

Pharmaceutical Raw Materials

CertiPro Series

Ver.4



Pharmaceutical Raw Materials [CertiPro Series]

FUJIFILM Wako Pure Chemical provides pharmaceutical raw materials that are 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 own specifications. These products are classified into two categories depending on compliant standards: CertiPro (GMP-compliant products) and CertiPro-L (ISO9001-compliant products). Some products conform the specifications items in the USP-NF and Ph. Eur. and undergo endotoxins test.

GMP-compliant Products

CertiPro

Pharmaceutical raw materials manufactured under GMP. The lineup includes products listed in the Japanese Pharmacopoeia (JP), Japanese Pharmaceutical Codex (JPC), and Japanese Pharmaceutical Excipients (JPE).

Features

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

ISO9001-compliant Products

CertiPro-L

Pharmaceutical raw materials manufactured under ISO 9001. The lineup includes products conforming to the Japanese Pharmacopoeia (JP) and Japanese Pharmaceutical Excipients (JPE). Non-compendial products not listed in official compendia are provided in accordance with our own specifications.

Features

- ISO9001 compliant
- Lineup including products listed in the JP and JPE, and non-compendial products

Management system of CertiPro Series

Production Management of CertiPro



	CertiPro	CertiPro-L
Quality management	GMP	ISO 9001
CoA available	●	●
Statement available	●	●
Supplier management	●	●*
Change control	●	●*
Deviation control	●	●*
Process control validation	●	

*Management using ISO quality management system

Production Sites

Aichi Plant **GMP**

- 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**

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

Hirono Plant **GMP**

- 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**

- GMP-compliant pharmaceutical manufacturing
- Licensed pharmaceutical manufacturer

■ Main Products

- Pharmaceutical raw materials
- Life science reagents (PCR detection reagent, DNA extraction kit etc.)
- Chemical reagent (powder · liquid reagents)
- Process solution
- Clinical diagnostic reagent

