



Raw Material for Pharmaceutical Production

Description

All CertiPro series products are manufactured under Japanese GMP, and meet the specifications defined in the latest version of JP, USP and Ph. Eur., among other pharmacopeias.

- » Endotoxin test
- » Various report (e.g.: Residual Solvents, Elemental Impurities, etc)
- » Customizing the Specification for USP/EP and Bioburden depends on the requests
- » Supporting program for Method Validation (MV*) for “Non Compendial” Chemicals

*Method validation (MV) is the in house process of analysis methods which complied to GMP guidelines as a reference, because of no existing guideline set by the authorities, such as “Non Compendial” Chemicals.



Ordering Information

Product Name	Molecular formula [CAS RN®]	grade	available grade		Endotoxin	Microbial limit.	Catalog No.	Package Size
			USP	Ph. Eur.				
Calcium Chloride Hydrate	CaCl ₂ · 2H ₂ O [10035-04-8]	JP	▲		In-House		030-19555	500 g
Calcium Gluconate Hydrate	C ₁₂ H ₂₂ CaO ₁₄ · H ₂ O [299-28-5]	JP			less than 1.5 EU/g		030-25785	500 g
Citric Acid Hydrate [CertiPro]	C₆H₈O₇ · H₂O [5949-29-1]	JP	●	●	less than 8 EU/g		032-25245 038-25247	500 g 10 kg
Dibasic Calcium Phosphate Hydrate	CaHPO ₄ · 2H ₂ O [7789-77-7]	JP	▲		In-House		046-29465	500 g
Dibasic Potassium Phosphate	K ₂ HPO ₄ [7758-11-4]	JPC	▲		In-House		047-29015 043-29017	500 g 20 kg
Dibasic Sodium Phosphate Hydrate [CertiPro]	Na₂HPO₄ · 12H₂O [10039-32-4]	JP	●	●	less than 0.2 EU/g		047-34385 043-34387	500 g 10 kg
Disodium Edetate Hydrate	C ₁₀ H ₁₄ N ₂ Na ₂ O ₈ · 2H ₂ O [6381-92-6]	JP			less than 10 EU/g		046-34615 042-34617	500 g 20 kg
Disodium Hydrogen Phosphate Anhydrous	Na ₂ HPO ₄ [7558-79-4]	JPE	▲		In-House		048-29665 044-29667	500 g 10 kg
Dried Sodium Carbonate [CertiPro]	Na₂CO₃ [497-19-8]	JP			less than 10 EU/g		049-34345 045-34347	500 g 10 kg
Fumaric Acid	C ₄ H ₄ O ₄ [110-17-8]	JPE	▲		In-House		068-05105	500 g
Glucono-δ-Lactone	C ₆ H ₁₀ O ₆ [90-80-2]	JPE	▲		In-House		075-05155	500 g
Glucose	C ₆ H ₁₂ O ₆ [50-99-7]	JP	▲		In-House		076-05705 072-05707	500 g 10 kg
Glycine	C ₂ H ₅ NO ₂ [56-40-6]	JP	▲		In-House		077-05095 073-00737	500 g 10 kg
Hydrochloric Acid	HCl [7647-01-0]	JP		●	less than 10 EU/g		082-10475	500 mL
Lactose Hydrate [CertiPro]	C₁₂H₂₂O₁₁ · H₂O [64044-51-5]	JP			less than 25 EU/g	●	121-06685	500 g
Magnesium Stearate	- [557-04-0]	JP	▲		In-House		136-15105	500 g
Magnesium Sulfate Hydrate [CertiPro]	MgSO₄ · 7H₂O [10034-99-8]	JP			less than 10 EU/g		130-18925	500 g
D-Mannitol	C ₆ H ₁₄ O ₆ [50-99-7]	JP	▲		In-House		133-14495	500 g
Methyl Parahydroxybenzoate Oxyben® M	C ₈ H ₈ O ₃ [99-76-3]	JP	▲		In-House		857-40412	5 kg
Monobasic Potassium Phosphate	KH ₂ PO ₄ [7778-77-0]	JPC	▲		In-House		136-14485 132-14487	500 g 25 kg
Monosodium L-Glutamate Monohydrate	C ₅ H ₉ NNaO ₄ · H ₂ O [6106-04-3]	JPC	▲		In-House		135-15555 131-15557	500 g 20 kg
Polysorbate20	- [9005-64-5]	JPE					168-22792	25 g

JP: Japanese Pharmacopoeia

JPC: Japanese Pharmaceutical Codex
JPE: Japanese Pharmaceutical Excipients

USP ▲: tested for specific clients in the past
Endotoxin: In-house (Internal management)

