

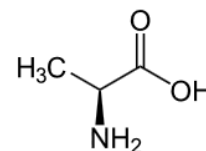
# L-ALANINE

## EP 9 INFUSION GRADE

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 <sub>2</sub> O)	≤ Ref. Susp. I
Test on colour (2.5 % (m/V) in H <sub>2</sub> O)	≤ BY <sub>6</sub>
Specific optical rotation (on dry basis) (10.0 % (m/V) in 25 % HCl at 20°C [ $\alpha$ ] <sub>D</sub> <sup>20</sup> )	+13.5° to +15.5°
Ninhydrin-positive substances (AAA) <ul style="list-style-type: none"> <li>▪ Each impurity</li> <li>▪ Total impurities</li> </ul>	≤ 0.10 % ≤ 0.5 %
Ammonium	≤ 0.02 %
Chlorides	≤ 200 ppm
Sulphates	≤ 300 ppm
Iron	≤ 10 ppm
Loss on drying	≤ 0.5 %
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 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)	< 6 EU/g

### CHEMICAL DATA

Formula: C<sub>3</sub>H<sub>7</sub>NO<sub>2</sub>  
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.