

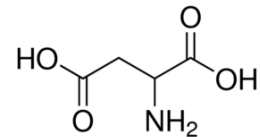
DL-ASPARTIC ACID

BASED ON EP 9 INFUSION GRADE (L-ASPARTIC ACID)

| PARAMETER | LIMIT |
|---|-------------------|
| Appearance: White or almost white crystalline powder or colourless crystals | passes |
| Identity (A. Specific optical rotation / B. IR) | passes |
| Test on turbidity (5.0 % (m/V) in 1 M HCl) | ≤ Ref. Susp. I |
| Test on colour (5.0 % (m/V) in 1 M HCl) | ≤ BY ₆ |
| Specific optical rotation (on dry basis) (8.0 % (m/V) in 25 % HCl at 20°C [α] _D ²⁰) | -0.1° to +0.1° |
| Ninhydrin-positive substances (TLC) | passes |
| Chlorides | ≤ 200 ppm |
| Sulphates | ≤ 300 ppm |
| Ammonium | ≤ 200 ppm |
| Iron | ≤ 10 ppm |
| Loss on drying | ≤ 0.5 % |
| Residue on ignition | ≤ 0.1 % |
| Assay (on dry basis) | 98.5 to 101.5 % |
| 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 (LAL-Assay) | < 8 EU/g |

CHEMICAL DATA

Formula: C₄H₇NO₄
CAS Number: 617-45-8



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.