Product Name	Molecular formula	grade	available grade		Endotoxin	Microbial limit.	Catalog No.	Package Size
	[CAS RN®]		USP	Ph. Eur.				
Potassium Acetate	CH ₃ COOK [127-08-2]	JPE					169-21965 165-21967	500 g 10 kg
Potassium Chloride	KCl [7447-40-7]	JP	▲		In-House		163-22105	500 g
Potassium Iodide	KI [7681-11-0]	JP	▲		In-House		161-21925	500 g
Probyl Parahydroxybenzoate Oxyben® P	C ₁₀ H ₁₂ O ₃ [94-13-3]	JP					857-40532	5 kg
Purified Glucose [CertiPro]	C6H12O6 [50-99-7]	JP	harmonization JP, USP, PH, Eur		less than 2 EU/g		168-28515 164-28517	500 g 10 kg
Sodium Acetate Hydrate	C ₂ H ₃ NaO ₂ · 3H ₂ O [6131-90-4]	JP	▲		In-House		197-13235	500 g
Sodium Bicarbonate [CertiPro]	NaHCO₃ [144-55-8]	JP		●	less than 10 EU/g		197-18475 193-18477	500 g 10 kg
Sodium Bisulfite	NaHSO ₃ [7631-90-5]	JP	▲		In-House		198-13265 194-13267	500 g 20 kg
Sodium Chloride [CertiPro]	NaCl [7647-14-5]	JP	●	●	less than 3.1 EU/g		194-18505 190-18507	500 g 10 kg
Sodium Citrate Hydrate [CertiPro]	C₆H₅Na₃O₇ · 2H₂O [6132-04-3]	JP	●	●	less than 5.2 EU/g		197-18855 193-18857	500 g 10kg
Sodium Dihydrogen Phosphate Dihydrate [CertiPro]	NaH₂PO₄ · 2H₂O [13472-35-0]	JPE	●	●	less than 2.0 EU/g		191-18495 197-18497	500g 10kg
Sodium Dihydrogen Phosphate Anhydrous	NaH ₂ PO ₄ [7558-80-7]	JPE	▲		In-House		194-14105 190-14107	500g 10kg
Sodium Hydroxide [CertiPro]	NaOH [1310-73-2]	JP	●	●	less than 10 EU/g		190-18465 196-18467	500g 10kg
Sodium Pyrosulfite	Na ₂ S ₂ O ₅ [7558-80-7]	JP	▲		In-House		193-14055 199-14057	500g 10kg
Sodium L-Tartrate	C ₄ H ₄ Na ₂ O ₆ · 2H ₂ O [57-50-1]	JPE	▲		In-House		197-13975	500g
Sodium Thiosulfate Hydrate	Na ₂ S ₂ O ₃ · 5H ₂ O [10102-17-7]	JP	▲		In-House		190-13845 196-13847	500g 20kg
Sucrose [CertiPro]	C₁₂H₂₂O₁₁ [57-50-1]	JP	●	●	less than 10 EU/g		198-18385 194-18387	500g 10kg
Titanium Oxide	TiO ₂ [1317-70-0]	JP	▲		In-House		204-16055 903-40303	500g 10kg
Trometamol [CertiPro]	C₄H₁₁NO₃ [77-86-1]	JPC	●	●	less than 0.03 IU/mg		203-21035 209-21037	500g 10kg
Urea	CH ₄ N ₂ O [57-13-6]	JP	▲		In-House		213-01295 219-01297	500g 10kg

JP: Japanese Pharmacopoeia

JPC: Japanese Pharmaceutical Codex

JPE: Japanese Pharmaceutical Excipients

USP ▲: tested for specific clients in the past
Endotoxin: In-house (Internal management)

Listed products are intended for laboratory research use only, and not to be used for drug, food or human use. / Please visit our online catalog to search for other products from FUJIFILM Wako; <https://labchem-wako.fujifilm.com> / This leaflet may contain products that can not be exported to your country due to regulations. / Bulk quote requests are welcome. Please contact us.

WFI Quality Water

Water for Injection (WFI)* Quality Water is the most suitable water available for producing cell culture media, reconstitution of biochemical reagents, and as a final rinse water for critical applications.

WFI Quality Water meets USP, PhEur, and JP grade specifications and is 0.1µm sterile filtered at time of fill. It contains no added substances.

+ WFI System Performance

Parameter	Specification
Bioburden	10 cfu/100mL
Endotoxin	≤ 0.25 EU/mL
TOC	≤ 500 ppb
Conductivity	≤ 2.1 µS/cm

Ordering Information

Manufacture Catalog No.	Product name	Package	Catalog No.	Package size
9309-1L	Water for Injection (WFI) Quality Water	Bottle	552-34261	1 L
9309-20LC	Water for Injection (WFI) Quality Water	Carboy packaging	552-34266	20 L
9309-20L BPC	Water for Injection (WFI) Quality Water	Bioprocess container	550-34267	20 L
9309-200L BPC	Water for Injection (WFI) Quality Water	Bioprocess container	558-34268	200 L

Listed products are intended for laboratory research use only, and not to be used for drug, food or human use. / Please visit our online catalog to search for other products from FUJIFILM Wako; <https://labchem-wako.fujifilm.com> / This leaflet may contain products that can not be exported to your country due to regulations. / Bulk quote requests are welcome. Please contact us.

Distribution & Inquiries

FUJIFILM Wako Chemicals Europe GmbH

Fuggerstr. 12 • 41468 Neuss, Germany

Telephone: +49-2131-311-271

Fax: +49-2131-311-110

E-mail: labchem_wkeu@fujifilm.com

FUJIFILM Wako Pure Chemical Corporation

1-2, Doshomachi 3-Chome Chuo-Ku, Osaka 540-8605, Japan

Telephone: +81-6-6203-3741

Fax: +81-6-6203-1999

E-mail: ffwk-cservice@fujifilm.com



<https://labchem-wako.fujifilm.com>

FUJIFILM Wako Chemicals U.S.A. Corporation

1600 Bellwood Road Richmond • VA 23237, USA

Telephone: +1-804-714-1920

Fax: +1-804-271-7791

E-mail: wkuslabchem@fujifilm.com