

SPECIFICATION

Glycine

Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP) Identification (JP) pH (JP) Purity (JP) (1) Clarity and color of solution (JP) (2) Chloride (JP) (3) Sulfates (JP) (4) Ammonium (JP) (5) Related substances (JP) Loss on drying (JP) Residue on ignition (JP) Assay (after drying) (JP)	White crystals or crystalline powder to pass test 5.6~6.6 - to pass test not more than 0.021% not more than 0.028% not more than 0.02% to pass test not more than 0.30% not more than 0.1% not less than 98.5%
* Bacterial endotoxins Identification (USP-NF) Assay (dried basis) (USP-NF) Impurities (USP-NF) (1) Residue on ignition (USP-NF) (2) Chloride (USP-NF) (3) Sulfate (USP-NF) (4) Hydrolyzable substances (USP-NF) (5) Related compounds (USP-NF) Specific test (USP-NF) (1) Loss on drying (USP-NF)	less than 1.2EU/g to pass test 98.5~101.5% - NMT 0.1% NMT 0.007% NMT 0.0065% to pass test to pass test - NMT 0.2%
* Appearance (Ph.Eur.) Identification (Ph.Eur.) Appearance of solution (Ph.Eur.) pH (Ph.Eur.) Related substances (Ph.Eur.) Ninhydrin-positive substances (Ph.Eur.)	White or almost white, crystalline powder to pass test to pass test 5.9 to 6.4 to pass test to pass test

Chlorides (Ph.Eur.)	maximum 75ppm
Ammonium (Ph.Eur.)	to pass test
Loss on drying (Ph.Eur.)	maximum 0.5%
Sulfated ash (Ph.Eur.)	maximum 0.1%
Assay (dried substance) (Ph.Eur.)	98.5~101.0%

Japanese Pharmacopoeia(Glycine)United States Pharmacopeia - National Formulary) (Glycine)European Pharmacopoeia (Glycine)(*):Additional test performed by Wako)