2024/07/01
Distributed by FUJIFILM Wako Pure Chemical Corporation
Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.07-0687

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)

revised on 2024/07/01