

# Pharmaceutical Raw Materials

## CertiPro Series

Ver.5



# 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

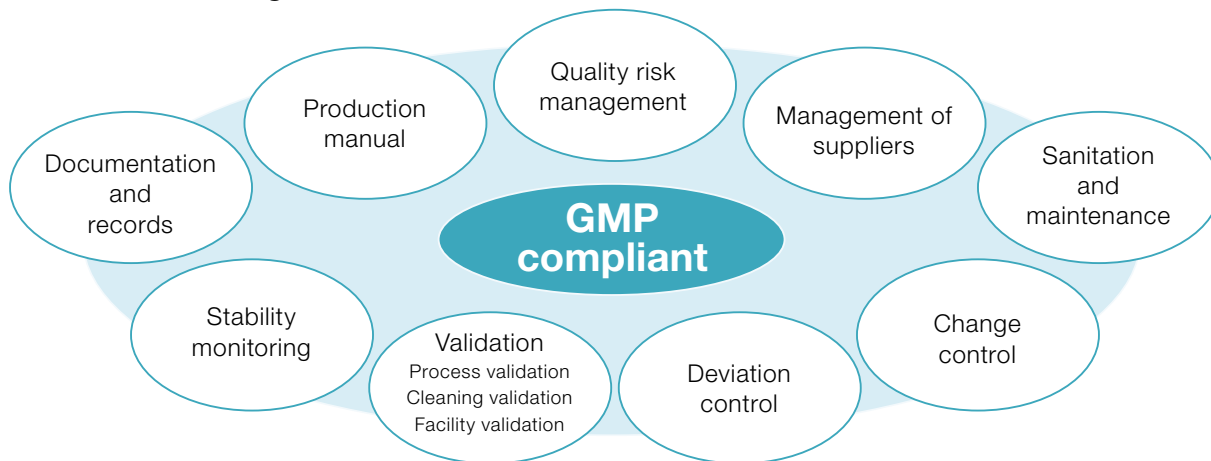
Pharmaceutical raw materials manufactured under ISO 9001. The lineup includes products conforming to the Japanese Pharmacopoeia (JP) and Japanese Pharmaceutical Excipients (JPE). Non-compendial products not listed in official compendia are provided in accordance with our own specifications.

