

Pharmaceutical Raw Materials CertiPro Series

April 2026 Edition



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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^{*1}
- Conforming to the specifications in the USP-NF and Ph.Eur.^{*1}

^{*1} Depending on the product.

ISO9001-compliant Products

CertiPro-L

Pharmaceutical raw materials manufactured under ISO9001. 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.

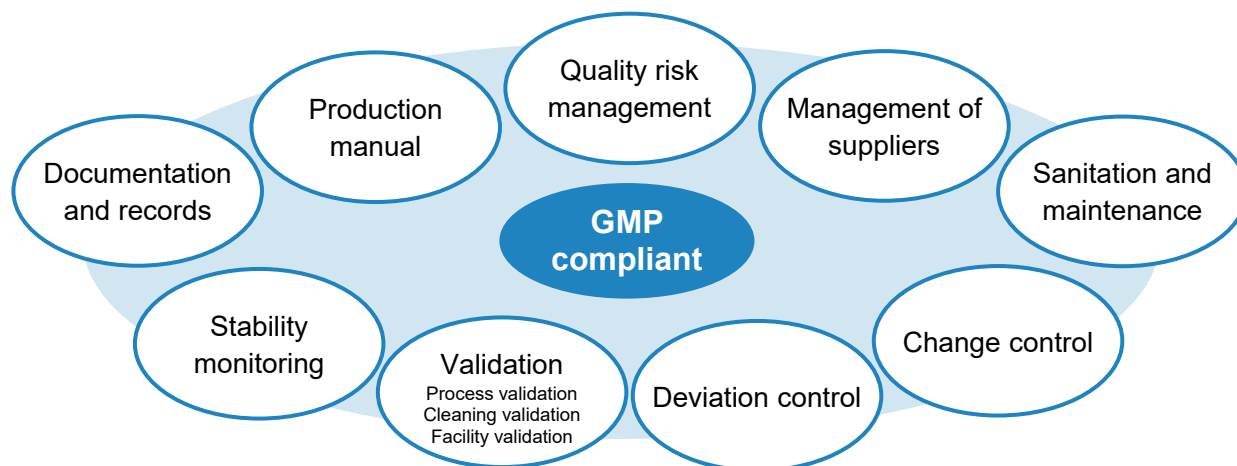
Features

- ISO9001 compliant^{*2}
- Lineup including products listed in the JP and JPE, and non-compendial products

^{*2} Some aspects of manufacturing and quality control are conducted in compliance with GMP.

Management System of CertiPro Series

Production Management of CertiPro



	CertiPro	CertiPro-L
Quality management	GMP	ISO9001
CoA available	●	●
Statement available	●	●
Supplier management	●	● ^{*3}
Change control	●	● ^{*3}
Deviation control	●	● ^{*4} (Nonconformity management)
Process control validation	●	

^{*3} Certain products are managed under GMP. ^{*4} For certain products, deviation control is implemented.

