

## SPECIFICATION

## Lactose Hydrate

Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description	White crystals, powder or granulated powder
Identification	to pass test
Optical rotation	+54.4~+55.9°
Purity	-
(1) Clarity and color of solution	to pass test
(2) Acidity or alkalinity	to pass test
(3) Proteins and light absorbing substances	to pass test
Loss on drying	not more than 0.5%
Water	4.5~5.5%
Residue on ignition	not more than 0.1%
Microbial limit	to pass test
* Bacterial endotoxins	less than 25EU/g

Japanese Pharmacopoeia(\*:Additional test performed by Wako)