■ Inspection and Audit History

Japanese authorities

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

Conduct 5-10 on-site quality audits each year from Japanese and overseas clients

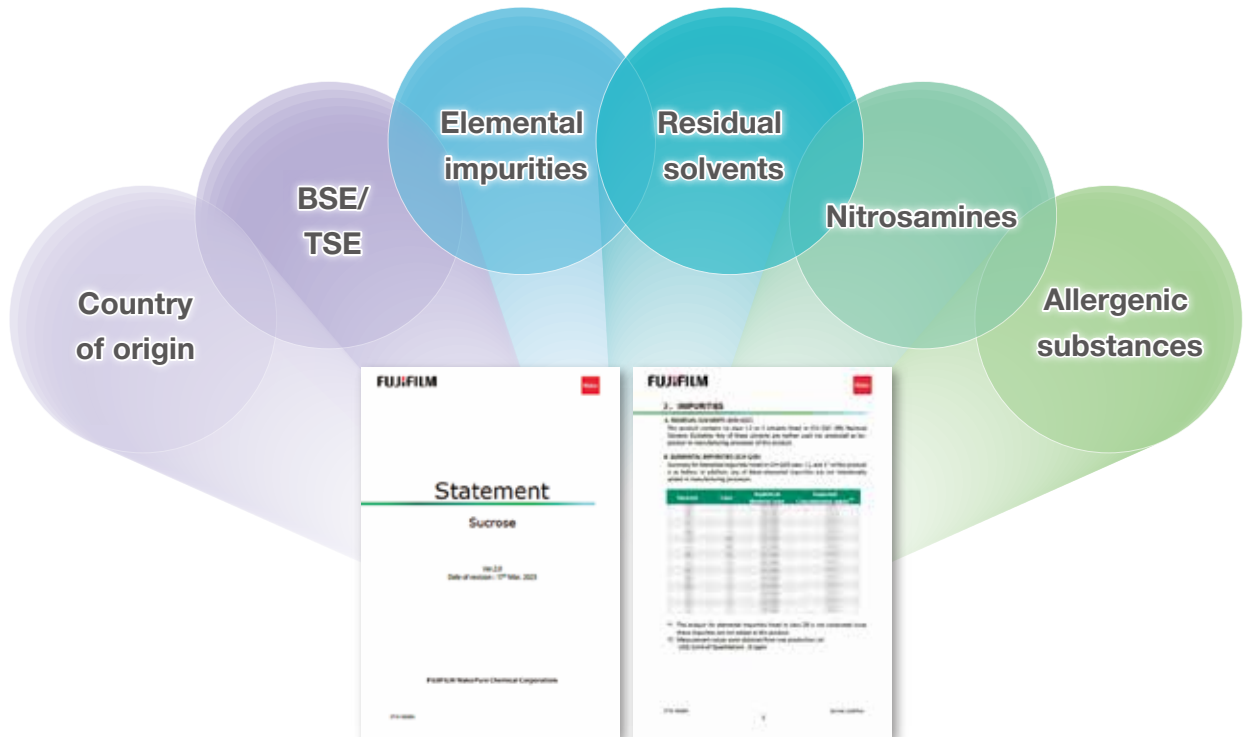


Location	Amagasaki City, Hyogo Prefecture
Site area	23,332 m ²
Number of employees	About 220
Start of operation	Since 1940
Certifications	ISO9001, ISO/IEC17025 ISO14001, ISO17034

※All GMP facilities except Aichi plant are audited by Japanese Authority

Statement

FUJIFILM Wako Pure Chemical issue our Statement on Raw Materials for Pharmaceutical Use to provide information about our products as well as information on the drug risk management. Here are some of the details included in the statement. Statements are obtainable from product introduction page on our website.



Product Profile : Chemical name, CAS RN®, Product code, Manufacturing control standard, Grade

Product Information : Country of origin, BSE/TSE, GMO, Allergenic substances
Highly potency substance, Nitrosamines, Melamine

Customized Service

FUJIFILM Wako Pure Chemical offer custom services to meet customer requirements. We respond to a variety of requests, including large-scale packaging for scale-up, and compliance with the standards of various compendial standards, including the JP, USP-NF and Ph. Eur. Please contact us for details.



Customize package



Compendial
JP, USP-NF, Ph. Eur.



Additional test
Endotoxin test etc.



Prepare
solution

*For more information, please visit website.
Top of our Raw material Pharmaceutical Industry website
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/index.html>



Packaging

The basic packaging of CertiPro series are 500g, 10kg and 20kg. Depending on your request, FUJIFILM Wako can change the package size and specifications.

Package Size	Basic Packaging	Customized Packaging
50kg } 25kg		
25kg } 5kg		
500g/ 500mL		

*For requests for package size and specifications other than those listed above, please contact us.

Basic Packaging (5kg~25kg)

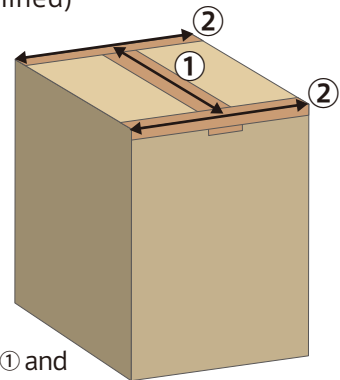
Inner packaging

- Double or triple polyethylene bags
- Designed for use in clean rooms, etc., the product can be removed in stages. (Label attached to the second layer of polyethylene bag from the outside)



Outer packaging

- Cardboard (H-lined)



Details of H-lined
Paste one piece of ① and then paste it in the gap of ②

Features

- GMP compliant
- Issuing a Statement*¹
- Conforming to the specifications in the USP-NF and Ph. Eur.*² (depending on the product)

*1 Statement containing quality information such as product information (origin, BSE/TSE, GMO, etc.), impurity data (residual solvents, elemental impurities), etc. can be obtained from website.

*2 Specification of products reflects latest versions of pharmacopeia.

Product Lineup

Please contact us for individual requests regarding capacity.

