

SPECIFICATION

Glycine

Japanese Pharmacopoeia

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