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	Package Size	Product Name	Grade	Conformity		Endotoxin	CAS RN®	Chemical Formula	Principal Use
				USP-NF	Ph. Eur.				
013-28757	10 kg	Acetylcysteine	JP	✓	✓	Less than 10 EU/g	616-91-1	C ₅ H ₉ NO ₃ S	Culture medium additive
030-19555	500 g	Calcium Chloride Hydrate	JP			Less than 2.5 EU/g	10035-04-8	CaCl ₂ · 2H ₂ O	Stabilizer
NEW 037-26035 031-26038	500 g	Calcium Gluconate Hydrate	JP			Less than 1.5 EU/g	299-28-5	C ₁₂ H ₂₂ CaO ₁₄ · H ₂ O	Calcium strengthener
	20 kg								
032-25245	500 g	Citric Acid Hydrate	JP	✓	✓	Less than 8 EU/g	5949-29-1	C ₆ H ₈ O ₇ · H ₂ O	Stabilizer/Buffer
076-05705 072-05707	500 g 10 kg	Glucose	JP			—	50-99-7	C ₆ H ₁₂ O ₆	Stabilizer
168-28515 164-28517	500 g 10 kg	Purified Glucose	JP	*3		Less than 2 EU/g	50-99-7	C ₆ H ₁₂ O ₆	Stabilizer
075-06875	500 g	Glycine	JP	✓	✓	Less than 1.2 EU/g	56-40-6	C ₂ H ₅ NO ₂	Stabilizer
NEW 083-10765 089-10767	500 g	L-Histidine	JP	✓	✓	Less than 2.0 EU/g	71-00-1	C ₆ H ₉ N ₃ O ₂	Stabilizer/Buffer
	20 kg								
NEW 080-10775 086-10777	500 g	L-Histidine Hydrochloride Hydrate	JP	—*4	✓	Less than 2.0 EU/g	5934-29-2	C ₆ H ₉ N ₃ O ₂ · HCl · H ₂ O	Stabilizer/Buffer
	20 kg								
082-10475	500 mL	Hydrochloric Acid	JP		✓	Less than 10 EU/g	7647-01-0	HCl	Stabilizer/Buffer
121-06685	500 g	Lactose Hydrate	JP	*3		Less than 25 EU/g	64044-51-5	C ₁₂ H ₂₂ O ₁₁ · H ₂ O	Excipients
130-18925	500 g	Magnesium Sulfate Hydrate	JP			Less than 10 EU/g	10034-99-8	MgSO ₄ · 7H ₂ O	Stabilizer
133-14495	500 g	D-Mannitol	JP	*3		Less than 2.5 EU/g	69-65-8	C ₆ H ₁₄ O ₆	Stabilizer
163-22105	500 g	Potassium Chloride	JP			—	7447-40-7	KCl	Buffer
161-21925	500 g	Potassium Iodide	JP			—	7681-11-0	KI	Stabilizer/Soluble agent
047-29015 043-29017	500 g 20 kg	Dibasic Potassium Phosphate	JPC	✓	✓	Less than 2.5 EU/g	7758-11-4	K ₂ HPO ₄	Buffer

Product Code	Package Size	Product Name	Grade	Conformity		Endotoxin	CAS RN®	Chemical Formula	Principal Use
				USP-NF	Ph. Eur.				
136-14485 132-14487	500 g 25 kg	Monobasic Potassium Phosphate	JPC	(NF)	✓	—	7778-77-0	KH ₂ PO ₄	Buffer
197-13235	500 g	Sodium Acetate Hydrate	JP			Less than 2.5 EU/g	6131-90-4	C ₂ H ₃ NaO ₂ · 3H ₂ O	Buffer
NEW 199-19415 195-19417	500 g 10 kg	Sodium Bicarbonate	JP	✓	✓	Less than 10 EU/g	144-55-8	NaHCO ₃	Buffer
049-34345 045-34347	500 g 10 kg	Dried Sodium Carbonate	JP	(NF)	✓	Less than 10 EU/g	497-19-8	Na ₂ CO ₃	Buffer
194-18505 190-18507	500 g 10 kg	Sodium Chloride	JP	✓	✓	Less than 3.1 EU/g	7647-14-5	NaCl	Stabilizer/ Buffer
197-18855 193-18857	500 g 10 kg	Sodium Citrate Hydrate	JP	✓	✓	Less than 5.2 EU/g	6132-04-3	C ₆ H ₅ Na ₃ O ₇ · 2H ₂ O	Stabilizer/ Buffer
191-18495 197-18497	500 g 10 kg	Sodium Dihydrogen Phosphate Dihydrate	JPE	✓	✓	Less than 2.0 EU/g	13472-35-0	NaH ₂ PO ₄ · 2H ₂ O	Buffer
NEW 136-19625 132-19627	500 g 10 kg	Monobasic Sodium Phosphate Monohydrate	—	✓		Less than 2.0 EU/g	10049-21-5	NaH ₂ PO ₄ · H ₂ O	Buffer
046-34615 042-34617	500 g 20 kg	Disodium Edetate Hydrate	JP			Less than 10 EU/g	6381-92-6	C ₁₀ H ₁₄ N ₂ Na ₂ O ₈ · 2H ₂ O	Stabilizer
135-15555 131-15557	500 g 20 kg	Sodium L-Glutamate Hydrate	JPC	(NF)	—*5	Less than 3.9 EU/g	6106-04-3	C ₅ H ₈ NNaO ₄ · H ₂ O	Stabilizer/ Buffer
190-18465 196-18467	500 g 10 kg	Sodium Hydroxide	JP	(NF)	✓	Less than 10 EU/g	1310-73-2	NaOH	Buffer
047-34385 043-34387	500 g 10 kg	Dibasic Sodium Phosphate Hydrate	JP	✓	✓	Less than 0.2 EU/g	10039-32-4	Na ₂ HPO ₄ · 12H ₂ O	Buffer
196-19165 192-19167	500 g 20 kg	Sodium Thiosulfate Hydrate	JP			Less than 10 EU/g	10102-17-7	Na ₂ S ₂ O ₃ · 5H ₂ O	Stabilizer/ Solubilizer
198-18385 194-18387	500 g 10 kg	Sucrose	JP	(NF)	✓	Less than 2 EU/g	57-50-1	C ₁₂ H ₂₂ O ₁₁	Stabilizer
197-19195 193-19197	500 g 10 kg	Sucrose [Low endotoxin type (Less than 0.2 EU/g)]	JP	(NF)	✓	Less than 0.2 EU/g	57-50-1	C ₁₂ H ₂₂ O ₁₁	Stabilizer
203-21035 209-21037	500 g 10 kg	Trometamol	JPC	✓	✓	Less than 0.03 IU/mg	77-86-1	C ₄ H ₁₁ NO ₃	Buffer
213-01295	500 g	Urea	JP			Less than 2.5 EU/g	57-13-6	CH ₄ N ₂ O	Stabilizer

