

International Certification Related to Production and Quality Management (As of December 31, 2022)

- The information covers consolidated group companies.
- The definitions of product categories are as follows.
 - Pharmaceuticals: Also includes infusions and in-vitro diagnostic drugs. Does not include investigational drugs.
 - Chemicals: Research reagents, pharmaceutical intermediates, and active pharmaceutical ingredients (bulk drugs) are included in chemicals.
- Figures in the table indicate the number of factories.

Company	Factory Information					Certification Status			
	Factory	Products				Pharmaceuticals	Foods		Others
		Pharmaceuticals	Foods	Chemical	Others	GMP	FSSC22000	Others	
Otsuka Pharmaceutical Co., Ltd.	8	6	6			PIC/S GMP(6) JGMP(6)	6		
Crystal Geyser Water Company	2		2				2	c-GMP(2) NS(2)	
Cambridge Isotope Laboratories, Inc.	1			1					ICH Q7(1) ISO/IEC17025(1) ISO17034(1) ISO13485(1)
CIL Isotope Separations, LLC	1			1					ICH Q7 GMP(1) ISO9001
CIL Canada	1			1					ISO9001(1)
Advanced Biochemical Compounds GmbH	1			1		IMP/GMP(1) API/GMP(1)			ISO13485(1)
Euriso-Top GmbH	1			1		GMP (1)			
Interpharma Praha, a.s.	1	1	1	1	1	PIC/S GMP (1)		HACCP(1)	
Korea Otsuka Pharmaceutical Co., Ltd.	1	1				PIC/S GMP (1)			
Sichuan Otsuka Pharmaceutical Co., Ltd.	1	1				GMP (1)			
Nutrition & Sante SAS	6		6					IFS (5) HACCP(6)	
Nutrition & Sante Iberia SL	2		2					IFS (2) BRC (1) HACCP(2)	
Otsuka Sims (Guangdong) Beverage Co., Ltd.	2		2				2		ISO9001 (2)
Pharmavite LLC	4		4					FDA,USP- QSGMP- DSVP(4)	
FoodState, Inc.	2		2						
PT Amerta Indah Otsuka	2		2				2	c GMP(2)	ISO9001 (2)
PT Otsuka Indonesia	1	1				PIC/S GMP(1)		ISO22000(1)	ISO9001 (1)
Ridge Vineyards, Inc.	2		2						USDA Organic (100% organic) (2)
Tianjin Otsuka Beverage Co., Ltd.	1		1				1	HACCP(1)	ISO9001 (1)
Taiwan Otsuka Pharmaceutical Co., Ltd.	1	1				PIC/S GMP(1)			
Zhejiang Otsuka Pharmaceutical Co., Ltd.	1	1				GMP(1)			
Otsuka Pakistan Ltd.	1	1				PIC/S GMP(1)			ISO9001 (1)
Daiya Foods Inc.	1		1					SQF(1) NSF(1)	
Nippon Pharmaceutical Chemicals Co., Ltd.	2		2						
Otsuka Electronics Co., Ltd.	1				Devices(1)				ISO17025
Otsuka Pharmaceutical Factory, Inc.	4	4				PIC/S GMP(4) JGMP(4)			
J.O.Pharma Co., Ltd.	1	1				PIC/S GMP(1) JGMP(1)			
EN Otsuka Pharmaceutical Co., Ltd.	2	1	1			PIC/S GMP(1) JGMP(1)			
Otsuka Techno Corporation	2				Synthetic resin molded products(2)				ISO900 (2)
Suzhou Otsuka Pharmaceutical Co., Ltd.	1	1				JGMP (1) CGMP(1)			
Otsuka Pharmaceutical India Private Limited	1	1				PIC/S GMP (1)			ISO9001 (1)
PT Widatra Bhakti	1	1				PIC/S GMP (1)			ISO9001 (1)
Nanjing Otsuka Techbond Techno Co., Ltd.	1				Pharmaceuticals(1)				ISO9001 (1)
Egypt Otsuka Pharmaceutical Co., S.A.E.	1	1				Egypt.GMP (1)			ISO9001 (1)
Otsuka Techno Vietnam Co., Ltd.	1				Packaging materials for pharmaceuticals(1)				ISO15378 (1)
Taiho Pharmaceutical Co., Ltd.	4	4				PIC/S GMP (3) JGMP (4)			

