

SINOSWEET

SinoSweet Co., Ltd.

Quality Control Department

Certificate of Analysis

Product Name: SinoSweet® Aspartame

Batch No: 22111708

Analysis Date: Nov. 18, 2022

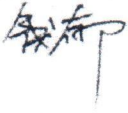
Mfg. Date: Nov. 17, 2022

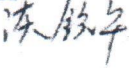
Expiration Date: Nov. 16, 2025

SinoSweet® Aspartame is an odorless, low-calorie intensive sweetener. It is chemically pure and contains no additives, preservatives, or colors. SinoSweet® Aspartame is GMO free and BSE free. It is widely used in products like table-top sweeteners, carbonated beverages, jams, instant coffee, frozen milk products, chewing gums and salad dressings. Aspartame is available in different grades, such as powder, granules, troche and liquid.

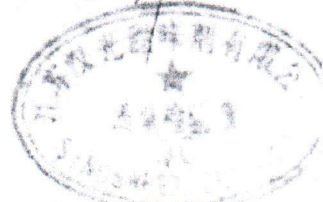
Physical and Chemical Tests

Product Grade		SinoSweet® Aspartame (Regular Powder)	
Structure	C₁₄H₁₈N₂O₅ 	CAS No	22839-47-0
		Quantity	9000kg
		Source of Product	From the package in workshop
Inspection Standard		FCCIX/USP 38/E951	
Parameter		Specification	Test Result / Remarks
Appearance		White crystalline Powder	White crystalline Powder
Assay (Titrimetric)		98.0% to 102.0% (dried basis) w/w ✓	99.78%
Specific Rotation [α] _D ²⁰		+14.5° to +16.5° ✓	+15.11°
Loss on Drying		≤4.5% ✓	2.81%
Residue on Ignition (Sulphated Ash)		≤0.2% ✓	0.15%
Diketopiperazine(DKP) (5-Benzyl-3, 6-Dioxo-2-Piperazineacetic Acid)		≤1.5% w/w ✓	0.08%
Residual Solvents		In Conformity with USP	Conforms
Other Related Substances		≤2.0% w/w ✓	1.60%
Transmittance		≥95.0% ✓	99.0%
Heavy Metals (as Pb)		≤10 mg/kg	0.5 mg/kg
Lead		≤1 mg/kg	0.08 mg/kg
pH		4.5 to 6.0 units	5.22
Particle Size		80% through 100 mesh	90%
Packaging/Shipping		◆ 25 kg net weight fiber drums with inner liner ; ◆ Custom packaging is available upon request ; ◆ Transportation: Non-hazardous.	
Storage		Store under dry and cool condition, and keep product air-tight.	
Conclusion		The product meets the requirements of FCCIX/USP 38/E951.	

Inspected
by: 

Checked
by: 

Person
in Charge: 




lawsim

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Butuh penyesuaian
terlampir

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

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	Aspartam	Sinosweet	UsP 38	USP 47/FI VI	pH	Kelarutan disesuaikan dengan USP 47	Pemerian disesuaikan dengan USP 47	RD.02-SBP/008.01	Penyesuaian CoA dari Manufacturer
					Lead				
					Residual Solvent				
					Identifikasi B (Nanoram)	Logam Berat : ≤ 10 ppm (PB) (FI VI) Particle distribution sesuai CoA	Transmittan: ≤ 0.95 (USP 47)		

Diperiksa Oleh

Disetujui Oleh,


25/24
Koordinator QC

Koordinator TS


31/09
Koordinator TS

Koordinator QA


25/10
Koordinator QA

Manager QA


25/10
Manager QA

Update SPBB

sparingly soluble in water and in alcohol; very slightly soluble in chloroform and in ether.

Apraclonidine Hydrochloride: White to off-white, odorless to practically odorless powder. Soluble in methanol; sparingly soluble in water and in alcohol; insoluble in chloroform, in ethyl acetate, and in hexanes.

Aprepitant: White to off-white powder. Sparingly soluble in alcohol; slightly soluble in acetonitrile; practically insoluble in water.

