

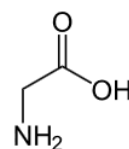
GLYCINE

EP 9 INFUSION GRADE

PARAMETER	LIMIT
Appearance: White or almost white crystalline powder	passes
Identity (A. IR)	passes
Test on turbidity (10.0 % (m/V) in H ₂ O)	≤ Ref. Susp. I
Test on colour (10.0 % (m/V) in H ₂ O)	≤ Y ₇
pH (5.0 % (m/V) in H ₂ O)	+5.9° to +6.4°
Related substances (HPLC) <ul style="list-style-type: none"> Glycine Anhydride Diglycine Triglycine each other impurity total of impurities 	≤ 0.10 % ≤ 0.10 % ≤ 0.10 % ≤ 0.10 % ≤ 0.2 %
Other amino acids (AAA) <ul style="list-style-type: none"> individual impurity total of impurities Ammonium 	≤ 0.10 % ≤ 1.0 % ≤ 0.02 %
Chlorides	≤ 75 ppm
Heavy metals (as Pb)	≤ 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	< 6 EU/g

CHEMICAL DATA

Formula: C₂H₅NO₂
CAS Number: 56-40-6



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.