2025/12/30
Distributed by FUJIFILM Wako Pure Chemical Corporation
Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.08-1076

SPECIFICATION

L-Histidine

Japanese Pharmacopoeia

REQUIREMENT		SPECIFICATION
*	Description (JP)	White crystals or crystalline powder
	Identification (JP)	to pass test
	Optical rotation [α]D20 (JP)	+11.8～+12.8°
	pH (JP)	7.0～8.5
	Purity (JP)	-
(1)	Clarity and color of solution (JP)	to pass test
(2)	Chloride (JP)	not more than 0.021%
(3)	Sulfate (JP)	not more than 0.028%
(4)	Ammonium (JP)	not more than 0.02%
(5)	Iron (JP)	not more than 10ppm
(6)	Related substances (JP)	to pass test
	Loss on drying (JP)	not more than 0.3%
	Residue on ignition (JP)	not more than 0.1%
	Assay (calculated on the dried basis) (JP)	99.0～101.0%
*	Bacterial endotoxins	less than 2.0EU/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 0.4%
(2)	Chloride (USP-NF)	NMT 0.05%
(3)	Sulfate (USP-NF)	NMT 0.03%
(4)	Iron (USP-NF)	NMT 30ppm
(5)	Related compounds (USP-NF)	to pass test
	Specific tests (USP-NF)	-
(1)	Optical rotation (USP-NF)	+12.6～+14.0°
(2)	pH (USP-NF)	7.0～8.5
(3)	Loss on drying (USP-NF)	NMT 0.2%
	Identification (Ph.Eur.)	to pass test
	Appearance of solution (Ph.Eur.)	to pass test

	Specific optical rotation (Ph.Eur.)	+11.4～+12.4°
	Ninhydrin-positive substances (Ph.Eur.)	-
(1)	For each impurity (Ph.Eur.)	maximum 0.2%
(2)	Total (Ph.Eur.)	maximum 0.5%
	Chlorides (Ph.Eur.)	maximum 200ppm
	Sulfates (Ph.Eur.)	maximum 300ppm
	Ammonium (Ph.Eur.)	maximum 0.02%
	Iron (Ph.Eur.)	maximum 10ppm
	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 (L-Histidine)(*:Additional test performed by Wako)United States Pharmacopeia - National Formulary (Histidine)European Pharmacopoeia (Histidine)

revised on 2025/11/26