



Pharmaceutical Raw Materials CertiPro Series



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Pharmaceutical Raw Materials [CertiPro Series]

FUJIFILM Wako provides pharmaceutical raw materials that can be used in the manufacturing process of pharmaceutical products. Ingredients listed in official compendia such as the Japanese Pharmacopoeia(JP), Japanese Pharmaceutical Codex (JPC), and Japanese Pharmaceutical Excipients (JPE) are available, and, in addition, non-compendial ingredients (not listed in official compendia) are provided in accordance with our in-house specifications. These products are classified into two categories depending on management standards: CertiPro (GMP management products) and CertiPro-L (non-GMP management products). Some products meet the specifications items in the USP and Ph. Eur. and are conducted endotoxins test.

GMP Management Products

CertiPro

Pharmaceutical raw materials manufactured under GMP management. The lineup includes products conforming to the JP, JPC, and part of the JPE.

Features

- GMP management
- Products listed in the JP and JPC, and some listed in the JPE
- Conforming to the specifications in the USP and Ph. Eur. (different depending on the product)

Non-GMP Products

CertiPro-L

The lineup includes products conforming to the JP and JPE. Non-compendial products (ingredients not listed in official compendia) are provided in accordance with our in-house specifications.

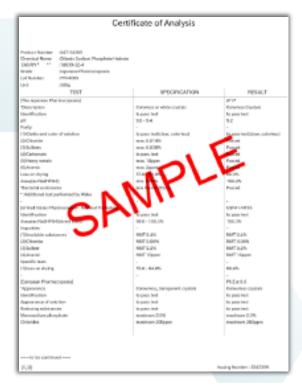
Features

- Lineup including products listed in the JP and JPE, and non-compendial products
- · ISO 9001 management

Certificate of analysis

Certificate of analysis(CoA) of each product can be viewed in our website.

Example of CoA



Product appearance



Facilities

Aichi Plant



- · Large-scale manufacturing plant for raw materials, intermediates and chemicals
- · Advanced pollution control
- · GMP-controlled media production

Harima Plant

- · Backup plant of Aichi plant
- · Medium-scale chemical manufacturing plant

Miyazaki Plant management

· Small-scale manufacturing plant for raw materials, intermediates and chemicals

Hirono Plant

GMP management

- · Manufacture of APIs with cGMP
- · Equipped with a super lowtemperature reactor, a hydrogenation reduction reactor, a fluoride resistant oven and various mills.

Tokyo Plant

- · non-GMP pharmaceutical intermediate manufacturing
- R&D laboratory

Hiratsuka Plant

- · non-GMP pharmaceutical intermediate manufacturing
- Multipurpose facilities

Osaka Plant management

- · GMP-compliant pharmaceutical manufacturing
- · Highly controlled manufacturing and working environment

■ Main Products

- · Pharmaceutical raw materials
- · Life science reagents (PCR detection reagent, DNA extraction
- · Chemical reagent (powder · liquid reagents)
- · Cell culture media reagent (powder · liquid media, process solution)
- · Clinical diagnostic reagent

■ Inspection and Audit History

Japanese authorities

- 2017.10 Drug conformity survey by Hyogo Prefectural Pharmaceutical Affairs Division (Regular/Export)
- 2018.10 Drug conformity survey by Hyogo Prefectural Pharmaceutical Affairs Division(Partial change)
- 2021.10 Drug conformity survey by Hyogo Prefectural Pharmaceutical Affairs Division (Regular/Export)

Quality audits of Japanese and overseas clients: Conduct 5-10 quality audits per year

GMP management: Manufactured in the facilities that has acquired a drug manufacturing license GMP control: Manufactured voluntarily with GMP facilities and management



Amagasaki City, Hyogo Prefecture 23,332 m

Number of employees Certifications

CertiPro

Features

- GMP management
- With each product offering the document support as requested*1
- Some products meet the USP and Ph. Eur. in addition to the JP, JPC, and JPE*2
- *1: To request information on ICH-Q3C (residual solvents) and ICH-Q3D (elemental impurities), etc., please contact individually. Information is provided partially for a fee depending on items.
- $^{*}2$: Products are controlled according to the latest versions.

