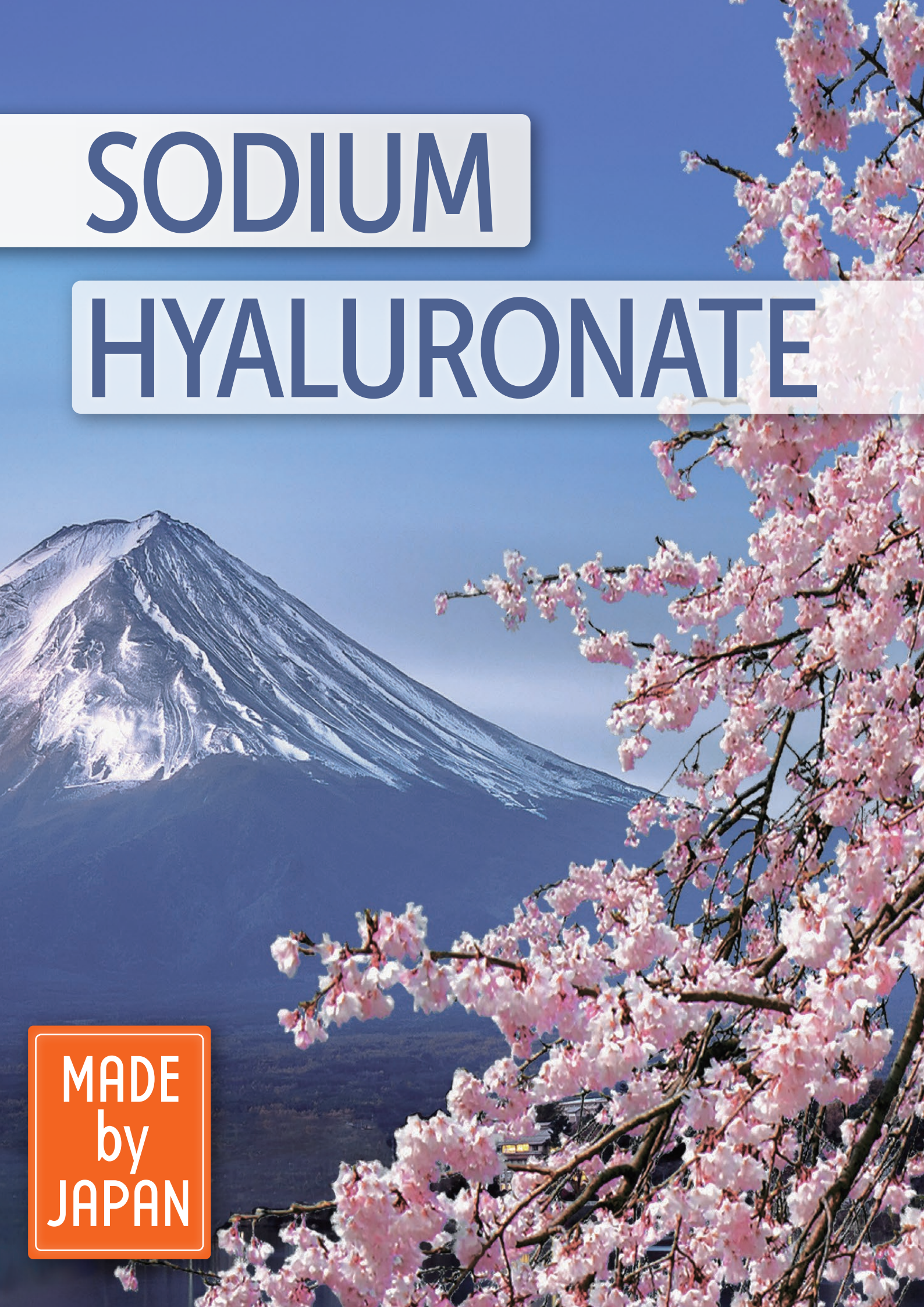
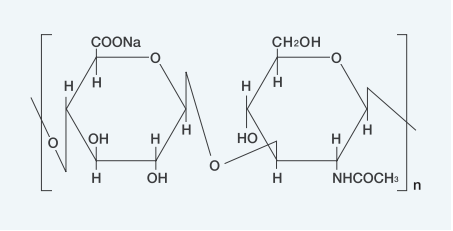

SODIUM
HYALURONATE
MADE
by
JAPAN

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.

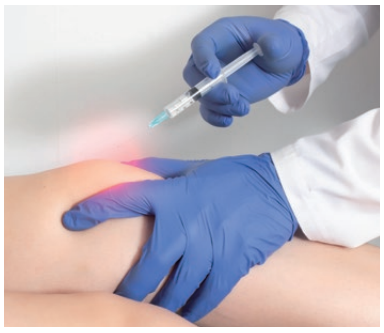
Fermented by "*Streptococcus zooepidemicus*".

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.