#### 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

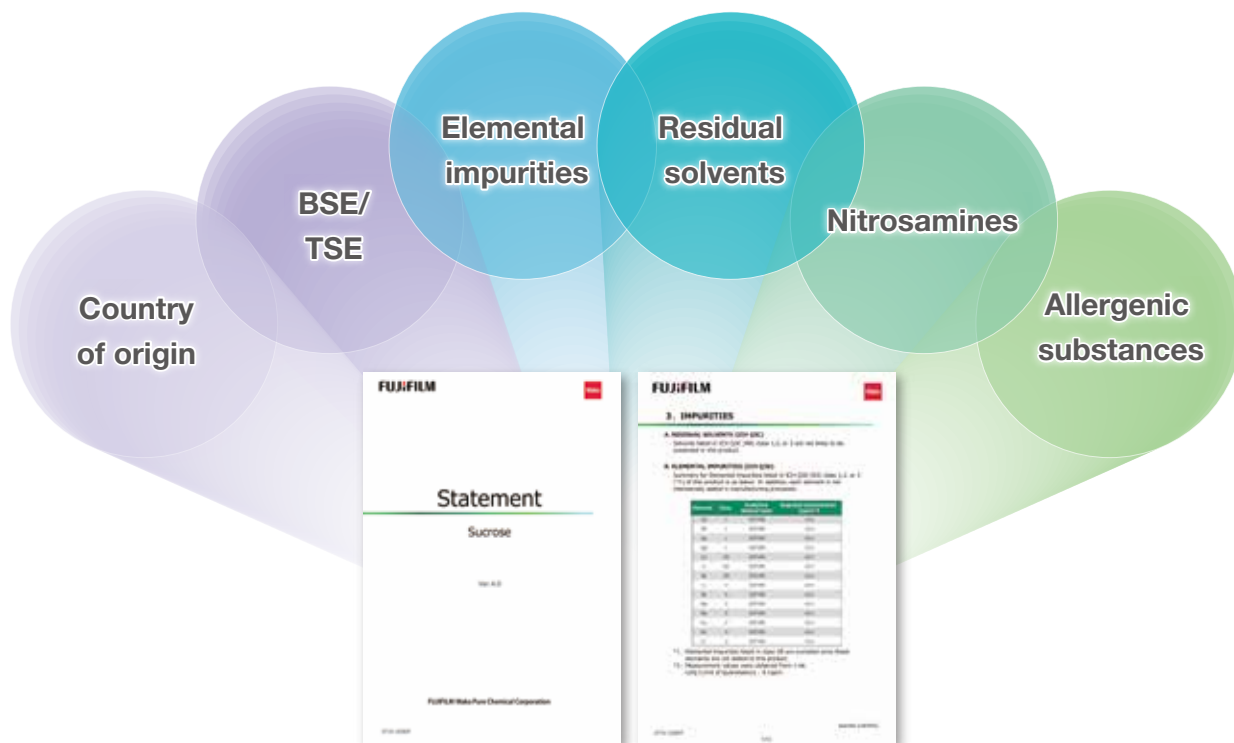


Location	Amagasaki City, Hyogo Prefecture
Site area	23,332㎡
Number of employees	About 220
Start of operation	Since 1940
Certifications	ISO9001, ISO/IEC17025 ISO14001, ISO17034

※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 name, Product code, Manufacturing control standards, Grade/Specification

**Product Information :** Country of origin, Derived material, BSE/TSE, GMO, Allergenic substances, Highly potency substances, Melamine, Nitrosamines, Impurities

## 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)

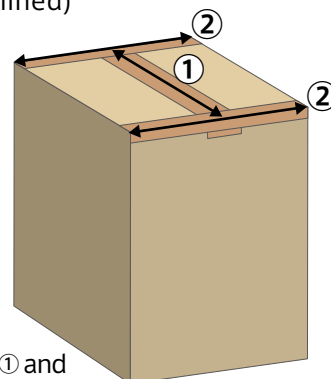
### Inner packaging

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



Product Code	Package Size	Product Name	Grade	Conformity		Endotoxin	Chemical Formula	CAS RN <sup>®</sup>	Principal Use
				USP-NF	Ph. Eur.				
135-15555	500 g	Sodium L-Glutamate Hydrate	JPC	(NF)	-*4	Less than 3.9 EU/g	C <sub>5</sub> H <sub>8</sub> NNaO <sub>4</sub> · H <sub>2</sub> O	6106-4-3	Stabilizer • Buffer
131-15557	20 kg								
163-22105	500 g	Potassium Chloride	JP			—	KCl	7447-40-7	Buffer
161-21925	500 g	Potassium Iodide	JP			—	KI	7681-11-0	Stabilizer • Soluble agent
168-28515	500 g	Purified Glucose	JP	*3		Less than 2 EU/g	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	50-99-7	Stabilizer
164-28517	10 kg								
197-13235	500 g	Sodium Acetate Hydrate	JP			Less than 2.5 EU/g	C <sub>2</sub> H <sub>3</sub> NaO <sub>2</sub> · 3H <sub>2</sub> O	6131-90-4	Buffer
197-18475	500 g	Sodium Bicarbonate	JP		✓	Less than 10 EU/g	NaHCO <sub>3</sub>	144-55-8	Buffer
193-18477	10 kg								
194-18505	500 g	Sodium Chloride	JP	✓	✓	Less than 3.1 EU/g	NaCl	7647-14-5	Stabilizer • Buffer
190-18507	10 kg								
197-18855	500 g	Sodium Citrate Hydrate	JP	✓	✓	Less than 5.2 EU/g	C <sub>6</sub> H <sub>5</sub> Na <sub>3</sub> O <sub>7</sub> · 2H <sub>2</sub> O	6132-04-3	Stabilizer • Buffer
193-18857	10 kg								
191-18495	500 g	Sodium Dihydrogen Phosphate Dihydrate	JPE	✓	✓	Less than 2.0 EU/g	NaH <sub>2</sub> PO <sub>4</sub> · 2H <sub>2</sub> O	13472-35-0	Buffer
197-18497	10kg								
190-18465	500 g	Sodium Hydroxide	JP	(NF)	✓	Less than 10 EU/g	NaOH	1310-73-2	Buffer
196-18467	10 kg								
196-19165	500 g	Sodium Thiosulfate Hydrate	JP			Less than 10 EU/g	Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> · 5H <sub>2</sub> O	10102-17-7	Stabilizer • Solubilizer
192-19167	20 kg								
198-18385	500 g	Sucrose	JP	(NF)	✓	Less than 2 EU/g	C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>	57-50-1	Stabilizer
194-18387	10 kg								
197-19195	500 g	Sucrose [Low endotoxin type (Less than 0.2EU/g)]	JP	(NF)	✓	Less than 0.2 EU/g	C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>	57-50-1	Stabilizer
193-19197	10 kg								
203-21035	500 g	Trometamol	JPC	✓	✓	Less than 0.03 IU/g	C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub>	77-86-1	Buffer
209-21037	10 kg								
213-01295	500 g	Urea	JP			Less than 2.5 EU/g	CH <sub>4</sub> N <sub>2</sub> O	57-13-6	Stabilizer

