

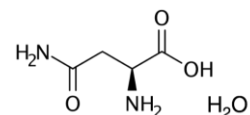
L-ASPARAGINE MONOHYDRATE

EP 9 INFUSION 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 | ≤ 100 CFU/g |
| Moulds and yeasts | ≤ 10 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. |
| Endotoxins | < 6 EU/g |

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.