

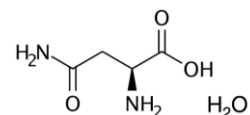
# L-ASPARAGINE MONOHYDRATE

EP 9 / NF 34

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 3 M HCl at 20°C [ $\alpha$ ] <sub>D</sub> <sup>20</sup> ) (1.0 % (m/V) in 6 M HCl at 20°C [ $\alpha$ ] <sub>D</sub> <sup>20</sup> )	+33.7° to +36.0° +33.0° to 36.5°
Ninhydrin-positive substances (TLC)	Passes
Other amino acids (HPLC): <ul style="list-style-type: none"> <li>▪ Aspartic Acid</li> <li>▪ Glutamic Acid</li> <li>▪ Any unspecific impurity</li> <li>▪ Total impurities</li> </ul>	≤ 0.5 % ≤ 0.5 % ≤ 0.05 % ≤ 0.5 %
pH (2 % (m/V) in H <sub>2</sub> O)	4.0 to 6.0
Chlorides	≤ 200 ppm
Sulphates	≤ 200 ppm
Ammonium	≤ 0.1 %
Iron	≤ 10 ppm
Lead	≤ 5 ppm
Loss on drying	11.5 % 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
Bile-tolerant gram-negative bacteria	In 1 g n.d.
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.
<i>Clostridia</i>	In 1 g n.d.
<i>Candida albicans</i>	In 1 g n.d.

## CHEMICAL DATA

Formula: C<sub>4</sub>H<sub>8</sub>N<sub>2</sub>O<sub>3</sub>·H<sub>2</sub>O  
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.