Company	Factory	Products				Pharmaceuticals	Foods		Others
		Pharmaceuticals	Foods	Chemical	Others	GMP	FSSC22000	Others	
Okayama Taiho Pharmaceutical Co., Ltd.	1	1			Quasi-drugs etc.(1)	JGMP (1)			ISO9001(1)
Otsuka Chemical Co., Ltd.	3			3					ISO9001(3)
Higashiyama Film Co., Ltd.	2			2					
Otsuka Ohmi Ceramics Co., Ltd.	1				Ceramic board(1)				
Otsuka-MGC Chemical Company, Inc.	1			1					ISO9001 (1)
Hebron S.A.	1			1					ISO9001 (1)
Trocellen Iberica S.A.	1			1					ISO9001 (1)
PT Lautan Otsuka Chemical	1			1					ISO9001 (1)
KOC Co., Ltd.	1			1					ISO9001 (1)
Zhangjiagang Otsuka Chemical Co., Ltd.	1			1					ISO9001 (1)
Otsuka Chemical (India) Private Limited	1			1					ISO9001 (1)
Otsuka Chemical America, Inc.	1			1					ISO9001 (1)
Otsuka South China Precision Instruments (Shenzhen) Co., Ltd.	1			1					IATF16949(1) ISO9001 (1) ISO13485
Otsuka Chemical (Shanghai) Co., Ltd.	1			1					
Otsuka Material Science & Technology (Shanghai) Co., Ltd.	1			1					Not applicable (The facility is used for R&D)
Otsuka Foods Co., Ltd.	4		4					JFS-B(1) HACCP(4)	ISO9001(4)
Shandong Otsuka Desheng Foods Co., Ltd.	1		1				1	ISO22000(1)	
Shandong Otsuka Desheng Foods Co., Ltd.	1		1					ISO22000(1)	
Otsuka Packaging Industries Co., Ltd.	4				Packaging materials(4)				ISO9001(4)
JIMRO	1				Medical devices(1)				ISO13485(1)

[References]

■FSSC 22000: A certification standard developed by the Food Safety System Certification (FSSC) Foundation based in the Netherlands in 2004. Standard approved by GFSI*

* Global Food Safety Initiative: A non-profit organization established in May 2000 by experts from retailers and manufacturers involved in the food industry worldwide with the aim of continuously improving food safety systems.

■ISO 22000: International standard for food safety management systems (FSMS). The scope of the audit covers products and product manufacturing flow.

■ISO 9001: An international standard for the quality management systems of design, development, manufacturing, and installation of products and services. Scope of audit in the manufacturing flow of products: Does not only cover factories, but also includes sales offices.

■ISO 17025: General requirements for the competence of testing and calibration laboratories (based on ISO 9001)

■ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.

■ISO 13485: International standard for the quality management systems of medical devices

■National Sanitation Foundation (NSF) Certification: A process that verifies compliance of products and systems with the requirements and policies of standards stipulated by the NSF. Only products that have gained certification are permitted to use the NSF mark, which helps signify a superior reputation for product quality, performance, and reliability.

■Safe Quality Food (SQF) Certification: A food safety and quality management standard which is owned and managed by the Food Industry Association (FMI) in the U.S. and covers all sectors of the food supply chain from primary product to processing, transportation, and distribution.

■ISO 17034: General requirements for the competence of reference material producers. The requirements are designed to ensure competence in the production of reference materials and to guarantee that international guidelines are observed in the production and assignment of material property values. ISO 17034 certification not only includes verification of technical competence and good quality management practices, but also the important production controls specific to reference material producers.

■Current Good Manufacturing Practice (c-GMP): One of the quality control programs for food and drugs established by the FDA.

■U.S. Pharmacopeia (USP): A quality standard for pharmaceuticals including dietary supplements in the U.S.

■BRC Global Standard: A food safety standard administered by the British Retail Consortium.

International Beverage Association (IBWA): Trade association of companies in the bottled water industry.

■International Featured Standards (IFS) Certification: Food safety standard for EU countries.

■JFS: A standard developed and operated by the Japan Food Safety Management Association to certify food safety management initiatives.

■ISO 15378: A quality standard for companies that manufacture primary packaging materials for medicinal products.