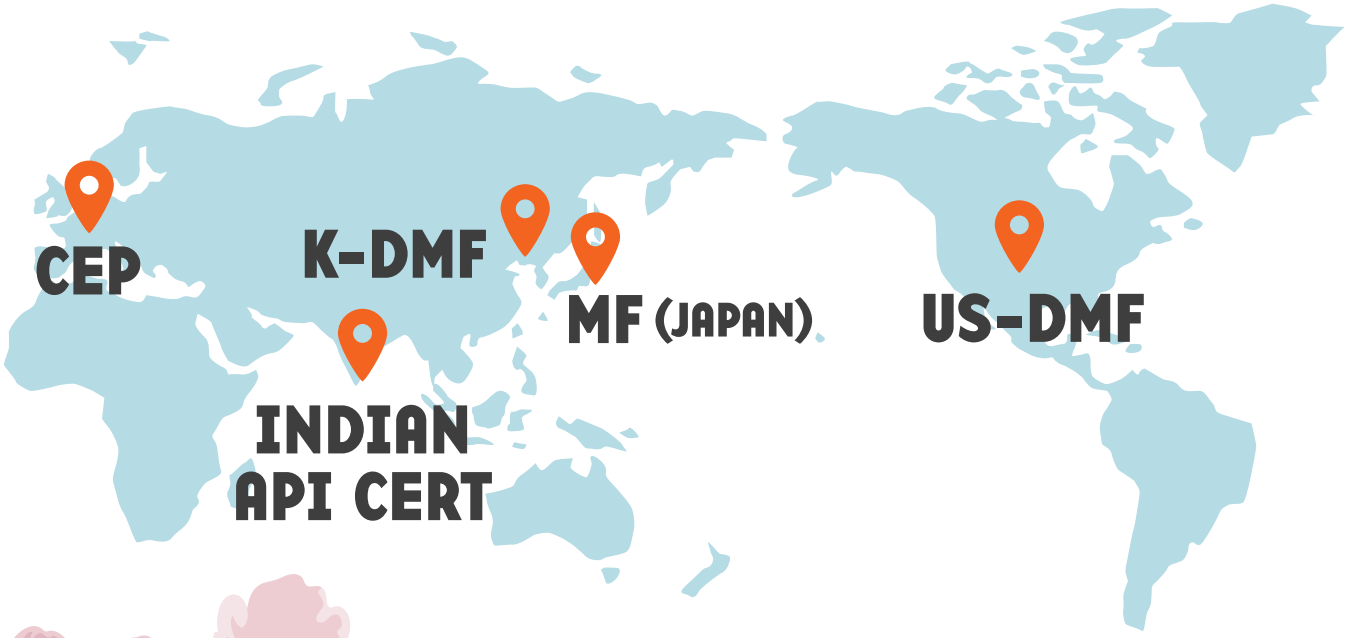
PRODUCT LINEUP

For Pharmaceutical & Medical Device

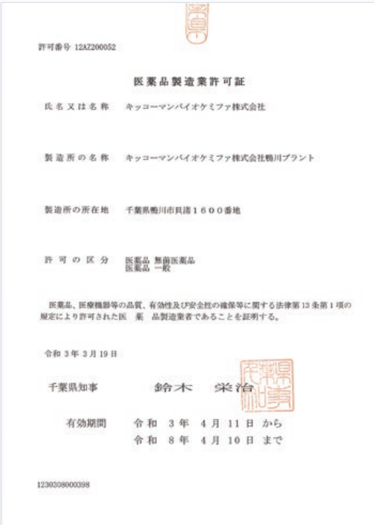
Product Name	SODIUM HYALURONATE (API/EXCIPIENT)				
	Pharma Grade 80	GS-40	GS-100	GS-200	GS-300
Intrinsic Viscosity (m^3/kg)	1.20–2.00	0.39–0.99	1.00–2.49	2.50–3.31	3.32–4.60
Shelf Life	3 Years★			1.5 Years★	3 Years★
Storage Conditions	2 to 8℃				-15 to -25℃
Packaging	100g	100g, 200g			100g
Endotoxin (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 standerd 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

製造所の名称　キッコーマンバイオケミファ株式会社鴨川プラント

製造所の所在地　千葉県鴨川市貝渚１６００番地

許可の区分　医薬品 無菌医薬品 医薬品 一般

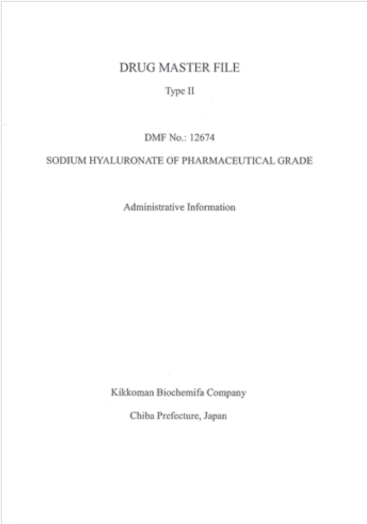
医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第13条第1項の規定により許可された医薬品製造業者であることを証明する。

令和3年3月19日

千葉県知事　鈴木　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

DMF No.: 12674

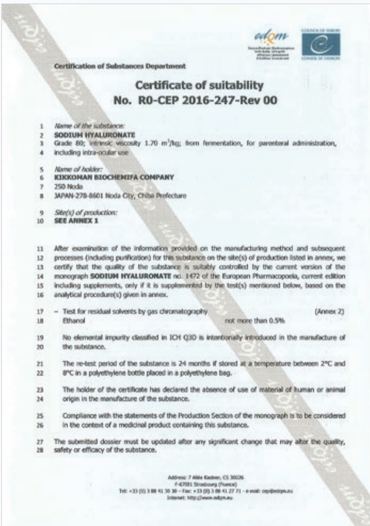
SODIUM HYALURONATE OF PHARMACEUTICAL GRADE

Administrative Information

Kikkoman Biochemifa Company

Chiba Prefecture, Japan

US-DMF



Certification of Substances Department

Certificate of suitability

No. R0-CEP 2016-247-Rev 00

CEP

원료의약품 등록증

K-DMF

GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation

Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

Form 41

REGISTRATION CERTIFICATE

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

Indian API Cert

شهادة الحلال

ハラール証明書

HALAL CERTIFICATE

Kikkoman Biochemifa Company

June 28, 2023

June 28, 2024

HALAL

kikkoman

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