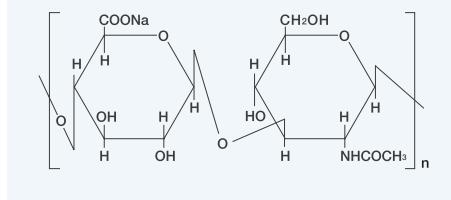


# SODIUM HYALURONATE

MADE  
by  
JAPAN

# SODIUM HYALURONATE



1

## Purified Sodium Hyaluronate (EP/JP) 100% MADE IN JAPAN

All the manufacturing process takes place in Japan.



2

## Microbial Fermentation from NON-ANIMAL ORIGIN and HALAL CERT.

Fermented by "*Streptococcus zooepidemicus*".



3

## Comply with GMP, ICH, and ISO

International Standard & Regulation



## APPLICATIONS

### Knee injection



### Dermal filler



### Eye drop



### Ophthalmic Viscosurgical Device



### Others

- Coating agent (Catherter etc.)
- Anti-adhesion agent
- Bladder anti-inflammatory agent etc.

# PRODUCT LINEUP

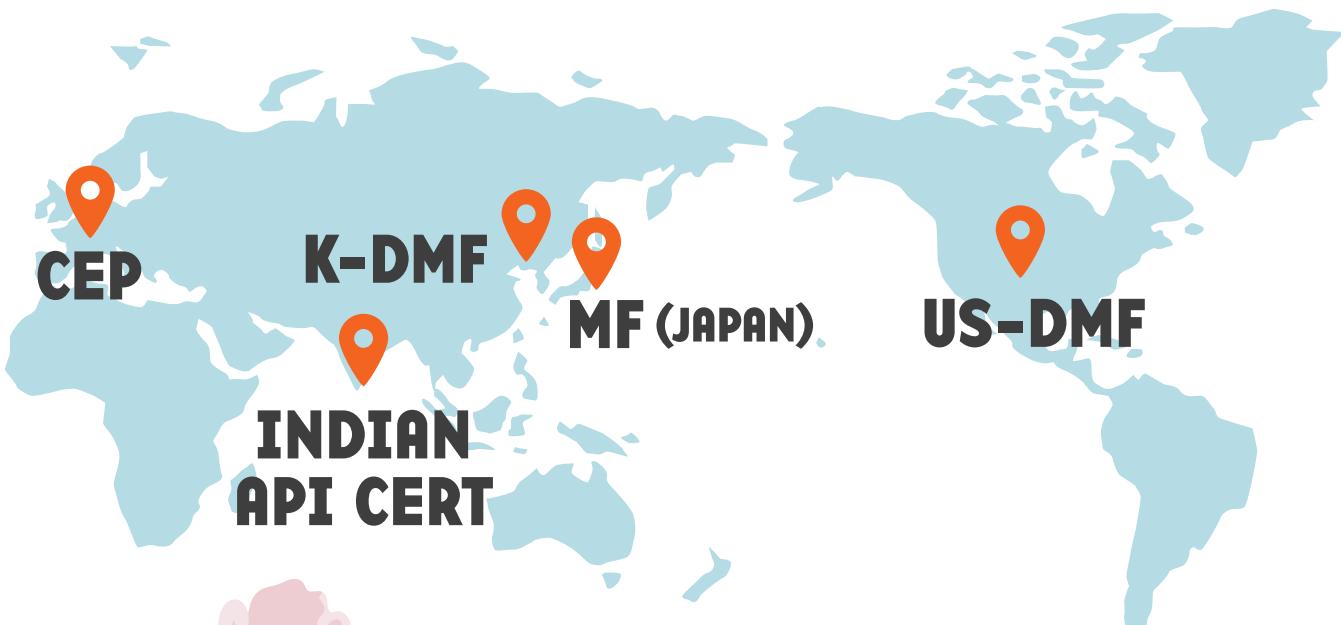
For Pharmaceutical & Medical Device

Product Name	SODIUM HYALURONATE (API/EXCIPIENT)				
	Pharma Grade 80	GS-40	GS-100	GS-200	GS-300
Intrinsic Viscosity (m <sup>3</sup> /kg)	1.20-2.00	0.39-0.99	1.00-2.49	2.50-3.31	3.32-4.60
Shelf Life	3 Years*			1.5 Years*	3 Years*
Storage Conditions	2 to 8°C			-15 to -25°C	
Packaging	100g	100g, 200g		100g	
Endotoxin (EU/mg)	Less than 0.0025**	Less than 0.04**		Not more than 0.05**	

\* The shelf life is based on the normal manufacturing I.V. of each grade.

\*\* EP standard is less than 0.05(EU/mg).