Product Lineup

Product Name	CAS RN®	Grade		ormity	Endotoxin	Code No.	Package
			USP/NF	Ph.Eur.			Size
Calcium Chloride Hydrate	10035-04-8	JP			_	030-19555	500 g
Calcium Gluconate Hydrate	299-28-5	JP			1.5EU/g ↓	030-25785	500 g
Citric Acid Hydrate	5949-29-1	JP			8EU/g↓	032-25245	500 g
Citile Acid Hydrate	3949-29-1	JI.				038-25247	10 kg
Dibasic Potassium	7758-11-4	JPC			_	047-29015	500 g
Phosphate	7700-11-4	JPC				043-29017	20 kg
Dibasic Sodium	10039-32-4	JP			0.2EU/g↓	047-34385	500 g
Phosphate Hydrate	10039-32-4	JP		·		043-34387	10 kg
Disodium Edetate	0001 00 0	ID.			10EU/g↓	046-34615	500 g
Hydrate	6381-92-6	JP				042-34617	20 kg
Duied Cedium Conhenete	407.40.0	JP			10EU/g↓	049-34345	500 g
Dried Sodium Carbonate	497-19-8	JP				045-34347	10 kg
Glucose	50.00.7	JP			10EU/g↓	076-05705	500 g
Giucose	50-99-7	JP				072-05707	10 kg
Glycine	56-40-6	JP			_	077-05095	500 g
Hydrochloric Acid	7647-01-0	JP		~	10EU/mg↓	082-10475	500 mL
Lactose Hydrate	64044-51-5	JP			25EU/g↓	121-06685	500 g
Magnesium Sulfate Hydrate	10034-99-8	JP			10EU/g ↓	130-18925	500 g

D-Mannitol	69-65-8	JP			_	133-14495	500 g
Monobasic Potassium	7778-77-0	JPC			_	136-14485	500 g
Phosphate	7776-77-0	31 0				132-14487	25 kg
Potassium Chloride	7447-40-7	JP			_	163-22105	500 g
Potassium Iodide	7681-11-0	JP			_	161-21925	500 g
Purified Glucose	50-99-7	JP	~	~	2EU/g ↓	168-28515	500 g
rumeu diacose						164-28517	10 kg
Sodium Acetate Hydrate	6131-90-4	JP			_	197-13235	500 g
Sodium Bicarbonate	144-55-8	10			10EU/mg ↓	197-18475	500 g
Sociali Bicarbonate	144-33-0	JP			TOLO/IIIg \$	193-18477	10 kg
Sodium Chloride					3.1EU/g ↓ -	194-18505	500 g
Socium Chloride	7647-14-5	JP				190-18507	10 kg
Codium Citrato I Industo	6132-04-3	JP			5.2EU/g ↓	197-18855	500 g
Sodium Citrate Hydrate	0132-04-3	JP			5.2E0/g ↓	193-18857	10 kg
Sodium Dihydrogen	13472-35-0	JPE			2EU/g ↓	191-18495	500 g
Phosphate Dihydrate	10472-00-0	JI"L			2L0/9 ¥	197-18497	10 kg
Sodium L-Glutamate	6106-04-3	JPC	(NF)		3.9EU/g↓	135-15555	500 g
Hydrate	0100-04-0	01 0	(141)		3.9L0/g ↓	131-15557	20 kg
Sodium Hydroxide	1310-73-2	JP	(NF)	~	/ 10EU/g ↓	190-18465	500 g
Souldin Hydroxide	1310-73-2	JI.	(141)	ľ		196-18467	10 kg
Sucrose	57-50-1	JP	(NF)	~	2EU/g ↓	198-18385	500 g
						194-18387	10 kg
	77-86-1	JPC	~	~	0.03IU/mg ↓	203-21035	500 g
Trometamol						209-21037	10 kg
Livon	57 10 6	ID				213-01295	500 g
Urea	57-13-6	JP				219-01297	10 kg

*For more information, please visit our website.

Top of our reagent HP >Pharma Manufacturing & QC>Pharmaceutical Raw Materials>CertiPro Series>CertiPro https://labchem-wako.fujifilm.com/us/category/00587.html



CertiPro-L

Features

- Lineup including products listed in the JP and JPE
- Non-compendial products (ingredients not listed in official compendia) are provided in accordance with our in-house specifications.
- ISO 9001 management
- With each product offering the document support as requested*
- * To request information on ICH-Q3C (residual solvents) and ICH-Q3D (elemental impurities), etc. please contact individually. Information is provided partially for a fee depending on items.