*3 These products are tested according to JP method. Some of the test items are harmonized to USP-NF or Ph.Eur.

For details, please check the product specifications.

*4 This product is not listed in USP-NF.

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

■ For more information

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*¹
- Issuing a Statement*²

*1 Some aspects of manufacturing and quality control are conducted in compliance with GMP.

*2 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	Package Size	Product Name	Grade	Conformity		Endotoxin	CAS RN®	Chemical Formula	Principal Use
				USP-NF	Ph. Eur.				
012-28445 018-28447	500 g 10 kg	2-Amino-2-hydroxymethyl-1,3-propanediol Hydrochloride	—			Max. 10 EU/g	1185-53-1	H ₂ NC(CH ₂ OH) ₃ ·HCl	Buffer
NEW 016-28541 018-28545	50 g 500 g	L-Ascorbic Acid Phosphate Magnesium Salt <i>n</i> -Hydrate	—			Less than 10 EU/g	1713265-25-8	C ₆ H ₆ O ₉ P·3/2Mg· <i>n</i> H ₂ O	Culture medium additive
027-19905	500 g	Bis-Tris	—			Less than 10 EU/g	6976-37-0	C ₈ H ₁₉ NO ₅	Buffer
068-05105 064-05107	500 g 20 kg	Fumaric Acid	JPE		—* ³	—	110-17-8	C ₄ H ₄ O ₄	Buffer
075-05155	500 g	Glucono-δ-Lactone	JPE		—* ³	Less than 2.0 EU/g	90-80-2	C ₆ H ₁₀ O ₆	Buffer
086-10755	500 g	HEPES	—			Less than 10 EU/g	7365-45-9	C ₈ H ₁₈ N ₂ O ₄ S	Buffer
136-15105	500 g	Magnesium Stearate	JP	* ⁴		—	557-04-0	C ₃₆ H ₇₀ MgO ₄	Lubricant
138-19565	500 g	MES	—			Less than 10 EU/g	145224-94-8	C ₆ H ₁₃ NO ₄ S·H ₂ O	Buffer
132-19421	5 kg	Methyl Parahydroxybenzoate (Oxyben® M)	JP	(NF)	✓	—	99-76-3	C ₈ H ₈ O ₃	Preservative
139-19615	500 g	MOPS	—			Less than 10 EU/g	1132-61-2	C ₇ H ₁₅ NO ₄ S	Buffer
168-22792	25 g	Polysorbate20	JPE			—	9005-64-5	—	Stabilizer
169-21965	500 g	Potassium Acetate	JPE			—	127-08-2	CH ₃ COOK	Buffer
169-29221	5 kg	Propyl Parahydroxybenzoate (Oxyben® P)	JP	(NF)	✓	—	94-13-3	C ₁₀ H ₁₂ O ₃	Preservative

