizing agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Sodium bicarbonate is generally used in pharmaceutical formulations as a source of carbon dioxide in effervescent tablets and granules. It is also widely used to produce or maintain an alkaline pH in a preparation.

In effervescent tablets and granules, sodium bicarbonate is usually formulated with citric and/or tartaric acid;[1] combinations of citric and tartaric acid are often preferred in formulations as citric acid alone produces a sticky mixture that is difficult to granulate, while if tartaric acid is used alone, granules lose firmness. When the tablets or granules come into contact with water, a chemical reaction occurs, carbon dioxide is evolved, and the product disintegrates.[2,3] Melt granulation in a fluidized bed dryer has been suggested as a one-step method for the manufacture of effervescent granules composed of anhydrous citric acid and sodium bicarbonate, for subsequent compression into tablets.[4]

Tablets may also be prepared with sodium bicarbonate alone since the acid of gastric fluid is sufficient to cause effervescence and disintegration. Sodium bicarbonate is also used in tablet formulations to buffer drug molecules that are weak acids, thereby increasing the rate of tablet dissolution and reducing gastric irritation.[5–8]

The effects of tablet binders, such as polyethylene glycols, microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, and povidone, on the physical and mechanical properties of sodium bicarbonate tablets have also been investigated.[9,10]

Additionally, sodium bicarbonate is used in solutions as a buffering agent for erythromycin,[11] lidocaine,[12] vancomycin hydrochloride,[13] local anesthetic solutions,[14] and total parenteral nutrition (TPN) solutions.[15] In some parenteral formulations, e.g. niacin, sodium bicarbonate is used to produce a sodium salt of the active ingredient that has enhanced solubility. Sodium bicarbonate has also been used as a freeze-drying stabilizer[16,17] and in toothpastes.

Sodium bicarbonate has been used as a gas-forming agent in alginate raft systems[18–20] and in floating, controlled-release oral dosage forms for a range of drugs.[21–26] Formulations containing sodium bicarbonate have also been used for fast-dissolving tablets[27,28] and orodispersible tablets.[29] Tablet formulations containing sodium bicarbonate have been shown to increase the absorption of paracetamol,[30,31] and improve the stability of levothyroxine.[32] Sodium bicarbonate has also been included in formulations of vaginal bioadhesive tablets,[33] sustained-release matrix tablets,[34] and in carbon dioxide-releasing suppositories.[35]

See Table I.

Table I: Uses of sodium bicarbonate.

Use	Concentration (%)
Buffer in tablets	10–40
Effervescent tablets	25–50
Isotonic injection/infusion	1.39

8 Description

Sodium bicarbonate occurs as an odorless, white, crystalline powder with a saline, slightly alkaline taste. The crystal structure is monoclinic prisms. Grades with different particle sizes, from a fine powder to free-flowing uniform granules, are commercially available.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for sodium bicarbonate.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	—	+	—
Loss on drying	—	—	≤0.25%
Insoluble substances	—	—	+
pH (5% w/v aqueous solution)	7.9–8.4	≤8.6	—
Appearance	+	+	—
Carbonate	+	+	≤0.23%[a]
Normal carbonate	—	—	+
Chloride	≤0.04%	≤150 ppm	≤0.015%
Sulfate	—	≤150 ppm	≤0.015%
Sulfur compounds	—	—	≤0.015%
Ammonium	+	≤20 ppm	≤20 ppm
Aluminum	—	—	≤2 μg/g[a]
Arsenic	≤2 ppm	≤2 ppm	≤2 ppm
Calcium	—	≤100 ppm	≤0.01%[a]
Magnesium	—	—	≤0.004%[a]
Copper	—	—	≤1 ppm[a]
Iron	—	≤20 ppm	≤5 ppm[a]
Heavy metals	≤5 ppm	—	≤5 ppm
Limit of organics	—	—	≤0.01%[a]
Assay (dried basis)	≥99.0%	99.0–101.0%	99.0–100.5%

(a) Where it is labeled as intended for use in hemodialysis.