Asparagine

1 Nonproprietary Names

BP: Asparagine Monohydrate
PhEur: Asparagine Monohydrate
USP-NF: Asparagine

2 Synonyms

Agedoite; altheine; (*S*)-2-aminosuccinic acid 4-amide; Asn; L-asparagine; (*S*)-asparagine; asparamide; aspartamic acid; L-aspartic acid 4-amide; L-aspartic acid β-amide; (2*S*)-2,4-diamino-4-oxobutanoic acid monohydrate.

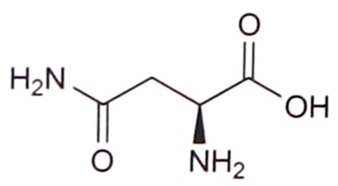
3 Chemical Name and CAS Registry Number

L-α-Aminosuccinamic acid [70-47-3]
L-α-Aminosuccinamic acid monohydrate [5794-13-8]

4 Empirical Formula and Molecular Weight

$C_4H_8N_2O_3$ (anhydrous)	132.12
$C_4H_8N_2O_3 \cdot H_2O$ (monohydrate)	150.13

5 Structural Formula



6 Functional Category

Buffering agent; dry powder inhaler carrier; lyophilization aid; tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Asparagine is used in nutritional supplements, vaccines, and intravesical injections; *see* Section 16. It is an ingredient in the strain growth medium for preparation of freeze-dried attenuated Bacillus Calmette-Guérin formulations.[1] It has been used experimentally as a lyophilization aid or buffering agent for stabilizing peptides,[2] proteins,[3] and antineoplastic agents in pharmaceutical preparations.[4] Asparagine has been investigated as a matrix supporting and disintegration enhancing agent in lyophilized rapid disintegrating tablets at concentrations of 10–70%,[5] and has also been studied in spray-dried disodium cromoglycate inhalation powder formulations at a concentration of 5.1%.[6]

Asparagine is used in the cosmetics industry in hair and skin conditioning products.[7]

8 Description

L-Asparagine occurs as a tasteless[8] white or almost white, crystalline powder or colorless crystals.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for asparagine.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Appearance of solution	+	–
Residue on ignition	–	≤0.1%
Sulfated ash	≤0.1%	–
Lead	–	≤5 ppm
Chlorides	≤200 ppm	–
Sulfates	≤200 ppm	–
Ammonium	≤0.1%	–
Iron	≤10 ppm	–
Chromatographic purity	–	+
Ninhydrin-positive substances	+	–
Specific rotation	+ 33.7° to + 36.0°	+33.0° to +36.5°
pH	4.0 to 6.0	–
Microbial Contamination		
Aerobic microbes	–	10^3 cfu/g
Yeasts and molds	–	10^2 cfu/g
Loss on drying		
Anhydrous	–	≤1.0%
Monohydrate	10.5–12.5%	11.5–12.5%
Assay	99.0–101.0%	98.0–101.5%

10 Typical Properties

Dissociation Content
pK_{a1} 2.02;
pK_{a2} 8.80[9]
Melting Point 234–235°C[9]
Partition Coefficient log K_{ow} (octanol : water) = -3.82[10]
Specific Gravity 1.543[9]
Solubility Soluble in acids, alkalis, and in water at 2.94×10^4 mg/L (25°C);[9] practically insoluble in methanol and benzene; insoluble in ethanol and ether.[11]
Vapor pressure 0.64×10^{-8} kPa (4.8×10^{-8} mmHg) at 25°C[9]

11 Stability and Storage Conditions

Exposure to temperatures above 30°C can cause decomposition. Preserve in well-closed, light-resistant containers at room temperature. Avoid moisture, direct sunlight, and contact with acids, bases, and oxidizers.[12]

12 Incompatibilities

Asparagine is incompatible with strong oxidizing agents.

13 Method of Manufacture

Asparagine is a naturally occurring amino acid, widely distributed in both plants and animals.[13] Industrially, it may be isolated from the by-products of potato starch production[14] or chemically synthesized from aspartic acid.[15,16] Direct microbial fermentation from carbohydrates is an alternative method for asparagine production.[17]