Product Code	Package Size	Product Name	Grade	Conformity		Endotoxin	CAS RN®	Chemical Formula	Principal Use
				USP-NF	Ph.Eur.				
198-13265 194-13267	500 g 20 kg	Sodium Bisulfite	JP	—*3		—	7631-90-5	NaHSO ₃	Stabilizer/ Buffer
196-19182 190-19185	25 g 500 g	Sodium Dextran Sulfate 5000	—			Less than 50 EU/g	9011-18-1	—	Culture medium additive
194-14105 190-14107	500 g 10 kg	Sodium Dihydrogen Phosphate Anhydrous	JPE		—*3	Less than 2.0 EU/g	7558-80-7	NaH ₂ PO ₄	Buffer
048-29665 044-29667	500 g 10 kg	Disodium Hydrogen Phosphate Anhydrous	JPE			Less than 2.5 EU/g	7558-79-4	Na ₂ HPO ₄	Buffer
197-13975	500 g	Sodium L-Tartrate	JPE		—*3	—	6106-24-7	C ₄ H ₄ Na ₂ O ₆ · 2H ₂ O	Buffer
193-14055 199-14057	500 g 10 kg	Sodium Pyrosulfite	JP			—	7681-57-4	Na ₂ S ₂ O ₅	Preservative
204-16055 903-40303	500 g 10 kg	Titanium Oxide	JP			—	13463-67-7	TiO ₂	Excipient

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

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

■ For more information

Top of our Raw Material Pharmaceutical Industry website > ISO9001-compliant Products CertiPro-L
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/product/certiprol.html>



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.

Country of origin

BSE/TSE

Elemental impurities

Residual solvents

Nitrosamines

Allergenic substances

Example of items to be listed

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 potent substances, Melamine, Nitrosamines, Impurities

Statement sample

FUJIFILM Wako

Statement

Sucrose

Ver. A.0

FUJIFILM Wako Pure Chemical Corporation

07/16-0000P

FUJIFILM Wako

3. IMPURITIES

A. RESIDUAL SOLVENTS (ICH Q3C)
Solvents listed in ICH Q3C (R8) class 1,2, or 3 are not likely to be presented in this product.

B. ELEMENTAL IMPURITIES (ICH Q3D)
Summary for Elemental impurities listed in ICH Q3D (R2) class 1,2, or 3 (*1) of this product is as below. In addition, each element is not intentionally added in manufacturing processes.

Element	Class	Analytical Method Used	Expected Concentration (ppm)*2
Cl	1	ICP-MS	<0.1
Br	1	ICP-MS	<0.1
As	1	ICP-MS	<0.1
Pb	1	ICP-MS	<0.1
Cd	2B	ICP-MS	<0.1
Hg	2B	ICP-MS	<0.1
Al	2B	ICP-MS	<0.1
Li	1	ICP-MS	<0.1
Na	1	ICP-MS	<0.1
K	1	ICP-MS	<0.1
Fe	1	ICP-MS	<0.1
Cu	1	ICP-MS	<0.1
Mn	1	ICP-MS	<0.1
Zn	1	ICP-MS	<0.1

*1 : Elemental impurities listed in class 2B are excluded since these elements are not added to this product.
*2 : Measurement values were obtained from 1 lot.
LOQ (Limit of Quantitation) : 0.1ppm

Sucrose (CertiPro)

07/16-0000P 7/11

■ For more information

Top of our Raw Material Pharmaceutical Industry website > Support
> Information about pharmaceutical drugs > Statement from FUJIFILM Wako Pure Chemical
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/medicine/definition.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	Example of Basic Packaging	Example of Customized Packaging
50 kg ~ 25 kg		
25 kg ~ 5 kg		
500 g/ 500 mL		

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

Basic Packaging (5kg~25kg)

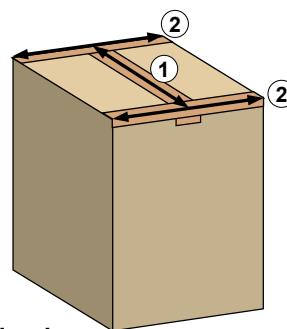
Inner packaging

- 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

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.