Product Code	Product Name	Grade	Conformity		Endotoxin	Package Size	CAS RN [®]	Chemical Formula	Principal Use
			USP-NF	Ph. Eur.					
NEW 013-28757	Acetylcysteine	JP	✓	✓	Less than 10EU/g	10kg	616-91-1	C ₃ H ₉ NO ₃ S	Culture medium additive
030-19555	Calcium Chloride Hydrate	JP			Less than 2.5EU/g	500 g	10035-04-8	CaCl ₂ · 2H ₂ O	Stabilizer
037-26035	Calcium Gluconate Hydrate	JP			Less than 1.5EU/g	500 g	299-28-5	C ₁₂ H ₂₂ CaO ₁₄ · H ₂ O	Calcium additive
033-26037						10 kg			
032-25245	Citric Acid Hydrate	JP	✓	✓	Less than 8EU/g	500 g	5949-29-1	C ₆ H ₈ O ₇ · H ₂ O	Stabilizer · Buffer
047-29015	Dibasic Potassium Phosphate	JPC			—	500 g	7758-11-4	K ₂ HPO ₄	Buffer
043-29017						20kg			
047-34385	Dibasic Sodium Phosphate Hydrate	JP	✓	✓	Less than 0.2EU/g	500g	10039-32-4	Na ₂ HPO ₄ · 12H ₂ O	Buffer
043-34387						10 kg			
046-34615	Disodium Edetate Hydrate	JP			Less than 10EU/g	500 g	6381-92-6	C ₁₀ H ₁₄ N ₂ Na ₂ O ₈ · 2H ₂ O	Stabilizer
042-34617						20 kg			
049-34345	Dried Sodium Carbonate	JP			Less than 10EU/g	500 g	497-19-8	Na ₂ CO ₃	Buffer
045-34347						10 kg			
076-05705	Glucose	JP			—	500 g	50-99-7	C ₆ H ₁₂ O ₆	Stabilizer
072-05707						10 kg			
NEW 075-06875	Glycine	JP	✓	✓	Less than 1.2EU/g	500 g	56-40-6	C ₂ H ₃ NO ₂	Stabilizer
082-10475	Hydrochloric Acid	JP		✓	Less than 10EU/g	500 mL	7647-01-0	HCl	Stabilizer · Buffer
121-06685	Lactose Hydrate	JP		*3	Less than 25EU/g	500 g	64044-51-5	C ₁₂ H ₂₂ O ₁₁ · H ₂ O	Excipient
130-18925	Magnesium Sulfate Hydrate	JP			Less than 10EU/g	500 g	10034-99-8	MgSO ₄ · 7H ₂ O	Stabilizer
133-14495	D-Mannitol	JP		*3	Less than 2.5EU/g	500 g	69-65-8	C ₆ H ₁₄ O ₆	Stabilizer
136-14485	Monobasic Potassium Phosphate	JPC			—	500 g	7778-77-0	KH ₂ PO ₄	Buffer
132-14487						25 kg			