Arginine: White, practically odorless crystals. Freely soluble in water; sparingly soluble in alcohol; insoluble in ether.

Arginine Hydrochloride: White crystals or crystalline powder, practically odorless. Freely soluble in water.

Aripiprazole: A white to off-white, crystalline powder. Freely soluble in dichloromethane; sparingly soluble in toluene; insoluble in methanol and in water.

Aromatic Elixir: *NF category:* Vehicle (flavored and/or sweetened).

Articaine Hydrochloride: White or almost white, crystalline powder. Freely soluble in water and in alcohol.

Ascorbic Acid: White or slightly yellow crystals or powder. On exposure to light it gradually darkens. In the dry state, is reasonably stable in air, but in solution rapidly oxidizes. Melts at about 190°. Freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, in ether, and in benzene. *NF category:* Antioxidant.

Ascorbyl Palmitate: White to yellowish white powder, having a characteristic odor. Soluble in alcohol; very slightly soluble in water and in vegetable oils. *NF category:* Antioxidant.

Asparagine: White crystals or a crystalline powder. Soluble in water; practically insoluble in alcohol and in ether. Its solutions are acid to litmus. It melts at about 234°.

Aspartame: White, odorless, crystalline powder, having a sweet taste. Sparingly soluble in water; slightly soluble in alcohol. Melts at about 246°. The pH of an 8 in 1000 solution is about 5. *NF category:* Sweetening agent.

Aspartame Acesulfame: White, odorless, crystalline powder. Slightly soluble in water and in ethanol. *NF category:* Sweetening agent.

Aspartic Acid: White or almost white, crystalline powder, or colorless crystals. Soluble in dilute solutions of alkali hydroxides and in dilute mineral acids; slightly soluble in water; practically insoluble in alcohol and in ether.

Aspirin: White crystals, commonly tabular or needle-like, or white, crystalline powder. Is odorless or has a faint odor. Is stable in dry air; in moist air it gradually hydrolyzes to salicylic and acetic acids. Freely soluble in alcohol; soluble in chloroform and in ether; sparingly soluble in absolute ether; slightly soluble in water.

Atazanavir Sulfate: White to pale-yellow, crystalline powder. Soluble in methanol and in ethyl alcohol; slightly soluble in water; practically insoluble in heptane.

Atenolol: White or practically white, odorless powder. Melting point 146°–148° (crystals from ethyl acetate). Freely soluble in methanol; sparingly soluble in alcohol; slightly soluble in water and in isopropanol.

Atomoxetine Hydrochloride: White to practically white solid. Sparingly soluble in water.

Atorvastatin Calcium: White to off-white powder. Soluble to freely soluble in methanol; slightly soluble in alcohol; insoluble to very slightly soluble in distilled water, in pH 7.4 phosphate buffer, and in acetonitrile; insoluble in aqueous solutions of pH 4 and below.

Atovaquone: Yellow powder. Freely soluble in *N*-methyl-2-pyrrolidone and in tetrahydrofuran; soluble in chloroform; sparingly soluble in acetone, in di-*n*-butyl adipate, in dimethyl sulfoxide, and in polyethylene glycol 400; slightly soluble in

alcohol, in 1,3-butanediol, in ethyl acetate, in glycerin, in octanol, and in polyethylene glycol 200; very slightly soluble in 0.1 N sodium hydroxide; insoluble in water.

Atracurium Besylate: White to yellowish white powder, slightly hygroscopic. Very soluble in acetonitrile, in alcohol, and in methylene chloride; soluble in water.

Atropine: White crystals, usually needle-like, or white, crystalline powder. Its saturated solution is alkaline to phenolphthalein TS. Is optically inactive, but usually contains some levorotatory hyoscyamine. Freely soluble in alcohol and in chloroform; soluble in glycerin and in ether; slightly soluble in water; sparingly soluble in water at 80°.

Atropine Sulfate: Colorless crystals, or white, crystalline powder. Odorless; effloresces in dry air; is slowly affected by light. Very soluble in water; freely soluble in alcohol and even more so in boiling alcohol; freely soluble in glycerin.