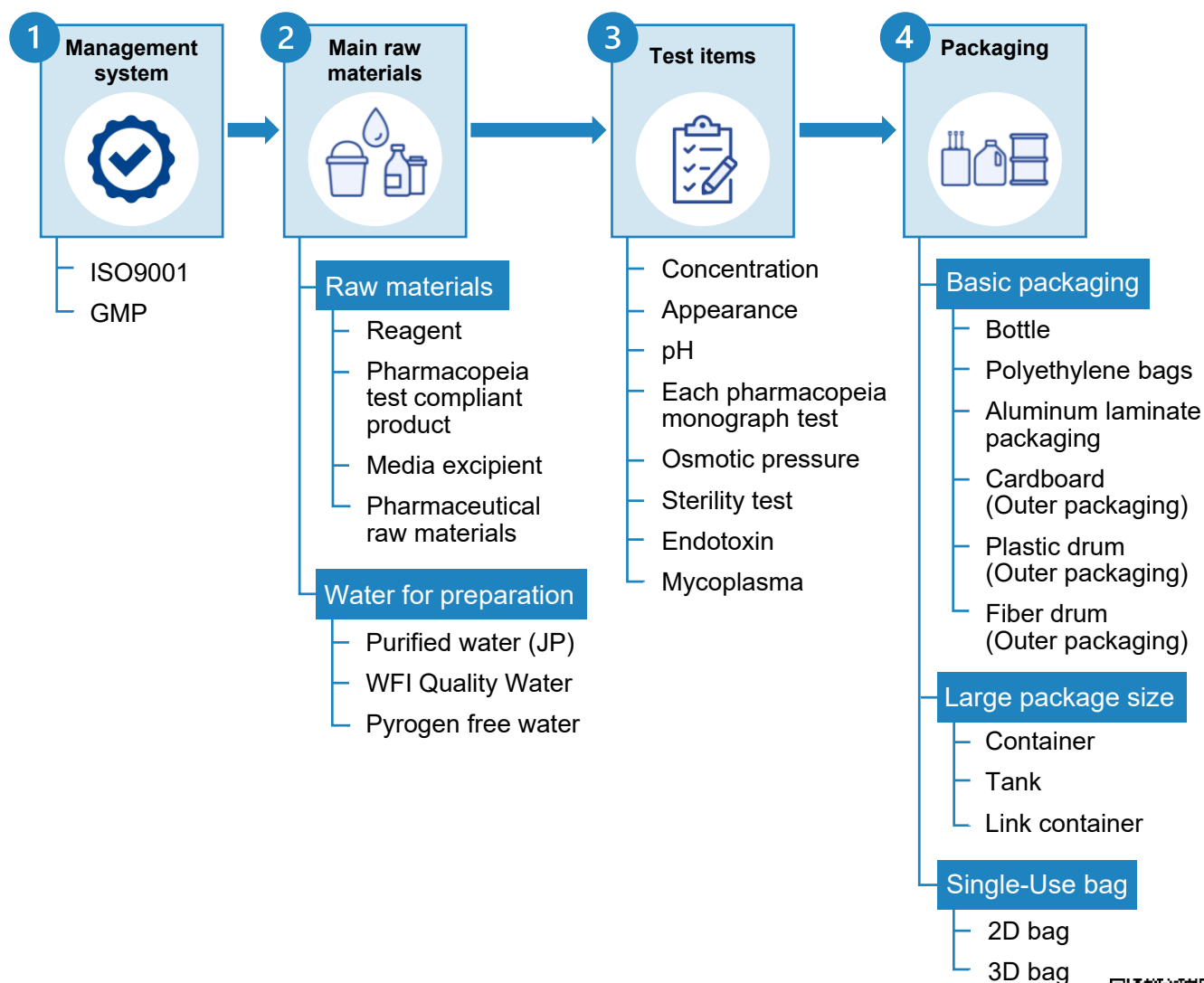
Additional test
Endotoxin test etc.



