



武汉有机实业有限公司

WUHAN YOUJI INDUSTRIES CO., LTD.

(AN ISO-9001 CERTIFICATED COMPANY)

ADDRESS: No.1, 2ND CHEMICAL RD.,

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CERTIFICATE OF ANALYSIS

NAME OF PRODUCT: BENZOIC ACID BP2013 POWDER

BATCH WEIGHT: 4MT

BATCH NO.: 20240619

DATE OF MANUFACTURER: JUN.19,2024

DATE OF EXPIRY: JUN.18,2026

DATE OF ANALYSIS: JUN.19,2024

PACKING: 25KG BAG

	SPECIFICATION	RESULT OF ANALYSIS
PURITY %:	99.0MIN	99.8 → update usp 47
* CHLORIDE PPM:	300MAX	290
HEAVY METAL PPM:	10MAX	8 ✓
RESIDUE ON IGNITION %:	0.1MAX	0.05 ✗
* CLARITY OF SOLUTION:	TRANSPARENT	PASSED
OXIDISABLE SUBSTANCE:	ACCEPTABILITY	PASSED → update usp 47
CARBONISABLE SUBSTANCE:	ACCEPTABILITY	PASSED → update usp 47

CONCLUSION:

UP TO THE SPECIFICATIONS

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2024.6.19

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Benzoic Acid	Wuhan Youji	BP2013	USP47/ FI VI	Klorida	Pemerian disesuaikan dengan USP 47	Sisa pengijaran : $\leq 0.05\%$ (USP 47)	RD-02-SBP/009.00	Penyesuaian CoA dari Manufacturer
					Clarity of Solution	Kelaurutan disesuaikan dengan USP 47	READILY CARBONIZABLE SUBSTANCES TEST : Warna larutan tidak lebih intensif dari larutan Padanan Q. (USP 47)		
						Identifikasi menyesuaikan dengan USP 47	Zat Mudah Teroksidasi : ≤ 0.50 mL Kalium Permanganat (KMnO4) 0.1 N yang diperlukan.		
						Jarak lebur : 121 C - 123 C.	Kadar : 99.5% - 100.5% C7H6O2, dihitung terhadap zat anhidrat (USP 47)		
						Kadar air : $\leq 0.7\%$.			

Diperiksa Oleh

Disetujui Oleh,

Koordinator QC

Koordinator TS

Koordinator QA

Manajer QA

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methanol and in alcohol; practically insoluble in all other organic solvents.

Adhesive Bandage: The compress of Adhesive Bandage is substantially free from loose threads or ravelings. The adhesive strip may be perforated, and the back may be coated with a water-repellent film.

Gauze Bandage: One continuous piece, tightly rolled, in various widths and lengths and substantially free from loose threads and ravelings.

Barium Sulfate: Fine, white, odorless, tasteless, bulky powder, free from grittiness. Practically insoluble in water, in organic solvents, and in solutions of acids and of alkalis.

Barium Sulfate for Suspension: White or colored, bulky or granular powder.

Beclomethasone Dipropionate: White to cream white, odorless powder. Very soluble in chloroform; freely soluble in acetone and in alcohol; very slightly soluble in water.

Behenoyl Polyoxylglycerides: Waxy solid or fine powder. Soluble in methylene chloride; insoluble in alcohol; dispersible in water. *NF category:* Lubricant; emulsifying agent; wetting and/or solubilizing agent.

Belladonna Leaf: When moistened, its odor is slight, somewhat tobacco-like. Its taste is somewhat bitter and acrid.

Benazepril Hydrochloride: White to off-white, crystalline powder. Soluble in water, in methanol, and in alcohol.

Bendamustine Hydrochloride: White or almost-white powder. Freely soluble in methanol; slightly soluble in isopropyl alcohol, in acetonitrile, and in tetrahydrofuran.

Bendroflumethiazide: White to cream-colored, finely divided, crystalline powder. Is odorless, or has a slight odor. Melts at about 220°. Freely soluble in alcohol and in acetone; practically insoluble in water.

