

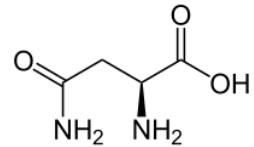
# L-ASPARAGINE ANHYDROUS

BASED ON EP 9 INFUSION GRADE (L-ASPARAGINE MONOHYDRATE)

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 <sub>2</sub> O)	≤ Ref. Susp. I
Test on colour (2.0 % (m/V) in H <sub>2</sub> O)	≤ B <sub>9</sub>
Specific optical rotation (on dry basis) (10.0 % (m/V) in 3M HCl at 20°C [ $\alpha$ ] <sub>D</sub> <sup>20</sup> )	+33.7° to +36.0°
Ninhydrin-positive substances (TLC)	Passes
Ammonium	≤ 0.1 %
Chlorides	≤ 200 ppm
Sulphates	≤ 200 ppm
Iron	≤ 10 ppm
Loss on drying	≤ 1.0 %
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: C<sub>4</sub>H<sub>8</sub>N<sub>2</sub>O<sub>3</sub>  
CAS Number: 70-47-3



## PACKAGING

25 kg Unit  
Outer container: Fiber drum  
Outer liner: Alu/PE comp.  
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.