

Code No.08-1077

SPECIFICATION

L-Histidine Hydrochloride Hydrate

Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP)	White crystals or crystalline powder
Identification (JP)	to pass test
Optical rotation [α]D ₂₀ (JP)	+9.2~+10.6°
pH (JP)	3.5~4.5
Purity (JP)	-
(1) Clarity and color of solution (JP)	to pass test
(2) Sulfate (JP)	not more than 0.028%
(3) Ammonium (JP)	not more than 0.02%
(4) Iron (JP)	not more than 10ppm
(5) Related substances (JP)	to pass test
Water (JP)	7.2~10.0%
Residue on ignition (JP)	not more than 0.1%
Assay (calculated on the dehydrous basis) (JP)	99.0~101.0%
* Bacterial endotoxins	less than 2.0EU/g
Identification (Ph.Eur.)	to pass test
Appearance of solution (Ph.Eur.)	to pass test
pH (Ph.Eur.)	3.0~5.0
Specific optical rotation (Ph.Eur.)	+9.2~+10.6°
Ninhydrin-positive substances (Ph.Eur.)	-
(1) For each impurity (Ph.Eur.)	maximum 0.2%
(2) Total (Ph.Eur.)	maximum 0.5%
Sulfates (Ph.Eur.)	maximum 300 ppm
Ammonium (Ph.Eur.)	maximum 0.02%
Iron (Ph.Eur.)	maximum 10ppm
Loss on drying (Ph.Eur.)	7.0~10.0%
Sulfated ash (Ph.Eur.)	maximum 0.1%
Assay (dried substance) (Ph.Eur.)	98.5~101.0%

Japanese Pharmacopoeia (L-Histidine Hydrochloride Hydrate)(* : Additional test performed by Wako) European Pharmacopoeia (Histidine Hydrochloride Monohydrate)