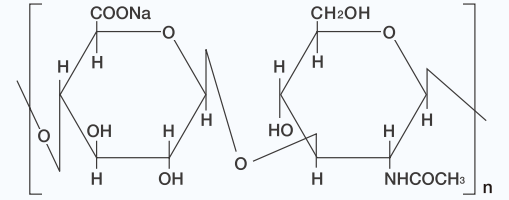


SODIUM HYALURONATE

SODIUM HYALURONATE



1 SUPER PURIFIED SODIUM HYALURONATE MADE IN JAPAN

———— All the manufacturing process is in Japan

2 MICROBIAL FERMENTATION AND NON-ANIMAL ORIGIN

———— Fermented from "*Streptococcus zooepidemicus*"

3 STERILE GRADE AVAILABLE AND HALAL CERTIFICATION

———— "Only one" technology



Applications

ARTHRITIS

Osteoarthritis
Rheumatoid arthritis
Bone regeneration
Viscosupplementation



DERMAL FILLER

Filling out wrinkles and lines
Body contouring
Lip plumping



OTHERS

Medical Device Coating
Post surgical device (anti-adhesion)
Wound dressing
Skin preparation for external use
Topical skin application
Vesicoureteral and reflux

OPHTHALMOLOGY

Ophthalmic Viscoelastic Device (OVD)
Cataract
Intraocular Lens (IOL)
Eye Drop
Contact lens solution



Product Line up

Product Name	SODIUM HYALURONATE			
	GS	Pharma Grade 80	Pharma Grade 150	FCH-80LE
Intrinsic Viscosity (m ³ /kg)	0.39 - 3.31	1.2 - 2.0	2.1 - 2.8	1.18 - 1.95
Average Molecular Weight (Mil.Da)	0.15 - 2.12	0.63 - 1.21	1.28 - 1.86	0.60 - 1.20
Endotoxin (IU/mg)	0.040	0.0025	0.040	0.003
Shelf Life	1.5 Years*	3 Years	1 Year	3 Years
Regulatory	US DMF**	CEP, US DMF	US DMF	J-DMF, K-DMF Indian API Cert
Packaging	100g	10g, 100g	10g, 100g	100g
Sterile/ Bioburden	Bioburden	Bioburden	Bioburden	Sterile

GQP contract is available within this range.

*To be reviewed after current long-term stability test is completed. (Max : 3 years) **Under processing.

International Standard & Regulatories

• GMP (ICH - Q7)	• EP Official Standard
• US DMF	• JP Official Standard
• CEP	• ISO9001
• J-DMF	• ISO14001
• K-DMF	• OHSAS 18001
• Indian API Cert	• SEDEX



Certifications

원료의약품 등록증

제출일: 2018.02.29 13:42 / 접수일: 2018.11.1 / 등록일: 2018.11.3 / 유효기간: 10년

20180202-99-9-107-02

제출인: Kikkoman Biochemifa Company (Kangawa Plant)
소재소: 1900, Kanagawa, Japan 236-0904, Japan
등록번호: K1310 / **제출인명:** Kikkoman Co., Ltd.
등록인명: Kikkoman Biochemifa Company (Kangawa Plant) / **등록인명:** Kikkoman Co., Ltd.

성분: 1. 정제된 유당 (정제된 유당) 2. 정제된 유당 (정제된 유당) 3. 정제된 유당 (정제된 유당) 4. 정제된 유당 (정제된 유당) 5. 정제된 유당 (정제된 유당) 6. 정제된 유당 (정제된 유당) 7. 정제된 유당 (정제된 유당) 8. 정제된 유당 (정제된 유당) 9. 정제된 유당 (정제된 유당) 10. 정제된 유당 (정제된 유당)

식품의약품안전처

K-DMF

Certification of Substances Department
Certificate of suitability
No. RO-CEP 2016-247-Rev 00

