

## International Certification Related to Production and Quality Management (As of December 31, 2023)

•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 Geysler Water Company	2		2				2		
Cambridge Isotope Laboratories, Inc.	1			1		ICH Q7 GMP(1)			ISO/IEC17025(1) ISO17034(1) ISO13485(1)
CIL Isotope Separations, LLC	1			1		ICH Q7 GMP(1)			ISO9001(1)
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) NSF/ANSI455-2 GMP(4)	
FoodState, Inc.	2		2						Not certified
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) Taiwan QMS(1)		ISO22000(1)	
Zhejiang Otsuka Pharmaceutical Co., Ltd.	1	1				Chinese GMP(1)			
Otsuka Pakistan Ltd.	1	1				PIC/S GMP(1)			ISO9001 (1)
Daiya Foods Inc.	1		1					SQF(1)	
Nippon Pharmaceutical Chemicals Co., Ltd.	2		2						Not certified

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Otsuka Electronics Co., Ltd.	1				Devices(1)				ISO/IEC17025(1) ISO13485(1)
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)				ISO9001(2)
Lilium Otsuka Co.,Ltd.	1				Medical devices(1)				ISO13485(1)
Leshan Otsuka Techno Co., Ltd.	1				Synthetic resin molded products(1)				not certified
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				Infusion-related products(1)				ISO9001 (1)
Egypt Otsuka Pharmaceutical Co., S.A.E.	1	1				Egypt.GMP (1)			ISO9001 (1)
Otsuka Al-Obour Pharmaceutical Egypt S.A.E.	2	2				Egypt.GMP (1)			ISO9001 (1)
Otsuka Pharmaceutical Vietnam Co., Ltd.	2	2				JGMP (1) WHO GMP(2) (MoH Vietnam) cGMP(2) (Philippines FDA)			
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)			
Okayama Taiho Pharmaceutical Co., Ltd.	1	1			Quasi-drugs etc.(1)	JGMP (1)			
Otsuka Chemical Co., Ltd.	3			3					ISO9001(3)
Higashiyama Film Co., Ltd.	2			2					Not certified
Otsuka Ohmi Ceramics Co., Ltd.	1				Ceramic board(1)				Not certified
Otsuka-MGC Chemical Company, Inc.	1			1					ISO9001 (1)
SynCrest Inc.	1								Not certified
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)

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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(1)
Otsuka Chemical (Shanghai) Co., Ltd.	1			1					Not certified
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) JFC-C(2) HACCP(4)	ISO9001(2)
Shandong Otsuka Desheng Foods Co.,Ltd.	1		1				1	ISO22000(1) HACCP(1)	
Shandong Otsuka Desheng Foods Co.,Ltd.	1		1					ISO22000(1)	
Otsuka Packaging Industries Co., Ltd.	4				Packaging materials(4)				ISO9001(4)
ReCor Medical Inc.	1				Medical devices(1)				ISO13485(1)
Otsuka medical Devices Co.,Ltd.	3				Medical devices(3)				ISO13485(3)
Veryan Medical Ltd.	1								ISO13485(1)
Biomedical Solutions Inc.	1								ISO13485(1)
JIMRO Co.,Ltd.	1				Medical devices(1)				ISO13485(1)

[References]

- GMP (Good Manufacturing Practice): A standard of manufacturing control and quality control for pharmaceuticals and quasi-pharmaceuticals.
- PIC/S GMP: The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is an informal co-operative arrangement between inspection authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use.
- ICHQ7 GMP: Guidance of Good Manufacturing Practice (GMP) for manufacturing of active pharmaceutical ingredients under an appropriate system for managing quality, established by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- 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: An international standard for food safety management systems (FSMS). The scope of the audit covers products and product manufacturing flow.
- HACCP: Food safety management system.
- 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/IEC 17025: General requirements for the competence of testing and calibration laboratories. Conformity to this requirements allows certification of the accuracy and reliability of tests and calibrations.
- 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.