Prepare solution

Examples of Consultation Topics

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



■ For more information

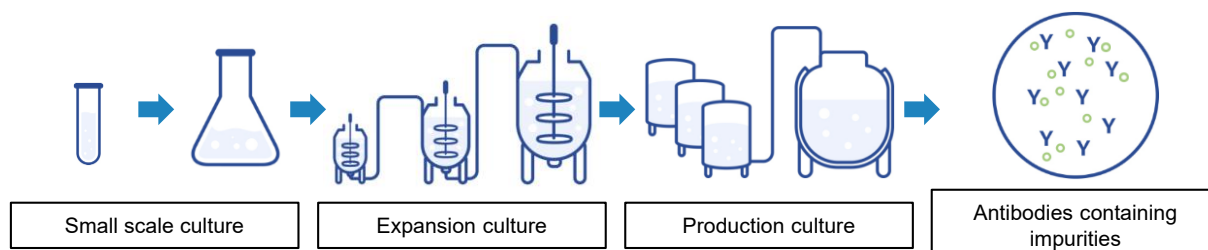
Top of our Raw Material Pharmaceutical Industry website > Services > Customized Services
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/case/top.html>



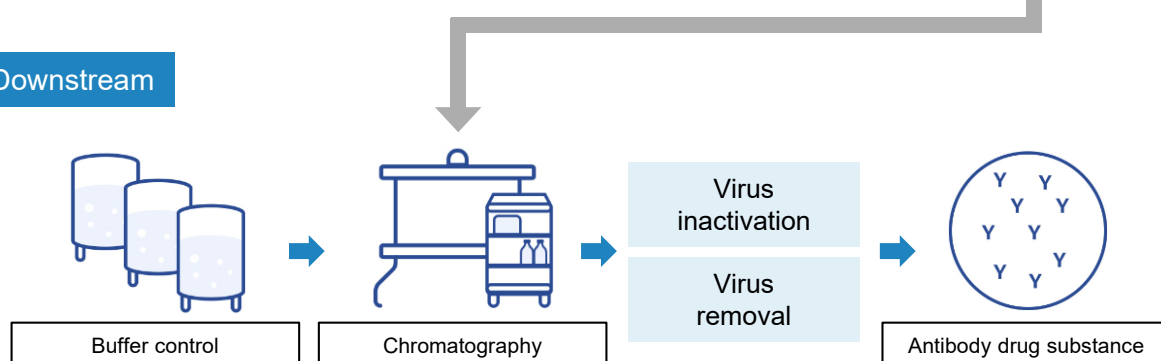
Product Examples by Manufacturing Process

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
NEW 083-10765 089-10767	L-Histidine	JP, USP, Ph.Eur.	500 g 20 kg	71-00-1
NEW 080-10775 086-10777	L-Histidine Hydrochloride Hydrate	JP, Ph.Eur.	500 g 20 kg	5934-29-2
135-15555 131-15557	Sodium L-Glutamate Hydrate	JPC, NF	500 g 20 kg	6106-04-3
Carbonate				
NEW 199-19415 195-19417	Sodium Bicarbonate	JP, USP, Ph.Eur.	500 g 10 kg	144-55-8
049-34345 045-34347	Dried Sodium Carbonate	JP, NF, Ph.Eur.	500 g 10 kg	497-19-8