Product Code	Product Name	Grade	Conformity		Endotoxin	Package Size	CAS RN®	Chemical Formula	Principal Use
			USP-NF	Ph. Eur.					
163-22105	Potassium Chloride	JP			—	500 g	7447-40-7	KCl	Buffer
161-21925	Potassium Iodide	JP			—	500 g	7681-11-0	KI	Stabilizer · Soluble agent
168-28515	Purified Glucose	JP	*3		Less than 2EU/g	500 g	50-99-7	C ₆ H ₁₂ O ₆	Stabilizer
164-28517						10 kg			
197-13235	Sodium Acetate Hydrate	JP			—	500 g	6131-90-4	C ₂ H ₃ NaO ₂ · 3H ₂ O	Buffer
197-18475	Sodium Bicarbonate	JP			Less than 10EU/g	500 g	144-55-8	NaHCO ₃	Buffer
193-18477						10 kg			
194-18505	Sodium Chloride	JP	✓	✓	Less than 3.1EU/g	500 g	7647-14-5	NaCl	Stabilizer · Buffer
190-18507						10 kg			
197-18855	Sodium Citrate Hydrate	JP	✓	✓	Less than 5.2EU/g	500 g	6132-4-3	C ₆ H ₅ Na ₃ O ₇ · 2H ₂ O	Stabilizer · Buffer
193-18857						10 kg			
191-18495	Sodium Dihydrogen Phosphate Dihydrate	JPE	✓	✓	Less than 2.0EU/g	500 g	13472-35-0	NaH ₂ PO ₄ · 2H ₂ O	Buffer
197-18497						10kg			
135-15555	Sodium L-Glutamate Hydrate	JPC	(NF)	- *4	Less than 3.9EU/g	500 g	6106-4-3	C ₅ H ₈ NNaO ₄ · H ₂ O	Stabilizer · Buffer
131-15557						20 kg			
190-18465	Sodium Hydroxide	JP	(NF)	✓	Less than 10EU/g	500 g	1310-73-2	NaOH	Buffer
196-18467						10 kg			
196-19165	Sodium Thiosulfate Hydrate	JP			Less than 10EU/g	500 g	10102-17-7	Na ₂ S ₂ O ₃ · 5H ₂ O	Stabilizer · Soluble agent
192-19167						20 kg			
198-18385	Sucrose	JP	(NF)	✓	Less than 2EU/g	500 g	57-50-1	C ₁₂ H ₂₂ O ₁₁	Stabilizer
194-18387						10 kg			
197-19195	Sucrose [Low endotoxin type (Less than 0.2EU/g)]	JP	(NF)	✓	Less than 0.2EU/g	500 g	57-50-1	C ₁₂ H ₂₂ O ₁₁	Stabilizer
193-19197						10 kg			
203-21035	Trometamol	JPC	✓	✓	Less than 0.03IU/g	500 g	77-86-1	C ₄ H ₁₁ NO ₃	Buffer
209-21037						10 kg			
213-01295	Urea	JP			Less than 2.5EU/g	500 g	57-13-6	CH ₄ N ₂ O	Stabilizer
						10 kg			

NEW

*3 These products are tested according to JP method. Some of the test items are harmonized to USP-NF Ph.Eur. For details, please check the product specifications.

*4 This product is not listed in Ph.Eur.

■ For more information, please visit website.

Top of our Raw material Pharmaceutical Industry website >GMP compliant Products CertiPro
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/product/certiopro.html>



Features

- Lineup including products listed in the JP and JPE
- Non-compendial products not listed in official compendia are provided in accordance with our own specifications.
- ISO9001 compliant
- Issuing a Statement*1

*1 Statement containing quality information such as product information (origin, BSE/TSE, GMO, etc.), impurity data (residual solvents, elemental impurities), etc. can be obtained from website.

Product Lineup

Please contact us for individual requests regarding capacity.

Product Code	Product Name	CAS RN [®]	Grade	Conformity		Endotoxin	Package Size	Chemical Formula	Principal Use
				USP-NF	Ph. Eur.				
012-28445	2-Amino-2-hydroxymethyl-1,3-propanediol Hydrochloride	1185-53-1	—			Max. 10EU/g	500 g	C ₄ H ₁₁ NO ₃ · HCl	Buffer
018-28447							10 kg		
NEW 018-28545	L-Ascorbic Acid Phosphate Magnesium Salt <i>n</i> -Hydrate	1713265-25-8	—			Less than 10EU/g	500 g	C ₆ H ₆ O ₉ P·3/2Mg·nH ₂ O	Culture medium additive
048-29665	Disodium Hydrogen Phosphate Anhydrous	7558-79-4	JPE			Less than 2.5EU/g	500 g	Na ₂ HPO ₄	Buffer
044-29667							10 kg		
068-05105	Fumaric Acid	110-17-8	JPE		—*2	—	500 g	C ₄ H ₄ O ₄	Buffer
064-05107							20 kg		
075-05155	Glucono-δ-Lactone	90-80-2	JPE		—*2	Less than 2.0EU/g	500 g	C ₆ H ₁₀ O ₆	Buffer
136-15105	Magnesium Stearate	557-04-0	JP		*3	—	500 g	C ₃₆ H ₇₀ MgO ₄	Lubricant
NEW 132-19421	Methyl Parahydroxybenzoate	99-76-3	JP	(NF)	✓	—	5 kg	C ₈ H ₈ O ₃	Preservative
168-22792	Polysorbate20	9005-64-5	JPE			—	25 g	—	Stabilizer
169-21965	Potassium Acetate	127-08-2	JPE			—	500 g	CH ₃ COOK	Buffer
NEW 169-29221	Propyl Parahydroxybenzoate	94-13-3	JP	(NF)	✓	—	5 kg	C ₁₀ H ₁₂ O ₃	Preservative
198-13265	Sodium Bisulfite	7631-90-5	JP		—*2	—	500 g	NaHSO ₃	Stabilizer · Buffer
194-13267							20 kg		
196-19182	Sodium Dextran Sulfate 5000	9011-18-1	—			Less than 50EU/g	25 g	—	Culture medium additive
190-19185							500 g		
194-14105	Sodium Dihydrogen Phosphate Anhydrous	7558-80-7	JPE		—*2	Less than 2.0EU/g	500 g	NaH ₂ PO ₄	Buffer
190-14107							10 kg		
197-13975	Sodium L-Tartrate	6106-24-7	JPE		—*2	—	500 g	C ₄ H ₄ Na ₂ O ₆ · 2H ₂ O	Buffer
193-14055	Sodium Pyrosulfite	7681-57-4	JP			—	500 g	Na ₂ S ₂ O ₅	Preservative
199-14057							10 kg		
204-16055	Titanium Oxide	13463-67-7	JP			—	500 g	TiO ₂	Excipient
903-40303							10 kg		