\*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/certiPro.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\*<sup>1</sup>

\*<sup>1</sup> 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 <sup>®</sup>	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.10 EU/g	500 g	C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub> · HCl	Buffer
	018-28447							10 kg		
	018-28545	L-Ascorbic Acid Phosphate Magnesium Salt <i>n</i> -Hydrate	1713265-25-8	—			Less than 10 EU/g	500 g	C <sub>6</sub> H <sub>8</sub> O <sub>9</sub> P · 3/2Mg·nH <sub>2</sub> O	Culture medium additive
NEW	027-19905	Bis-Tris	6976-37-0	—			Less than 10 EU/g	500 g	C <sub>8</sub> H <sub>19</sub> NO <sub>5</sub>	Buffer
NEW	021-19925	Butyl Parahydroxybenzoate (Oxyben <sup>™</sup> B)	94-26-8	JP	(NF)	✓	Less than 10 EU/g	500 g	C <sub>11</sub> H <sub>14</sub> O <sub>3</sub>	Preservative
	027-19927							10 kg		
	048-29665	Disodium Hydrogen Phosphate Anhydrous	7558-79-4	JPE			Less than 2.5 EU/g	500 g	Na <sub>2</sub> HPO <sub>4</sub>	Buffer
	044-29667							10 kg		
	068-05105	Fumaric Acid	110-17-8	JPE		—* <sup>2</sup>	—	500 g	C <sub>4</sub> H <sub>4</sub> O <sub>4</sub>	Buffer
	064-05107							20 kg		
	075-05155	Glucono-δ-Lactone	90-80-2	JPE		—* <sup>2</sup>	Less than 2.0 EU/g	500 g	C <sub>6</sub> H <sub>10</sub> O <sub>6</sub>	Buffer
NEW	086-10755	HEPES	7365-45-9	—			Less than 10 EU/g	500 g	C <sub>8</sub> H <sub>18</sub> N <sub>2</sub> O <sub>4</sub> S	Buffer
	136-15105	Magnesium Stearate	557-04-0	JP	* <sup>3</sup>		—	500 g	C <sub>36</sub> H <sub>70</sub> MgO <sub>4</sub>	Lubricant
NEW	138-19565	MES	145224-94-8	—			Less than 10 EU/g	500 g	C <sub>6</sub> H <sub>13</sub> NO <sub>4</sub> ·H <sub>2</sub> O	Buffer
	132-19421	Methyl Parahydroxybenzoate (Oxyben <sup>®</sup> M)	99-76-3	JP	(NF)	✓	—	5 kg	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>	Preservative
NEW	139-19615	MOPS	1132-61-2	—			Less than 10 EU/g	500 g	C <sub>7</sub> H <sub>15</sub> NO <sub>4</sub> S	Buffer
	168-22792	Polysorbate20	9005-64-5	JPE			—	25 g	—	Stabilizer
	169-21965	Potassium Acetate	127-08-2	JPE			—	500 g	CH <sub>3</sub> COOK	Buffer
	169-29221	Propyl Parahydroxybenzoate (Oxyben <sup>®</sup> P)	94-13-3	JP	(NF)	✓	—	5 kg	C <sub>10</sub> H <sub>12</sub> O <sub>3</sub>	Preservative
	198-13265	Sodium Bisulfite	7631-90-5	JP		—* <sup>2</sup>	—	500 g	NaHSO <sub>3</sub>	Stabilizer · Buffer
	194-13267							20 kg		
	196-19182	Sodium Dextran Sulfate 5000	9011-18-1	—			Less than 50 EU/g	25 g	—	Culture medium additive
	190-19185							500 g		
	194-14105	Sodium Dihydrogen Phosphate Anhydrous	7558-80-7	JPE		—* <sup>2</sup>	Less than 2.0 EU/g	500 g	NaH <sub>2</sub> PO <sub>4</sub>	Buffer
	190-14107							10 kg		
	197-13975	Sodium L-Tartrate	6106-24-7	JPE		—* <sup>2</sup>	—	500 g	C <sub>4</sub> H <sub>4</sub> Na <sub>2</sub> O <sub>6</sub> · 2H <sub>2</sub> O	Buffer
	193-14055	Sodium Pyrosulfite	7681-57-4	JP			—	500 g	Na <sub>2</sub> S <sub>2</sub> O <sub>5</sub>	Preservative
	199-14057							10 kg		
	204-16055	Titanium Oxide	13463-67-7	JP			—	500 g	TiO <sub>2</sub>	Excipient
	903-40303							10 kg		

\*<sup>2</sup> These products are not listed in USP-NF and Ph.Eur.