Activated Attapulgate: Cream-colored, micronized, nonswelling powder, free from gritty particles. The high heat treatment used in its preparation causes it to yield only moderately viscous aqueous suspensions, its dispersion consisting mainly of particle groups. Insoluble in water. *NF category:* Suspending and/or viscosity-increasing agent.

Colloidal Activated Attapulgate: Cream-colored, micronized, nonswelling powder, free from gritty particles. Yields viscous aqueous suspensions, as a result of dispersion into its constituent ultimate particles. Insoluble in water. *NF category:* Suspending and/or viscosity-increasing agent.

Aurothioglucose: Yellow, odorless or practically odorless powder. Is stable in air. An aqueous solution is unstable on long standing. The pH of its 1 in 100 solution is about 6.3. Freely soluble in water; practically insoluble in acetone, in alcohol, in chloroform, and in ether.

Azathioprine: Pale yellow, odorless powder. Soluble in dilute solutions of alkali hydroxides; sparingly soluble in dilute mineral acids; very slightly soluble in alcohol and in chloroform; insoluble in water.

Azathioprine Sodium for Injection: Bright yellow, hygroscopic, amorphous mass or cake.

Azelastine Hydrochloride: White or almost white, crystalline powder. Soluble in ethanol and in methylene chloride; sparingly soluble in water.

Azithromycin: White or almost white powder. Freely soluble in anhydrous ethanol and in methylene chloride; practically insoluble in water.

Aztreonam: White, odorless, crystalline powder. Soluble in dimethylformamide and in dimethyl sulfoxide; slightly soluble in methanol; very slightly soluble in dehydrated alcohol; practically insoluble in ethyl acetate, in chloroform, and in toluene.

Bacampicillin Hydrochloride: White or practically white powder. Is hygroscopic. Freely soluble in alcohol and in chloroform; soluble in methylene chloride and in water; very slightly soluble in ether.

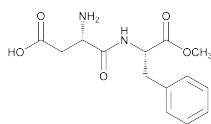
Bacitracin: White to pale buff powder, odorless or having a slight odor. Is hygroscopic. Its solutions deteriorate rapidly at room temperature. Is precipitated from its solutions and is inactivated by salts of many of the heavy metals. Freely soluble in water; soluble in alcohol, in methanol, and in glacial acetic acid, the solution in the organic solvents usually showing some insoluble residue; insoluble in acetone, in chloroform, and in ether.

Bacitracin Zinc: White to pale tan powder, odorless or having a slight odor. Is hygroscopic. Sparingly soluble in water.

Baclofen: White to off-white, crystalline powder. Is odorless or practically so. Slightly soluble in water; very slightly soluble in methanol; insoluble in chloroform.

Balsalazide Disodium: Orange to yellow powder. Freely soluble in water and in isotonic saline; sparingly soluble in

Aspartame



$C_{14}H_{18}N_2O_5$ 294.30
L-Phenylalanine, N-L-α-aspartyl-, 1-methyl ester;
3-Amino-N-(α-carboxyphenethyl)succinamic acid N-methyl
ester CAS RN®: 22839-47-0.

DEFINITION

Aspartame contains NLT 98.0% and NMT 102.0% of
aspartame ($C_{14}H_{18}N_2O_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. ▲SPECTROSCOPIC IDENTIFICATION TESTS** <197>, *Infrared Spectroscopy*: **197M▲** (CN 1-May-2020)
[NOTE—Do not dry specimens.]

ASSAY

• PROCEDURE

Buffer: 0.05 M monobasic potassium phosphate, adjusted
with phosphoric acid to a pH of 4.3

Mobile phase: Methanol and *Buffer* (18:82)

Diluent: Methanol and water (1:9)

System suitability solution: 0.1 mg/mL each of USP
Aspartame Related Compound A RS and USP
L-Phenylalanine RS in *Diluent*

Standard solution: 0.5 mg/mL of USP Aspartame RS in
Diluent

Sample solution: 0.5 mg/mL of Aspartame in *Diluent*.
[NOTE—Avoid heat and excessive holding times.]