*2 These products are not listed in USP-NF and Ph.Eur.

*3 These products are tested according to JP method. Some of the test items are harmonized to USP-NF Ph.Eur. For details, please check the product specifications.


■ For more information, please visit website.

Top of our Raw material Pharmaceutical Industry website >ISO 9001 compliant Products CertiPro-L
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/product/certiprol.html>



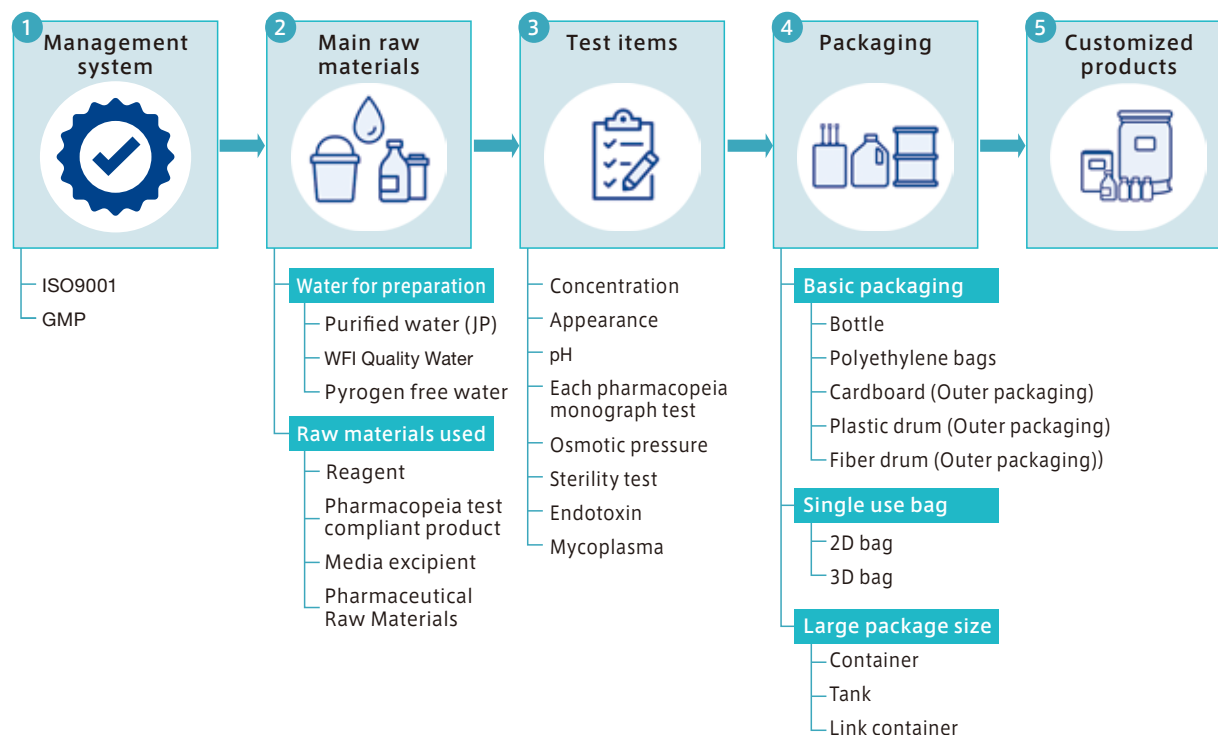
Semi-custom made liquid for biopharmaceutical

