

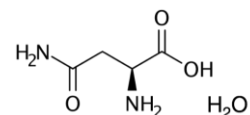
L-ASPARAGINE MONOHYDRATE

EP 9 ORAL GRADE

PARAMETER	LIMIT
Appearance: White or almost white crystalline powder or colourless crystals	passes
Identity (A. Specific optical rotation / B. IR)	passes
Test on turbidity (2.0 % (m/V) in H ₂ O)	≤ Ref. Susp. I
Test on colour (2.0 % (m/V) in H ₂ O)	≤ B ₉
Specific optical rotation (on dry basis) (10.0 % (m/V) in 3 M HCl at 20°C [α] _D ²⁰)	+33.7° to +36.0°
Ninhydrin-positive substances (TLC)	Passes
Other amino acids (HPLC): <ul style="list-style-type: none"> ▪ Aspartic Acid ▪ Glutamic Acid ▪ Any unspecific impurity ▪ Total impurities 	≤ 0.5 % ≤ 0.5 % ≤ 0.05 % ≤ 0.5 %
pH (2 % (m/V) in H ₂ O)	4.0 to 6.0
Chlorides	≤ 200 ppm
Sulphates	≤ 200 ppm
Ammonium	≤ 0.1 %
Iron	≤ 10 ppm
Loss on drying	10.5 % to 12.5 %
Residue on ignition	≤ 0.1 %
Assay (on dry basis)	99.0 to 101.0 %
Total viable aerobic count	≤ 1000 CFU/g
Moulds and yeasts	≤ 100 CFU/g
Salmonella	In 1 g n.d.
<i>Escherichia coli</i>	In 1 g n.d.
<i>Pseudomonas aeruginosa</i>	In 1 g n.d.
<i>Staphylococcus aureus</i>	In 1 g n.d.

CHEMICAL DATA

Formula: C₄H₈N₂O₃·H₂O
CAS Number: 5794-13-8



PACKAGING

25 kg Unit
Outer container: Fiber drum
Outer liner: LDPE
Inner liner: LDPE

STORAGE

Dry and dark at room temperature in tightly closed container

STABILITY

Product is stable for 4 years from date of production if stored under recommended conditions in original packaging.