

Pharmaceutical Raw Materials CertiPro Series

level
Discovering
new boundaries

進階生物科技股份有限公司

服務專線：0800-251302

THE **FUTURE LAB** | **FUTURE CMC**

進階與您一同邁入新未來



Multi-color Flow



Confocal Live Image



Energy Metabolism



Biosensor



Organ Chip



Digital PCR



Multiplex Assay



IP Western

Facilities

Aichi Plant

GMP control

- 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

GMP 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

GMP management

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

■ Main Products

- Pharmaceutical raw materials
- Life science reagents (PCR detection reagent, DNA extraction kit etc.)
- 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



Location	Amagasaki City, Hyogo Prefecture
Site area	23,332 m ²
Number of employees	About 215
Start of operation	Since 1940
Certifications	ISO9001, ISO/IEC17025

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

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	Conformity		Endotoxin	Code No.	Package Size
			USP/NF	Ph.Eur.			
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
						038-25247	10 kg
Dibasic Potassium Phosphate	7758-11-4	JPC			—	047-29015	500 g
						043-29017	20 kg
Dibasic Sodium Phosphate Hydrate	10039-32-4	JP	✓	✓	0.2EU/g ↓	047-34385	500 g
						043-34387	10 kg
Disodium Edetate Hydrate	6381-92-6	JP			10EU/g ↓	046-34615	500 g
						042-34617	20 kg
Dried Sodium Carbonate	497-19-8	JP			10EU/g ↓	049-34345	500 g
						045-34347	10 kg
Glucose	50-99-7	JP			10EU/g ↓	076-05705	500 g
						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 Phosphate	7778-77-0	JPC			—	136-14485	500 g
						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
						164-28517	10 kg
Sodium Acetate Hydrate	6131-90-4	JP			—	197-13235	500 g
Sodium Bicarbonate	144-55-8	JP		✓	10EU/mg ↓	197-18475	500 g
						193-18477	10 kg
Sodium Chloride	7647-14-5	JP	✓	✓	3.1EU/g ↓	194-18505	500 g
						190-18507	10 kg
Sodium Citrate Hydrate	6132-04-3	JP	✓	✓	5.2EU/g ↓	197-18855	500 g
						193-18857	10 kg
Sodium Dihydrogen Phosphate Dihydrate	13472-35-0	JPE	✓	✓	2EU/g ↓	191-18495	500 g
						197-18497	10 kg
Sodium L-Glutamate Hydrate	6106-04-3	JPC	(NF)		3.9EU/g ↓	135-15555	500 g
						131-15557	20 kg
Sodium Hydroxide	1310-73-2	JP	(NF)	✓	10EU/g ↓	190-18465	500 g
						196-18467	10 kg
Sucrose	57-50-1	JP	(NF)	✓	2EU/g ↓	198-18385	500 g
						194-18387	10 kg
Trometamol	77-86-1	JPC	✓	✓	0.03IU/mg ↓	203-21035	500 g
						209-21037	10 kg
Urea	57-13-6	JP			—	213-01295	500 g
						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>



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

Product Name	CAS RN [®]	Grade	Code No.	Package Size
Adipic Acid	124-04-9	JPE	017-20575	500 g
			013-20577	10 kg
Disodium Hydrogen Phosphate Anhydrous	7558-79-4	JPE	048-29665	500 g
			044-29667	10 kg
Fumaric Acid	110-17-8	JPE	068-05105	500 g
Glucono-δ-Lactone	90-80-2	JPE	075-05155	500 g
Magnesium Stearate	557-04-0	JP	136-15105	500 g
Methyl Parahydroxybenzoate	99-76-3	JP	857-40412	5 kg
Polysorbate20	9005-64-5	JPE	168-22792	25 g
Potassium Acetate	127-08-2	JPE	169-21965	500 g
Propyl Parahydroxybenzoate	94-13-3	JP	857-40532	5 kg
Sodium Bisulfite	7631-90-5	JP	198-13265	500 g
			194-13267	20 kg
Sodium Dihydrogen Phosphate Anhydrous	7558-80-7	JPE	194-14105	500 g
			190-14107	10 kg
Sodium L-Tartrate	6106-24-7	JPE	197-13975	500 g
Sodium Pyrosulfite	7681-57-4	JP	193-14055	500 g
			199-14057	10 kg
Titanium Oxide	1317-70-0	JP	204-16055	500 g
			903-40303	10 kg

*For more information, please visit our website.

Top of our reagent HP >Pharma Manufacturing & QC>Pharmaceutical Raw Materials>CertiPro Series>CertiPro-L
<https://labchem-wako.fujifilm.com/us/category/02390.html>

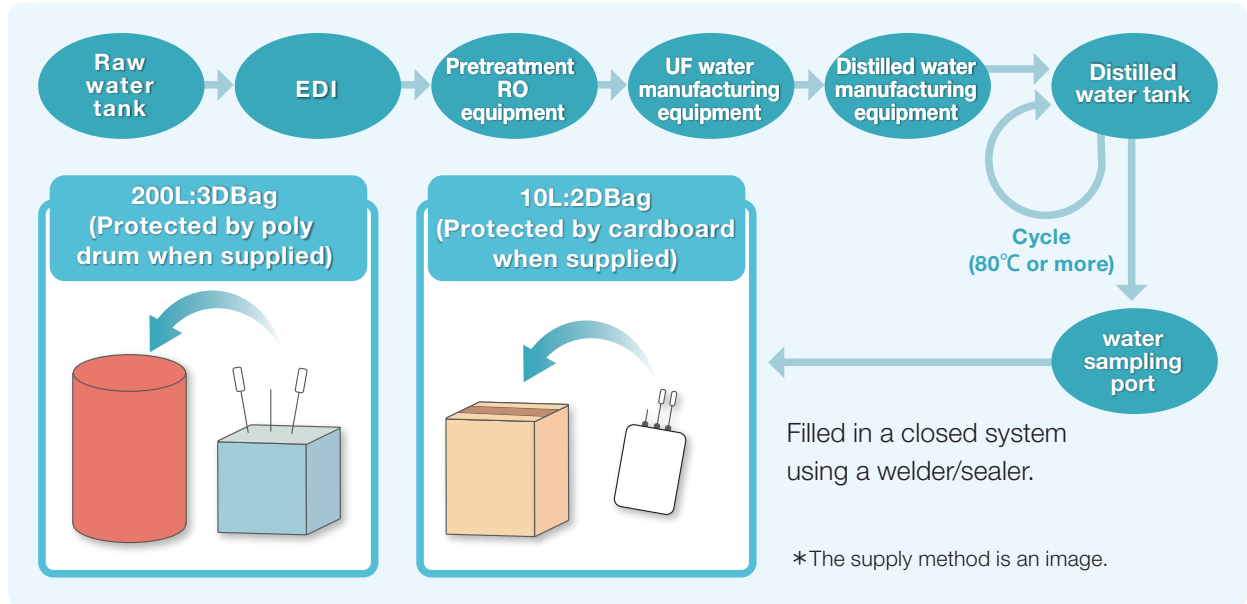


Related Products

◆ 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