FUJIFILM Wako Pure Chemical offer a lineup of prepared process solutions that can be used in biopharmaceutical manufacturing processes. You can choose your desired concentration, package size, and format.

Product Name	Concentration	Package Size	Product appearance image
Sodium hydroxide solution	0.5mol/L	10L : Plastic bottle 200L : Plastic drum Upon request, we can also fill single-use bags that are ready to use.	
	1mol/L		
	5mol/L		
Ethanol aqueous solution	20%		
	50%		
Acetic acid solution	40%		
Hydrochloric acid solution	1mol/L		
	0.1mol/L		
Sodium chloride solution	0.5mol/L		
	1mol/L		
	2mol/L		
Phosphoric acid solution	0.5mol/L		
	1mol/L		
	2mol/L		

Customized liquid preparation service

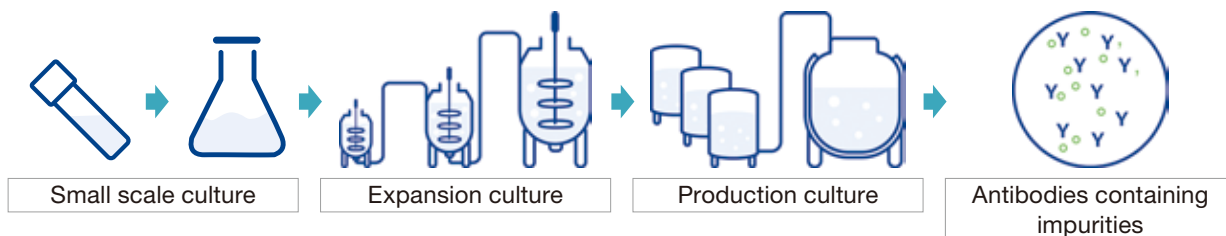
FUJIFILM Wako Pure Chemical provide process solutions tailored to customer requests. You can freely design the management system, raw materials used, test items, package size and format, etc. according to your application.



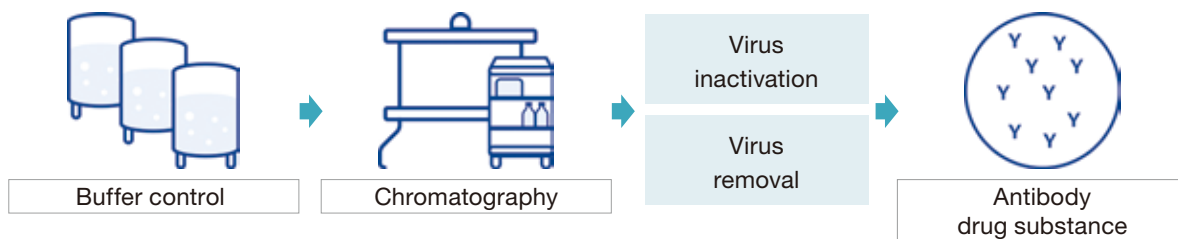
Product examples by manufacturing process

Manufacturing process of antibody drugs

Upstream



Downstream



Upstream

Product Code	Product Name	Conformity	Package Size	CAS RN [®]
Amino acid				
075-06875	Glycine	JP, USP, Ph.Eur.	500g	56-40-6
135-15555	Sodium L-Glutamate Hydrate	JPC,NF	500g	6106-04-3
131-15557			20kg	
Buffer				
049-34345	Dried Sodium Carbonate	JP	500g	497-19-8
045-34347			10kg	
197-18475	Sodium Bicarbonate	JP, Ph.Eur.	500g	144-55-8
193-18477			10kg	
Other				
068-05105	Fumaric Acid	JPE	500g	110-17-8
064-05107			20kg	
196-19182	Sodium Dextran Sulfate 5000	—	25g	9011-18-1
190-19185			500g	