\*<sup>3</sup> 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.

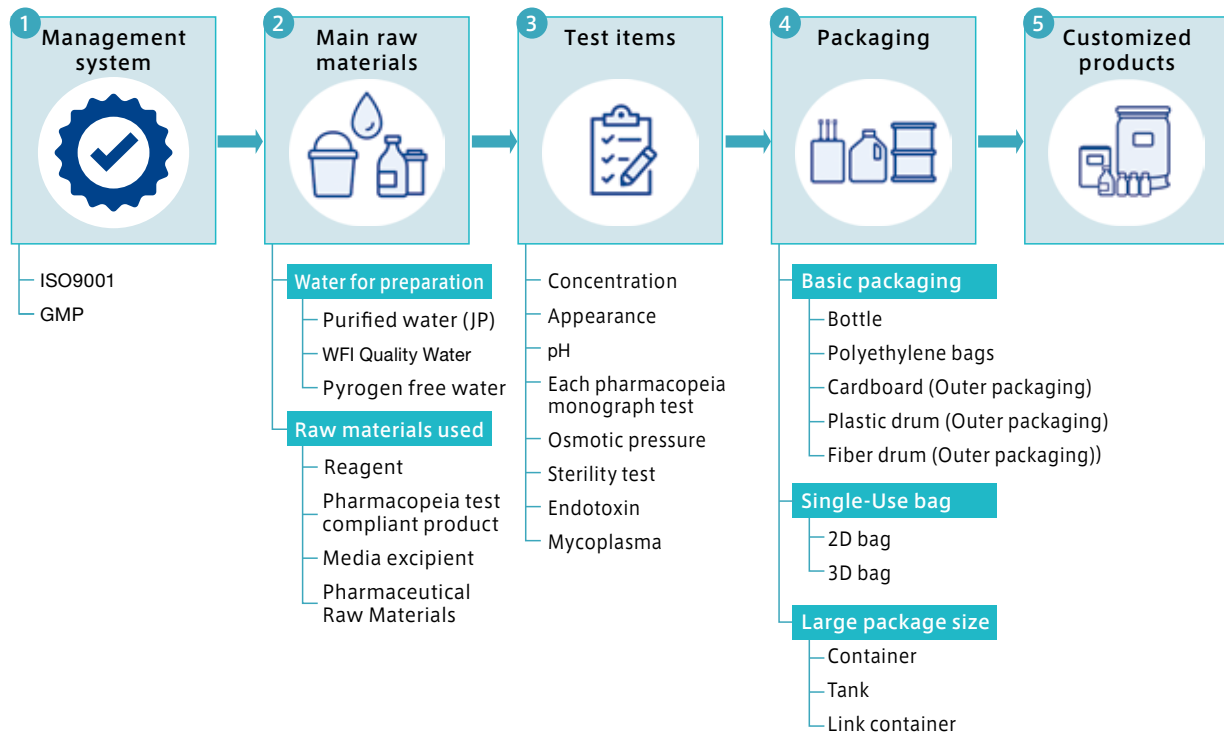
Top of our Raw material Pharmaceutical Industry website >ISO 9001 compliant Products CertiPro-L  
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/product/certiprol.html>





# Customized liquid preparation service

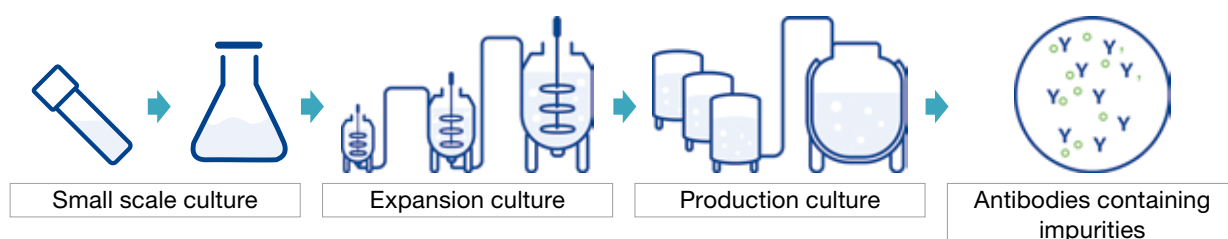
FUJIFILM Wako Pure Chemical provide process solutions tailored to customer requests. You can freely design the management system, raw materials used, test items, package size and format, etc. according to your application.