Product Lineup

polic Acid redium Hydrogen Phosphate ydrous raric Acid raric Acid resono- b - Lactone ynesium Stearate resorbate 20 resorb	79-4 JPE 7-8 JPE 1-2 JPE 4-0 JP	013-205 048-296 044-296 E 068-051 E 075-051 0 136-151 0 857-404	577 10 kg 565 500 g 567 10 kg 105 500 g 155 500 g 105 500 g
podium Hydrogen Phosphate ydrous paric Acid 110-1 cono- à -Lactone pnesium Stearate phyl Parahydroxybenzoate prorbate 20 possium Acetate pyl Parahydroxybenzoate	79-4 JPE 7-8 JPE 1-2 JPE 4-0 JP	013-205 048-296 044-296 E 068-051 E 075-051 0 136-151 0 857-404	565 500 g 667 10 kg 105 500 g 155 500 g 105 500 g 112 5 kg
ydrous paric Acid 110-1 cono- b - Lactone gnesium Stearate 557-0 hyl Parahydroxybenzoate 99-76 rsorbate20 9005-6 assium Acetate 127-0 pyl Parahydroxybenzoate 94-13 ium Bisulfite 7631-8	7-8 JPE 1-2 JPE 1-0 JP 1-3 JP	E 044-296 E 068-051 E 075-051 D 136-151 D 857-404	10 kg 105 500 g 155 500 g 105 500 g 112 5 kg
ydrous paric Acid 110-1 cono- \(\delta \text{-Lactone} \) gnesium Stearate 557-0 hyl Parahydroxybenzoate 99-76 rsorbate20 9005-6 assium Acetate 127-0 pyl Parahydroxybenzoate 94-13 ium Bisulfite 7631-6 ium Dihydrogen Phosphate	7-8 JPE 1-2 JPE 1-0 JP 1-3 JP	044-296 E 068-051 E 075-051 O 136-151 O 857-404	105 500 g 155 500 g 105 500 g 112 5 kg
ynesium Stearate sorbate 20 assium Acetate pyl Parahydroxybenzoate	1-2 JPE 4-0 JP	E 075-051 0 136-151 0 857-404	55 500 g 105 500 g 112 5 kg
hyl Parahydroxybenzoate sorbate20 assium Acetate 127-0 pyl Parahydroxybenzoate 127-0 ium Bisulfite 7631-9 ium Dihydrogen Phosphate	4-0 JP	9 136-151 9 857-404	105 500 g 112 5 kg
hyl Parahydroxybenzoate 99-76 9005-6 assium Acetate 127-0 pyl Parahydroxybenzoate 94-13 ium Bisulfite 7631-6 ium Dihydrogen Phosphate	6-3 JP	9 857-404	112 5 kg
psorbate 20 9005-6 pssium Acetate 127-0 pyl Parahydroxybenzoate 94-13 pium Bisulfite 7631-9 pium Dihydrogen Phosphate			
pyl Parahydroxybenzoate 94-13 ium Bisulfite 7631-9 ium Dihydrogen Phosphate	64-5 JPE	E 168-227	'92 25 g
oyl Parahydroxybenzoate 94-13 ium Bisulfite 7631-9 ium Dihydrogen Phosphate			
ium Bisulfite 7631-9	8-2 JPE	E 169-219	965 500 g
ium Dihydrogen Phosphate	3-3 JP	857-405	532 5 kg
ium Dihydrogen Phosphate	00-5 JP	198-132	265 500 g
	90-5 JP	194-132	267 20 kg
ydrous / ODB-G	30-7 JPE	194-141	105 500 g
	5U-7 JPE	190-141	107 10 kg
ium L-Tartrate 6106-2	.4-7 JPE	E 197-139	975 500 g
Tool I	7.4	193-140	055 500 g
ium Pyrosulfite 7681-8	57-4 JP	199-140	057 10 kg
aium Ovida		004 400	055 500 g
nium Oxide 1317-7	'0-0 JP	204-160	

^{*}For more information, please visit our website.



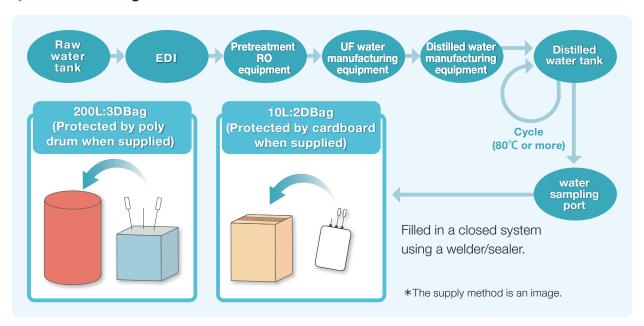
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Related Products

WFI Quality Water

FUJIFILM Wako provide water equivalent to distilled water for injection that conforms to the standards of JP/USP/EP.

Manufacturing Flow



Process Solution

FUJIFILM Wako offer customized process solutions that can be used in biopharmaceutical manufacturing processes.

After preparation with WFI Quality Water, we can provide ready-to-use solutions in single-use bags. Bag manufacturer, tubing, connectors, and other specifications are determined upon consultation with the customer.

Item	Status of support
Water for liquid preparation	Pyrogen-free water (water quality : Purified water grade for injection) WFI Quality Water
Capacity	10L, 20L, 200L
Test case	Appearance, pH, osmotic pressure, sterility test, endotoxin, mycoplasma, concentration, (filter integrity test)
Change management of raw materials	CultureSure® Series, CertiPro Series