1. Name of the substance:
SODIUM HYALURONATE
 Grade: 90; viscosity: 1.20 m/kg, from fermentation, for parenteral administration, including intra-ocular use
 2. Name of holder:
KIKKOMAN BIOCHEMIFA COMPANY
 7 250 Noda
JAPAN-278-8601 Noda City, Chiba Prefecture
 3. Shelf of production:
SEE ANNEX 1

11. After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **SODIUM HYALURONATE** no. 1472 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.
 12. - Test for residual solvents by gas chromatography (Annex 2)
 Ethanol not more than 0.5%
 13. No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of the substance.
 14. The re-kept period of the substance is 24 months if stored at a temperature between 2°C and 8°C in a polyethylene bottle placed in a polyethylene bag.
 15. The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.
 16. Compliance with the statements of the Production Section of the monograph is to be considered in the context of a medicinal product containing this substance.
 17. The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Address: 7-250 Noda, Chiba 278-8601, Japan
 Tel: +81 (0) 476 95 30 30 / Fax: +81 (0) 476 95 17 71 / e-mail: cep@kikkoman.com
 Internet: www.kikkoman.com

CEP

DRUG MASTER FILE
 Type II

DMF No.: 12674

SODIUM HYALURONATE OF PHARMACEUTICAL GRADE

Administrative Information

Kikkoman Biochemifa Company
 Chiba Prefecture, Japan

US-DMF

معتمد المركز العربي
شهادة الحلال
HALAL CERTIFICATE

No.: 127-TSR118 / رقم
 (Page 1 / 1)

بعد فحص معهد دراسات الشريعة بجامعة توكيو لتوكيو المنتجات المذكورة أعلاه بصفتهم كشعبه جمعيه مسلميه الدين بانها لا توجد فيها المحرمات من الشريعة الإسلامية.
 After investigation of the below mentioned product at its factory by Shariat Research Institute of Tokyo University (JAPAN MUSLIM ASSOCIATION) certifies the whole product as HALAL and this item is not forbidden under the Shariah (Islamic Law).

Pharmaceutical and Medical Device Ingredient
 (Oral Solution, Eye Solution, Eye Drops)

製成品名 / Name of Product: **ハラル 注射薬** / اسم المنتج
 (原薬 H.A. Sodium Hyaluronate Pharma Grade)
 1. 7%溶液 FCH-80LE SODIUM HYALURONATE FCH-80LE
 2. Sodium Hyaluronate Pharma Grade 90
 3. Sodium Hyaluronate Pharma Grade 150

会社名 / Name and Address of Company: **Kikkoman Biochemifa Company**, 2-1-1, Nishi-shinbashi, Minato-ku, Tokyo, Japan
 製造工場名 / Name and Address of Plant: **Kikkoman Biochemifa Company, Kanagawa Plant**, 1900, Kanagawa, Kanagawa City, Chiba Pref., Japan
 発行日 / Issued on: **June 28, 2018**
 有効期限 / Valid until: **June 28, 2019**

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 2-1-1, Rokubunji, Hajime-ku, Tokyo, 112-8553, Japan
 Tel: +81 3 5521 5481 / Fax: +81 3 5521 5498

HALAL

許可番号 1247200052

医薬品製造業許可証

氏名又は名称: **カッコーマンバイオケミファ株式会社**

製造者の名称: **カッコーマンバイオケミファ株式会社川口プラント**

製造所の所在地: **千葉県鴨川市貝須1600番地**

許可の区分: **医薬品 薬品医薬品**
医薬品 薬品

医薬品、医薬機器等の品質、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。

平成28年3月4日

千葉県知事 **鈴木 栄彦**

有効期間 **平成28年4月11日から平成33年4月10日まで**

1222898000522

Manufacturing Approval in Japan



Kikkoman Biochemifa Company <http://biochemifa.kikkoman.co.jp/e>
 2-1-1 Nishi-shinbashi, Minato-Ku, Tokyo, 105-0003 Tel +81-3-5521-5481 Fax +81-3-5521-5498