## INTERNATIONAL REGULATIONS



# CERTIFICATIONS

許可番号	12AZ200052	
医薬品製造業許可証		
氏名又は名称	キッコーマンバイオケミファ株式会社鶴川工場	
製造所の名称	キッコーマンバイオケミファ株式会社鶴川工場	
製造所の所在地	千葉県鶴川市興津 1600番地	
許可の区分	医薬品無菌医薬品 医薬品一般	
医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第15条第1項の規定により許可された医薬品製造業者であることを証明する。		
令和3年3月19日		
千葉県知事	金子木	栄治
有効期間	令和3年4月11日から 令和8年4月10日まで	

## Manufacturing Approval in Japan

DRUG MASTER FILE  
Type II

US-DMF

<p style="text-align: center;"><b>Certification of Substances Department</b></p> <p style="text-align: center;"><b>Certificate of suitability</b></p> <p style="text-align: center;"><b>No. RO-CEP 2016-247 Rev 00</b></p>	
<p>1 Name of the substance: <b>SODIUM HYALURONATE</b></p> <p>2 Grade: 80; Viscosity: 1.70 mPa·s; from fermentation; for parenteral administration, including intraocular use</p> <p>3 Name of the manufacturer: <b>EDISONIA BIOCHEMIA COMPANY</b></p> <p>4 250 Noda 5 250 Noda 6 250 Noda 7 250 Noda 8 250 Noda 9 250 Noda 10 SEE ANNEX 1</p> <p>11 After assessment of the information provided on the manufacturing method and subsequent promises (including promises) for the substance on the sketch of production listed in Annex, we certify that the quality of the substance is controlled by the current version of the European Pharmacopoeia (Ph. Eur.) and the Japanese Pharmacopoeia (Ph. Jpn.) including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedures given in Annex.</p> <p>12 – Test for residual solvents by gas chromatography (Annex 2)</p> <p>13 Ethanol not more than 0.5%</p> <p>14 No elemental impurity classified in I (IC1 Q3D) is intentionally introduced in the manufacture of the substance.</p> <p>15 The re-test period of the substance is 6 months if stored at a temperature between 2°C and 8°C in a plastic bottle placed in a polyethylene bag.</p> <p>16 The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.</p> <p>17 Compliance with the statements of the Production Section of the monograph to be considered in the content of a medicinal product containing this substance.</p> <p>18 The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.</p>	
<p style="text-align: center;">Address: 47000 Noda, Chiba 290-0036 Tel: +81 (3) 384 81 30 80 ~ +81 (3) 384 81 30 80 ~ e-mail: cep@edisonia.jp Internet: <a href="http://www.edisonia.jp">http://www.edisonia.jp</a></p>	

CEP

## K-DMF

File No.: (W)90000007  
**GOVERNMENT OF INDIA**  
 Central Drugs Standard Control Organisation  
 Ministry of Health & Family Welfare  
 FDA BHAWAN, NEW DELHI (INDIA)

Form 41  
 (See Rule 27-A)

**REGISTRATION CERTIFICATE**

**REGISTRATION CERTIFICATE TO BE ISSUED FOR IMPORT OF DRUGS INTO INDIA UNDER DRUGS AND COSMETICS RULES 1945**

**Registration Certificate No. RC/BD-002305**

1. M/s. KIKKOMAN BIOCHEMICA COMPANY, Kanegawa Plant, 1600 Kainaka, Kamogawa-shi, Chiba Kamogawa - 2960048 Chiba (Japan) having factory premises at M/s. Kikkoman Biochemica Company, 1600 Kainaka, Kamogawa-shi, Chiba (Japan) and M/s. Kikkoman Biochemica Company (Manufacturing Site Bunkyo Release Site) has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.

2. Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs):

3. This Registration Certificate shall be in force from 19-February-2019 to 18-February-2022 unless it is sooner suspended or cancelled under the rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorized agent in India, M/s. YASHODA SPECIALITY INGREDIENTS PVT. LTD, Building No. 5, Gali No. 30-31, Parbat Compound, Pala Pada, Maski (Anjan-Rao Bhawan), Maharashtra, Bhivdwar, The 421302 (India) who will be responsible for the business activities of the manufacturer in India in all respects.

5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.

COSCO (Central Organisation for Standardisation, Control and Certification of Drugs and Cosmetics)

S. ESWARA  
 REDDY  
 LICENSING AUTHORITY  
 COSCO

Place: New Delhi  
 Date: 01 May 2019

Indian API Cert

HALAL



Kikkoman Biochemifa Company <https://biochemifa.kikkoman.com/e/>

2-1-1 Nishi-shinbashi, Minato-Ku, Tokyo, 105-0003 Tel +81-3-5521-5481 Fax +81-3-5521-5498



2023.07h