Product Code	Product Name	Conformity	Package Size	CAS RN®
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 193-18857	Sodium Citrate Hydrate	JP, USP, Ph.Eur.	500 g 10 kg	6132-04-3
Phosphate Buffer				
047-29015 043-29017	Dibasic Potassium Phosphate	JPC, USP, Ph.Eur.	500 g 20 kg	7758-11-4
136-14485 132-14487	Monobasic Potassium Phosphate	JPC, NF, Ph.Eur.	500 g 25 kg	7778-77-0
194-14105 190-14107	Sodium Dihydrogen Phosphate Anhydrous	JPE	500 g 10 kg	7558-80-7
191-18495 197-18497	Sodium Dihydrogen Phosphate Dihydrate	JPE, USP, Ph.Eur.	500 g 10 kg	13472-35-0
136-19625 132-19627	Monobasic Sodium Phosphate Monohydrate	USP	500 g 10 kg	10049-21-5
048-29665 044-29667	Disodium Hydrogen Phosphate Anhydrous	JPE	500 g 10 kg	7558-79-4
047-34385 043-34387	Dibasic Sodium Phosphate Hydrate	JP, USP, Ph.Eur.	500 g 10 kg	10039-32-4
Acid/Base				
082-10475	Hydrochloric Acid	JP, Ph.Eur.	500 mL	7647-01-0
190-18465 196-18467	Sodium Hydroxide	JP, NF, Ph.Eur.	500 g 10 kg	1310-73-2
Other				
196-19182 190-19185	Sodium Dextran Sulfate 5000	—	25 g 500 g	9011-18-1

