

## SPECIFICATION

## Butyl Parahydroxybenzoate

## Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP)	White crystals or crystalline powder **
Identification (JP)	to pass test
Melting point (JP)	68~71°C
Purity (JP)	-
(1) Clarity and color of solution (JP)	to pass test
(2) Acidity (JP)	to pass test
(3) Related substances (JP)	to pass test
Residue on ignition (JP)	not more than 0.1%
Assay (JP)	98.0~102.0%
* Bacterial endotoxins	less than 10.0EU/g
Identification (USP-NF)	to pass test
Assay (USP-NF)	98.0~102.0%
Impurities (USP-NF)	-
(1) Residue on ignition (USP-NF)	NMT 0.1%
(2) Related substances (USP-NF)	to pass test
Specific tests (USP-NF)	-
(1) Acidity (USP-NF)	to pass test
(2) Color of solution (USP-NF)	to pass test
* Appearance (Ph.Eur.)	Colourless or white or almost white, crystals or crystalline powder **
Identification (Ph.Eur.)	to pass test
Appearance of solution (Ph.Eur.)	to pass test
Acidity (Ph.Eur.)	to pass test
Related substances (Ph.Eur.)	to pass test
Sulfated ash (Ph.Eur.)	maximum 0.1%
Assay (Ph.Eur.)	98.0~102.0%

The Japanese Pharmacopoeia (Butyl Parahydroxybenzoate)(\*:Additional test performed by Wako)\*\*:The specification is originally set by Wako)United States Pharmacopeia - National Formulary (Butylparaben)European Pharmacopoeia (Butyl Parahydroxybenzoate)