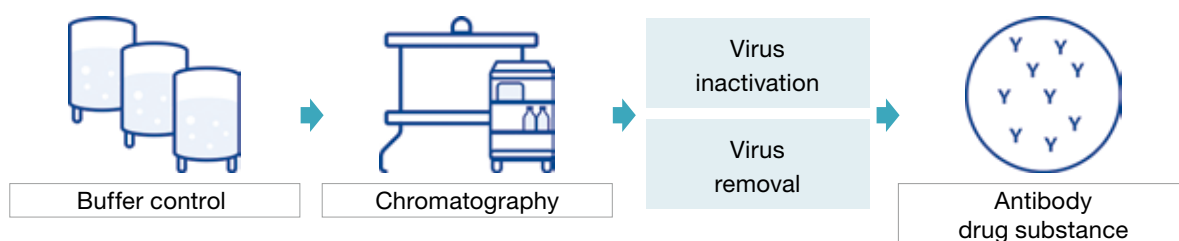
# Product examples by manufacturing process

## 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.	500 g	56-40-6
135-15555	Sodium L-Glutamate Hydrate	JPC,NF	500 g	6106-04-3
131-15557			20 kg	
Buffer				
049-34345	Dried Sodium Carbonate	JP, NF, Ph.Eur.	500 g	497-19-8
045-34347			10 kg	
197-18475	Sodium Bicarbonate	JP, Ph.Eur.	500 g	144-55-8
193-18477			10 kg	
Other				
068-05105	Fumaric Acid	JPE	500 g	110-17-8
064-05107			20 kg	
196-19182	Sodium Dextran Sulfate 5000	—	25 g	9011-18-1
190-19185			500 g	

## Downstream

Product Code	Product Name	Conformity	Package Size	CAS RN®
Phosphate buffer				
048-29665	Disodium Hydrogen Phosphate Anhydrous	JPE	500 g	7558-79-4
044-29667			10 kg	
047-29015	Dibasic Potassium Phosphate	JPC, USP, Ph.Eur.	500 g	7758-11-4
043-29017			20 kg	
047-34385	Dibasic Sodium Phosphate Hydrate	JP, USP, Ph.Eur.	500 g	10039-32-4
043-34387			10 kg	
136-14485	Monobasic Potassium Phosphate	JPC, NF, Ph.Eur.	500 g	7778-77-0
132-14487			25 kg	
194-14105	Sodium Dihydrogen Phosphate Anhydrous	JPE	500 g	7558-80-7
190-14107			10 kg	
191-18495	Sodium Dihydrogen Phosphate Dihydrate	JPE, USP, Ph.Eur.	500 g	13472-35-0
197-18497			10 kg	
Acetate buffer				
197-13235	Sodium Acetate Hydrate	JP	500 g	6131-90-4
Citrate buffer				
032-25245	Citric Acid Hydrate	JP, USP, Ph.Eur.	500 g	5949-29-1
197-18855	Sodium Citrate Hydrate	JP, USP, Ph.Eur.	500 g	6132-04-3
193-18857			10 kg	
Other Buffer				
012-28445	2-Amino-2-hydroxymethyl-1,3-propanediol Hydrochloride	—	500 g	1185-53-1
018-28447			10 kg	
027-19905	Bis-Tris	—	500 g	6976-37-0
086-10755	HEPES	—	500 g	7365-45-9
138-19565	MES	—	500 g	145224-94-8
139-19615	MOPS	—	500 g	1132-61-2
203-21035	Trometamol	JPC, USP, Ph.Eur.	500 g	77-86-1
209-21037			10 kg	
Carbonate				
049-34345	Dried Sodium Carbonate	JP, NF, Ph.Eur.	500 g	497-19-8
045-34347			10 kg	
197-18475	Sodium Bicarbonate	JP, Ph.Eur.	500 g	144-55-8
193-18477			10 kg	
Acid/Base				
082-10475	Hydrochloric Acid	JP, Ph.Eur.	500 mL	7647-01-0
190-18465	Sodium Hydroxide	JP, NF, Ph.Eur.	500 g	1310-73-2
196-18467			10 kg	
Salts				
030-19555	Calcium Chloride Hydrate	JP	500 g	10035-04-8
163-22105	Potassium Chloride	JP	500 g	7447-40-7
194-18505	Sodium Chloride	JP, USP, Ph.Eur.	500 g	7647-14-5
190-18507			10 kg	
Surfactant				
168-22792	Polysorbate20	JPE	25 g	9005-64-5

**For inquiries about estimates and custom services,  
please use the contact form on our website.**

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



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