Benoxinate Hydrochloride: White, or slightly off-white, crystals or crystalline powder. Is odorless, or has a slight characteristic odor, has a salty taste, and exhibits local anesthetic properties when placed upon the tongue. Its solutions are neutral to litmus, and it melts at about 158°. Very soluble in water; freely soluble in chloroform and in alcohol; insoluble in ether.

Bentonite: Very fine, odorless, pale buff or cream-colored to grayish powder, free from grit. Has a slightly earthy taste. Is hygroscopic. Insoluble in water, but swells to approximately twelve times its volume when added to water; insoluble in, and does not swell in, organic solvents. *NF category:* Suspending and/or viscosity-increasing agent.

Purified Bentonite: Odorless, tasteless, fine (micronized) powder or small flakes that are creamy when viewed on their flat surfaces and tan to brown when viewed on their edges. Insoluble in water and in alcohol. Swells when added to water or glycerin. *NF category:* Suspending and/or viscosity-increasing agent.

Bentonite Magma: *NF category:* Suspending and/or viscosity-increasing agent.

Benzaldehyde: Colorless, strongly refractive liquid. Is affected by light. Slightly soluble in water. Miscible with alcohol, with ether, and with fixed and volatile oils. The specific gravity is 1.041–1.046 at 25° (see *Specific Gravity* <841>), and the refractive index is 1.544–1.546 at 20° (see *Refractive Index* <831>). *NF category:* Flavors and fragrance.

Benzaldehyde Elixir, Compound: *NF category:* Flavored and/or sweetened vehicle.

Benzalkonium Chloride: White or yellowish-white, thick gel or gelatinous pieces. Usually has a mild, aromatic odor. Its aqueous solution has a bitter taste, foams strongly when shaken, and usually is slightly alkaline. Very soluble in water and in alcohol. Anhydrous form freely soluble in benzene, and slightly soluble in ether. *NF category:* Antimicrobial preservative; wetting and/or solubilizing agent; emulsifying agent.

Benzalkonium Chloride Solution: Clear liquid; colorless or slightly yellow unless a color has been added. Has an aromatic odor and a bitter taste. *NF category:* Antimicrobial preservative.

Benzethonium Chloride: White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus. Soluble in water, in alcohol, and in chloroform; slightly soluble in ether. *NF category:* Antimicrobial preservative; wetting and/or solubilizing agent.

Benzethonium Chloride Solution: Odorless, clear liquid, slightly alkaline to litmus.

Benzethonium Chloride Tincture: Clear liquid, having the characteristic odor of acetone and of alcohol.

Benzocaine: Small, white crystals or white, crystalline powder. Is odorless, is stable in air, and exhibits local anesthetic properties when placed upon the tongue. Freely soluble in alcohol, in chloroform, and in ether; sparingly soluble in almond oil and in olive oil; very slightly soluble in water. Dissolves in dilute acids.

Benzoic Acid: White crystals, scales, or needles. Has a slight odor, usually suggesting benzaldehyde or benzoïn. Somewhat volatile at moderately warm temperatures. Freely volatile in steam. Freely soluble in alcohol, in chloroform, and in ether; slightly soluble in water. *NF category:* Antimicrobial preservative.

Benzoin: Sumatra Benzoin has an aromatic and balsamic odor. When heated it does not emit a pinaceous odor. When Sumatra Benzoin is digested with boiling water, the odor suggests cinnamates or storax. Its taste is aromatic and slightly acrid. Siam Benzoin has an agreeable, balsamic, vanilla-like odor. Its taste is aromatic and slightly acrid.

Benzonate: Clear, pale yellow, viscous liquid, having a faint, characteristic odor. Has a bitter taste, and exhibits local anesthetic properties when placed upon the tongue. Miscible with water in all proportions. Freely soluble in chloroform, in alcohol, and in benzene.

Hydrous Benzoyl Peroxide: White, granular powder, having a characteristic odor. Soluble in acetone, in chloroform, and in ether; sparingly soluble in water and in alcohol.