Chromatographic system

(See *Chromatography* <621>, *System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 2 mL/min

Injection volume: 20 μL

Run time: 30 min

System suitability

Samples: *System suitability solution* and *Standard solution*
[NOTE—The relative retention times for the
L-phenylalanine and aspartame related compound A
peaks are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8 between the L-phenylalanine and
aspartame related compound A peaks, *System suitability*
solution

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard*
solution

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aspartame ($C_{14}H_{18}N_2O_5$) in the
portion of Aspartame taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of aspartame from the *Sample solution*

r_S = peak area of aspartame from the *Standard solution*

C_S = concentration of USP Aspartame RS in the
Standard solution (mg/mL)

C_U = concentration of Aspartame in the *Sample*
solution (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION** <281>: NMT 0.2%

- **LIMIT OF 5-BENZYL-3,6-DIOXO-2-PIPERAZINEACETIC ACID**
Mobile phase, Diluent, System suitability solution, and
Chromatographic system: Proceed as directed in the
Assay.

Standard solution: 75 μg/mL of USP Aspartame Related
Compound A RS in *Diluent*

Sample solution: 5 mg/mL of Aspartame in *Diluent*.
[NOTE—Avoid heat and excessive holding times.]

System suitability

Samples: *System suitability solution* and *Standard solution*
Suitability requirements

Resolution: NLT 8 between the L-phenylalanine and
aspartame related compound A peaks, *System suitability*
solution

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 4.0%, *Standard*
solution

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—Continue the elution of the *Sample solution* for
45 min.]

Calculate the percentage of aspartame related compound A
in the portion of Aspartame taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of aspartame related compound A
from the *Sample solution*

r_S = peak response of aspartame related compound A
from the *Standard solution*

C_S = concentration of 5-benzyl-3,6-dioxo-
2-piperazineacetic acid in the *Standard solution*
(mg/mL)

C_U = concentration of Aspartame in the *Sample*
solution (mg/mL)

Acceptance criteria: NMT 1.5%

• CHROMATOGRAPHIC PURITY

Mobile phase, Diluent, System suitability solution, and
Chromatographic system: Proceed as directed in the
Assay.

Sample stock solution: Proceed as directed in the *Sample*
solution in the test for *Limit of 5-Benzyl-3,6-dioxo-*
2-piperazineacetic Acid.

Sample solution: 0.1 mg/mL of Aspartame from the *Sample*
stock solution in *Diluent*

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 8 between the L-phenylalanine and
aspartame related compound A peaks, *System suitability*
solution

Analysis

Samples: *Sample stock solution* and *Sample solution*

[NOTE—Continue the elution of the *Sample stock*
solution for 45 min.]

Acceptance criteria: The sum of all of the peak responses of
the *Sample stock solution*, excluding the 5-benzyl-
3,6-dioxo-2-piperazineacetic acid and aspartame peak
responses, is NMT the aspartame peak response of the
Sample solution, corresponding to NMT 2.0% of
chromatographic impurities.

SPECIFIC TESTS

• TRANSMITTANCE

Sample solution: 10 mg/mL of Aspartame in 2 N hydrochloric acid, prepared by means of sonication

Analysis: Determine the transmittance in a 1-cm cell at 430 nm with a suitable spectrophotometer.

Acceptance criteria: Transmittance of NLT 0.95, corresponding to an absorbance of NMT about 0.022

• OPTICAL ROTATION, *Specific Rotation* <781 S>

Sample solution: 40 mg/mL in 15 N formic acid

Acceptance criteria: +14.5° to +16.5°, determined at 20° within 30 min after preparation of the *Sample solution*

• LOSS ON DRYING <731>

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 4.5%

ADDITIONAL REQUIREMENTS

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

• USP REFERENCE STANDARDS <11>

USP Aspartame RS

USP Aspartame Related Compound A RS

5-Benzyl-3,6-dioxo-2-piperazineacetic acid.

$C_{13}H_{14}N_2O_4$ 262.27

USP L-Phenylalanine RS