

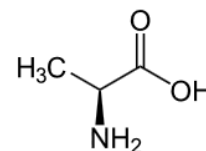
L-ALANINE

EP 9 / USP 39

PARAMETER	LIMIT
Appearance: White or almost white crystalline powder or colourless crystals	passes
Identity (A. Specific optical rotation / B. IR)	passes
Test on turbidity (2.5 % (m/V) in H ₂ O)	≤ Ref. Susp. I
Test on colour (2.5 % (m/V) in H ₂ O)	≤ BY ₆
Specific optical rotation (on dry basis) (10.0 % (m/V) in 25 % HCl at 20°C [α] _D ²⁰) (10.0 % (m/V) in 6 N HCl at 25°C [α] _D ²⁵)	+13.5° to +15.5° +13.7° to +15.1°
Ninhydrin-positive substances (AAA) <ul style="list-style-type: none"> Each impurity Total impurities 	≤ 0.10 % ≤ 0.5 %
Organic impurities (HPLC): <ul style="list-style-type: none"> Maleic acid Malic acid Fumaric acid Any unspecific impurity Total unspecific impurities 	≤ 0.05 % ≤ 0.05 % ≤ 0.05 % ≤ 0.05 % ≤ 0.20 %
Ammonium	≤ 0.02 %
Chlorides	≤ 200 ppm
Sulphates	≤ 300 ppm
Iron	≤ 10 ppm
Heavy metals (as Pb)	≤ 15 ppm
pH (5.0 % (m/V) in H ₂ O)	5.5 to 7.0
Loss on drying	≤ 0.2 %
Residue on ignition	≤ 0.1 %
Assay (on dry basis)	98.5 to 101.0 %
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: C₃H₇NO₂
CAS Number: 65-41-7



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.