Benzoyl Peroxide Gel: A soft, white gel, having a characteristic odor.

Benzoyl Peroxide Lotion: White, viscous, creamy lotion, having a characteristic odor.

Benzphetamine Hydrochloride: White to off-white, crystalline powder. Freely soluble in alcohol and soluble in chloroform.

Benzotropine Mesylate: White, slightly hygroscopic, crystalline powder. Very soluble in water; freely soluble in alcohol; very slightly soluble in ether.

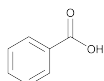
Benzyl Alcohol: Clear, colorless, oily liquid. Boils at about 206°, without decomposition. Is neutral to litmus. Freely soluble in 50% alcohol; sparingly soluble in water. Miscible with alcohol, with ether, and with chloroform. The specific gravity is between 1.042 and 1.047. *NF category:* Antimicrobial preservative; solvent.

Benzyl Benzoate: Clear, colorless, oily liquid having a slight aromatic odor and producing a sharp, burning sensation on the tongue. Practically insoluble in water and in glycerin. Miscible with alcohol, with ether, and with chloroform. *NF category:* Solvent; emulsifying agent; plasticizer.

Beta Carotene: Red or reddish-brown to violet-brown crystals or crystalline powder. Soluble in carbon disulfide, in benzene, and in chloroform; sparingly soluble in ether, in solvent hexane, and in vegetable oils; practically insoluble in methanol and in alcohol; insoluble in water, in acids, and in alkalis.

Betadex: White, practically odorless, fine crystalline powder having a slightly sweet taste. Sparingly soluble in

Benzoic Acid



$C_7H_6O_2$ 122.12
Benzoic acid CAS RN®: 65-85-0.

DEFINITION

Benzoic Acid contains NLT 99.5% and NMT 100.5% of benzoic acid ($C_7H_6O_2$), calculated on the anhydrous basis.

IDENTIFICATION

• A.

Sample solution: Prepare a saturated solution of Benzoic Acid in water, and filter twice.

Analysis 1: To one portion of the filtrate add ferric chloride TS.

Acceptance criteria 1: A salmon-colored precipitate is formed.

Analysis 2: To a separate 10-mL portion of the filtrate add 1 mL of 7 N sulfuric acid, and cool the mixture.

Acceptance criteria 2: A white precipitate forms in 10 min. This precipitate is soluble in ether.

ASSAY

• PROCEDURE

Sample: 500 mg of Benzoic Acid

Analysis: Dissolve the *Sample* in 25 mL of diluted alcohol that previously has been neutralized with 0.1 N sodium hydroxide. Add phenolphthalein TS, and titrate with 0.1 N

sodium hydroxide VS to a pink color. Each mL of 0.1 N sodium hydroxide is equivalent to 12.21 mg of benzoic acid ($C_7H_6O_2$).

Acceptance criteria: 99.5%–100.5% on the anhydrous basis

IMPURITIES

• **RESIDUE ON IGNITION** (281): NMT 0.05%

SPECIFIC TESTS

• **CONGEALING TEMPERATURE** (651): 121°–123°

• **WATER DETERMINATION, Method I** (921)

Sample solution: A 1-in-2 solution of methanol in pyridine is used as the solvent.

Acceptance criteria: NMT 0.7%

• **READILY CARBONIZABLE SUBSTANCES TEST** (271)

Sample solution: 500 mg in 5 mL of sulfuric acid

Acceptance criteria: The solution has no more color than *Matching Fluid Q*.

• **READILY OXIDIZABLE SUBSTANCES**

Sample solution: Add 1.5 mL of sulfuric acid to 100 mL of water. Heat to boiling, and add 0.1 N potassium permanganate, dropwise, until the pink color persists for 30 s. Dissolve 1.00 g of Benzoic Acid in the hot solution.

Analysis: Titrate with 0.1 N potassium permanganate VS to a pink color that persists for 15 s.

Acceptance criteria: NMT 0.50 mL of 0.10 N potassium permanganate is consumed.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.