Downstream

Product Code	Product Name	Conformity	Package Size	CAS RN®
Tris				
012-28445	2-Amino-2-hydroxymethyl-1,3-propanediol Hydrochloride	—	500g	1185-53-1
018-28447			10kg	
203-21035	Trometamol	JPC, USP, Ph.Eur.	500g	77-86-1
209-21037			10kg	
Phosphate buffer				
048-29665	Disodium Hydrogen Phosphate Anhydrous	JPE	500g	7558-79-4
044-29667			10kg	
047-29015	Dibasic Potassium Phosphate	JPC, USP, Ph.Eur.	500g	7758-11-4
043-29017			20kg	
047-34385	Dibasic Sodium Phosphate Hydrate	JP, USP, Ph.Eur.	500g	10039-32-4
043-34387			10kg	
136-14485	Monobasic Potassium Phosphate	JPC, NF, Ph.Eur.	500g	7778-77-0
132-14487			25kg	
194-14105	Sodium Dihydrogen Phosphate Anhydrous	JPE	500g	7558-80-7
190-14107			10kg	
191-18495	Sodium Dihydrogen Phosphate Dihydrate	JPE, USP, Ph.Eur.	500g	13472-35-0
197-18497			10kg	
Acetate buffer				
197-13235	Sodium Acetate Hydrate	JP	500g	6131-90-4
Citrate buffer				
032-25245	Citric Acid Hydrate	JP, USP, Ph.Eur.	500g	5949-29-1
197-18855	Sodium Citrate Hydrate	JP, USP, Ph.Eur.	500g	6132-04-3
193-18857			10kg	
Carbonate				
049-34345	Dried Sodium Carbonate	JP	500g	497-19-8
045-34347			10kg	
197-18475	Sodium Bicarbonate	JP, Ph.Eur.	500g	144-55-8
193-18477			10kg	
Acid/Base				
082-10475	Hydrochloric Acid	JP, Ph.Eur.	500mL	7647-01-0
190-18465	Sodium Hydroxide	JP, NF, Ph.Eur.	500g	1310-73-2
196-18467			10kg	
Salts				
030-19555	Calcium Chloride Hydrate	JP	500g	10035-04-8
163-22105	Potassium Chloride	JP	500g	7447-40-7
194-18505	Sodium Chloride	JP, USP, Ph.Eur.	500g	7647-14-5
190-18507			10kg	
Surfactant				
168-22792	Polysorbate20	JPE	25g	9005-64-5

FUJIFILM Wako Pure Chemical Corporation

<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/index.html>

1-2 Doshomachi 3-Chome, Chuo-Ku, Osaka 540-8605, Japan
Tel : +81 6 6203 3741 Fax : +81 6 6203 1999
ffwk-cservice@fujifilm.com

FUJIFILM Wako Chemicals U.S.A. Corporation

1600 Bellwood Road, Richmond, VA 23237, U.S.A.
Toll-Free(U.S.only):+1 877 714 1920
Tel: +1 804 271 7677 Fax: +1 804 271 7791
wkuslabchem@fujifilm.com

FUJIFILM Wako Chemicals Europe GmbH

Fuggerstr 12,41468 Neuss, Germany
Tel: +49 2131 311 0 Fax: +49 2131 311 100
labchem_wkeu@fujifilm.com

FUJIFILM Wako Chemicals (Hong Kong) Limited

Room 1111,11/F,International Trade Centre,11-19 Sha Tsui Road,
Tsuen Wan, N.T.,Hong Kong
Tel: +852-2799-9019 Fax: +852-2799-9808
wkhk.info@fujifilm.com

FUJIFILM Wako (Guangzhou)Trading Corporation

Room 3003,30/F.,Dong Shan Plaza 69, Xian Lie Zhong Road,
Guangzhou, 510095, China
Tel: +86-20-8732-6381(Guangzhou)
Tel: +86-21-6288-4751(Shingahal)
Tel: +86-10-6413-6388(Beijing)
whgz.info@fujifilm.com