NEW

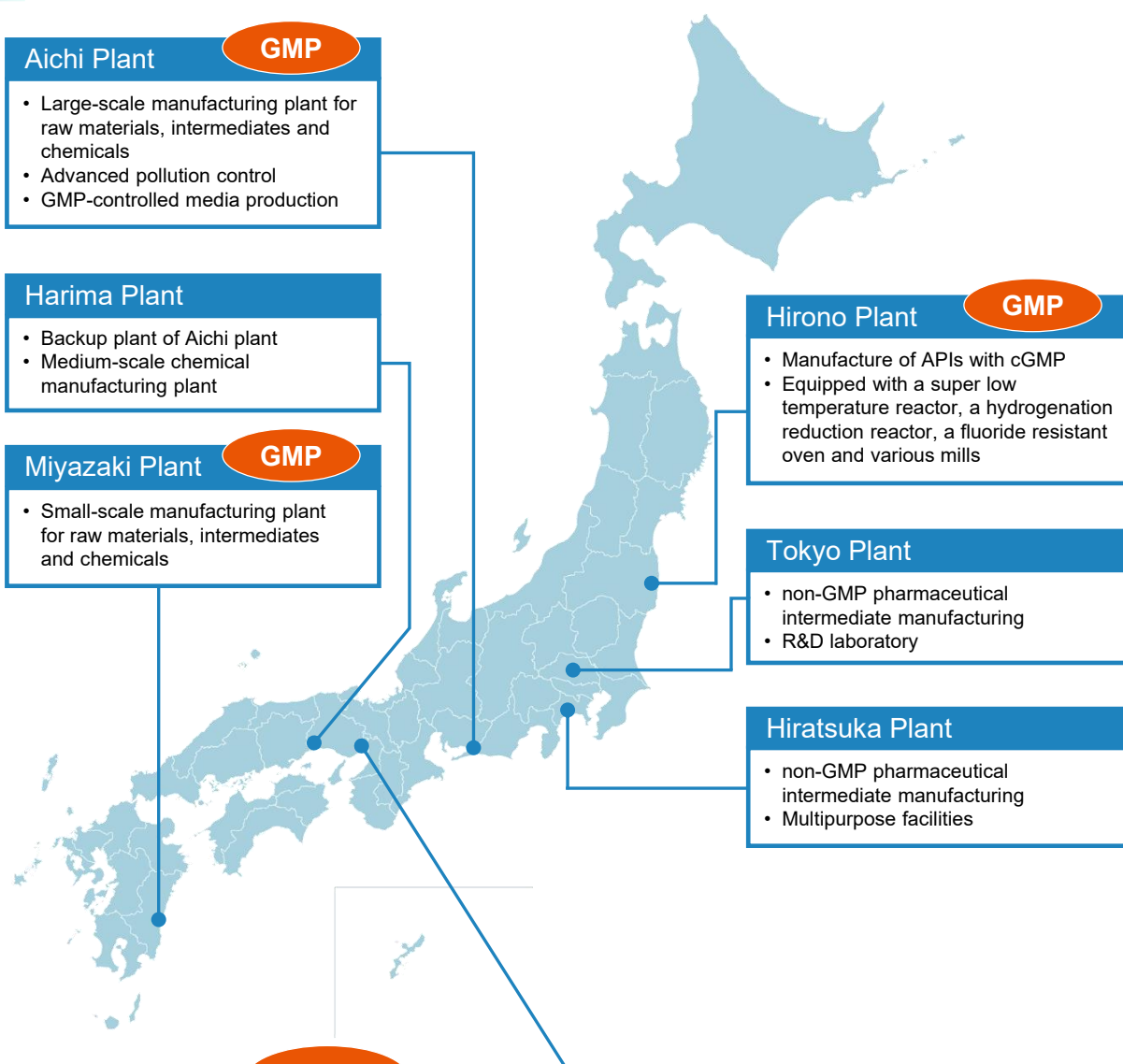
Downstream

Product Code	Product Name	Conformity	Package Size	CAS RN®
Amino Acid				
075-06875	Glycine	JP, USP, Ph.Eur.	500 g	56-40-6
NEW 083-10765 089-10767	L-Histidine	JP, USP, Ph.Eur.	500 g 20 kg	71-00-1
NEW 080-10775 086-10777	L-Histidine Hydrochloride Hydrate	JP, Ph.Eur.	500 g 20 kg	5934-29-2
Phosphate Buffer				
047-29015 043-29017	Dibasic Potassium Phosphate	JPC, USP, Ph.Eur.	500 g 20 kg	7758-11-4
136-14485 132-14487	Monobasic Potassium Phosphate	JPC, NF, Ph.Eur.	500 g 25 kg	7778-77-0
194-14105 190-14107	Sodium Dihydrogen Phosphate Anhydrous	JPE	500 g 10 kg	7558-80-7
191-18495 197-18497	Sodium Dihydrogen Phosphate Dihydrate	JPE, USP, Ph.Eur.	500 g 10 kg	13472-35-0
NEW 136-19625 132-19627	Monobasic Sodium Phosphate Monohydrate	USP	500 g 10 kg	10049-21-5
048-29665 044-29667	Disodium Hydrogen Phosphate Anhydrous	JPE	500 g 10 kg	7558-79-4
047-34385 043-34387	Dibasic Sodium Phosphate Hydrate	JP, USP, Ph.Eur.	500 g 10 kg	10039-32-4
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 193-18857	Sodium Citrate Hydrate	JP, USP, Ph.Eur.	500 g 10 kg	6132-04-3
Other Buffer				
012-28445 018-28447	2-Amino-2-hydroxymethyl-1,3-propanediol Hydrochloride	—	500 g 10 kg	1185-53-1
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 209-21037	Trometamol	JPC, USP, Ph.Eur.	500 g 10 kg	77-86-1

NEW

Product Code	Product Name	Conformity	Package Size	CAS RN®
Carbonate				
199-19415 195-19417	Sodium Bicarbonate	JP, USP, Ph.Eur.	500 g 10 kg	144-55-8
049-34345 045-34347	Dried Sodium Carbonate	JP, NF, Ph.Eur.	500 g 10 kg	497-19-8
Acid/base				
082-10475	Hydrochloric Acid	JP, Ph.Eur.	500 mL	7647-01-0
190-18465 196-18467	Sodium Hydroxide	JP, NF, Ph.Eur.	500 g 10 kg	1310-73-2
Salts				
030-19555	Calcium Chloride Hydrate	JP	500 g	10035-04-8
163-22105	Potassium Chloride	JP	500 g	7447-40-7
194-18505 190-18507	Sodium Chloride	JP, USP, Ph.Eur.	500 g 10 kg	7647-14-5
Surfactant				
168-22792	Polysorbate20	JPE	25 g	9005-64-5
Other				
068-05105 064-05107	Fumaric Acid	JPE	500 g 20 kg	110-17-8

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 low temperature 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)
- 2025.10 GMP conformity survey by Hyogo Prefectural Pharmaceutical Affairs Division (Regular/Export)

Conduct 5-10 on-side 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

■ For more information

Top of our Raw Material Pharmaceutical Industry website > Corporate information > Production Sites
<https://labchem-wako.fujifilm.com/us/pharmaceutical-raw-materials/logistics/index.html>

