TOPSCIENCE众山

MEDIHYA

Medical Device Grade Sodium Hyaluronate

Master Files Registration Number:
M2022071-000, M2022107-000, M2024075-000, etc.(Totaling Nine)

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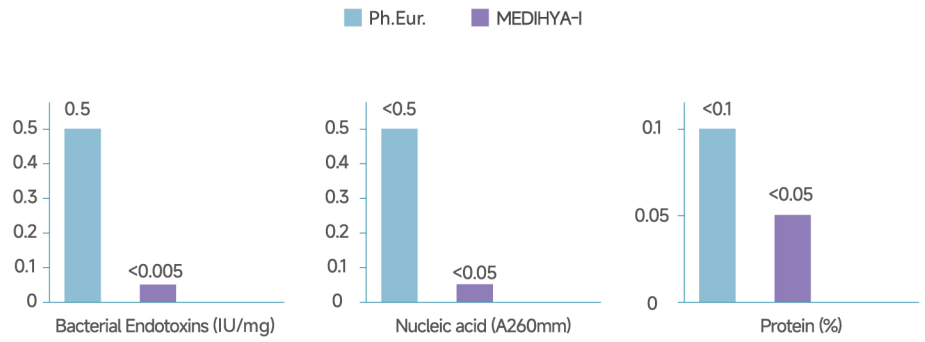
PRODUCT MESSAGE

	MEDIHYA-I	MEDIHYA-M	MEDIHYA-S	MEDIHYA-T
Description	Medical Device Grade I Sodium Hyaluronate	Medical Device Grade M Sodium Hyaluronate	Medical Device Grade S Sodium Hyaluronate	Medical Device Grade T Sodium Hyaluronate
Intrinsic Viscosity	0.2~4.0 m^3/kg	0.2~4.0 m^3/kg	0.2~4.0 m^3/kg	0.03 ~ 3.5 m^3/kg
Specification	• Tested according to the latest edition of the Ph. Eur. • Bacterial endotoxins <0.015 IU/mg • Pass sterility test	• Tested according to the latest edition of the Ph. Eur. • Bacterial endotoxins <0.05 IU/mg	• Tested according to the latest edition of the Ph. Eur. • Bacterial endotoxins <0.5 IU/mg	• Tested according to the latest edition of the Ph. Eur.
Application	Suitable for medical device of class II and Class III	Suitable for medical device of class II and Class III	Suitable for medical device of class II	Suitable for medical device of external application
GMP	Written Confirmation	Written Confirmation	Written Confirmation	——

QUALITY & SPECIALITY



Quality of MEDIHYA series has been controlled strictly by high standards and requirements. Key indicators Bacterial Endotoxin can be controlled at a minimum of ≤0.005IU/mg, Nucleic Acid and Protein content can be controlled at a minimum of ≤0.05 and <0.05%.

EFFICACY STUDY

Safety Tests

Test project	Pyrogen test	Cytotoxicity test
Conclusion	No pyrogenicity	No potential cytotoxicity
Test project	Skin sensitization test	Acute systemic toxicity test
Conclusion	No obvious sensitization reaction observed	No obvious acute systemic toxicity observed

Efficacy Tests

Topscience Biotech has also completed efficacy experiments on **"Product Impermeability Absorption Effect Experiment"** and **"Wound Impermeability Effect Experiment"**, which fully comply with the requirements of the "Announcement on the Categories Management of Medical Sodium Hyaluronate Products(No. 103 of 2022)", that when Sodium Hyaluronate is applied as medical dressings, it cannot be absorbed by the human body and used for non-chronic wounds. Medical dressings are managed according to Medical Device Class II.

PACKAGE AND STORAGE

1. 50g/bottle, 100g/bottle, 100g/bag, 1kg/bag, pharmaceutical glass bottle, low-density polyethylene (LDPE) bag+Aluminiu m foil bag
2. In an airtight container, protected from light and humidity, 2-8°C.