

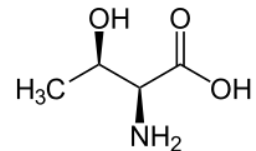
L-THREONINE

EP 9 / USP 39

PARAMETER	LIMIT
Appearance: White crystalline powder or colourless flakes	passes
Identity (A. Specific optical rotation/ B. IR)	passes
Test on turbidity (2.5 % (m/V) in H ₂ O)	≤ Ref. Susp. I
Test on colour (2.5 % (m/V) in H ₂ O)	≤ B ₉
pH-value (2.5 % (m/V) in H ₂ O at 20°C) (5.0 % (m/V) in H ₂ O at 25°C)	5.0 to 6.5 5.0 to 6.5
Specific optical rotation (on dry basis) (6.0 % (m/V) in H ₂ O at 20°C [α] _D ²⁰) (6.0 % (m/V) in H ₂ O at 20°C [α] _D ²⁰)	-27.6° to -29.0° -26.7° to -29.1°
Ninhydrin-positive substances (TLC)	passes
Ninhydrin-positive substances (HPLC) <ul style="list-style-type: none"> Each impurity Sum of impurities 	≤ 0.2 % ≤ 0.5 %
Ammonium	≤ 0.02 %
Chlorides	≤ 200 ppm
Sulphates	≤ 300 ppm
Iron	≤ 10 ppm
Heavy metals (as Pb)	≤ 15 ppm
Loss on drying	≤ 0.2 %
Residue on ignition	≤ 0.1 %
Assay (on dry basis)	99.0 to 101.0 %
Residual solvents	passes
Total viable aerobic count	≤ 100 CFU/g
Moulds and yeasts	≤ 10 CFU/g
Salmonella	In 10 g n.d.
<i>Escherichia coli</i>	In 10 g n.d.
<i>Pseudomonas aeruginosa</i>	In 10 g n.d.
<i>Staphylococcus aureus</i>	In 10 g n.d.

CHEMICAL DATA

Formula: C₄H₉NO₃
CAS Number: 72-19-5



PACKAGING

25 kg Unit
Outer container: Fiber drum
Outer liner: HDPE
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.