

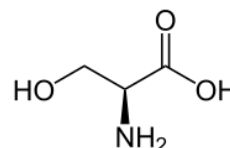
L-SERINE

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 (5.0 % (m/V) in H ₂ O)	≤ Ref. Susp. I
Test on colour (5.0 % (m/V) in H ₂ O)	≤ BY ₆
Specific optical rotation (on dry basis) (10.0 % (m/V) in 2 M HCl at 20°C [α] _D ²⁰)	+14.0° to +16.0°
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
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: C₃H₇NO₃
CAS Number: 56-45-1



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.