

NEWS RELEASE

Otsuka Pharmaceutical Factory, Inc.

September 26, 2019

Otsuka Holdings Co., Ltd.

Otsuka Pharmaceutical Factory develops Cellstor®-S cell suspension and preservation solution and Cellstor®-W cell wash and preservation solution

- Research reagents leading to applications in regenerative medicine products -

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara; "OPF") has developed and manufactured the cell suspension and preservation solution Cellstor®-S and the cell wash and preservation solution Cellstor®-W, which are research reagents. FUJIFILM Wako Pure Chemical Corporation (Head Office: Chuo-ku, Osaka, Japan; President and CEO: Kazuo Shiraki) has launched these products on September 26, 2019.

Cellstor-S and Cellstor-W are cell preservation solutions that enable not only refrigerated storage but also room-temperature storage. The products currently sold are not for room-temperature storage. The solutions have been confirmed to maintain high survival rates of human adipose-derived mesenchymal stem cells*1 in both refrigerated and room-temperature storage conditions. They do not contain any components of human or animal origin. Making use of our technologies cultivated in the manufacture of IV products, we manufacture these products under manufacturing control and quality control in accordance with GMP.*2 Cellstor-S has been confirmed to maintain the suspension of human adiposederived mesenchymal stem cells for a certain period of time.

Currently, various cryopreservation solutions are available on the market, but there are limited options for solutions for refrigerated storage, and solutions for room-temperature storage are not available on the market. Cellstor-S and Cellstor-W are expected to contribute to basic research on mesenchymal stem cells and lead to applications in regenerative medicine products.*3

OPF will continue to promote research and development in the area of regenerative medicine and aim to contribute to medical care by creating innovative products.

Based on the corporate philosophy of "Otsuka-people creating new products for better health worldwide," the Otsuka Group is dedicated to contributing to the health of people around the world.

^{*1} A type of cell being studied for cell therapies

^{*2} GMP (Good Manufacturing Practice)

^{*3} In the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Devices Act), the "Regenerative medicine product" refers to the items obtained after culturing or other processes using human cells which are intended to be used for "reconstruction, repairing or formation of the structure or function of the bodies of humans," and "treatment or prevention of disease in humans," or the items intended for use in the treatment of disease in humans which are introduced into cells of humans and contain genes to be expressed in their bodies.

Product Overview

Brand name	Cellstor _® -S		Cellstor _® -W	
General name	Cell suspension and preservation solution		Cell wash and preservation solution	
Classification	Research reagents (These products cannot be used for medical purposes in humans or animals.)			
Composition	Dextran 40	12.5 g	Trehalose hydrate	8.29 g
per container (250 mL)	Trehalose hydrate	8.29 g	Calcium chloride hydrate	0.05 g
	Calcium chloride hydrate	0.05 g	Potassium chloride	0.075 g
	Potassium chloride	0.075 g	Sodium chloride	1.5 g
	Sodium chloride	1.5 g	L-sodium lactate	0.775 g
	L-sodium lactate	0.775 g	pH adjuster	Proper amount
	pH adjuster	Proper amount	Water for injection	Proper amount
	Water for injection	Proper amount		
Packaging	250 mL in soft bags			
Storage	Store at room temperature			
Expiration date	3 years			
Suggested retail price*	52,500 JPY/bag (excluding tax)			
Developed and manufactured by	Otsuka Pharmaceutical Factory, Inc.			
Distributed by	FUJIFILM Wako Pure Chemical Corporation			

^{*} The suggested retail price is presented as a reference price.

Company Profiles

Otsuka Pharmaceutical Factory, Inc.

Established : October 7, 1969 (founded September 1, 1921)

Capital : 80 million yen

Representative : Shinichi Ogasawara, President and Representative Director

Head Office : 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan

Employees : 2,266 (as of December 31, 2018)

Business : Manufacture, sale, import and export of clinical nutrition products and other

Description pharmaceutical products, medical devices, functional foods, etc.

U R L : https://www.otsukakj.jp/en/

FUJIFILM Wako Pure Chemical Corporation

Established : June 1922

Capital : 2,339 million yen

Representative : Kazuo Shiraki, President and CEO

Head Office : 1-2 Doshomachi, 3-Chome, Chuo-ku, Osaka 540-8605, Japan

Business : Providing laboratory chemicals, specialty chemicals and

Description diagnostic reagents

U R L : http://ffwk.fujifilm.co.jp/en/