



# MEDIHYA

## Medical Device Grade Sodium Hyaluronate

Master Files Registration Number:  
M2022071-000, M2022107-000, M2024075-000, M2024098-000

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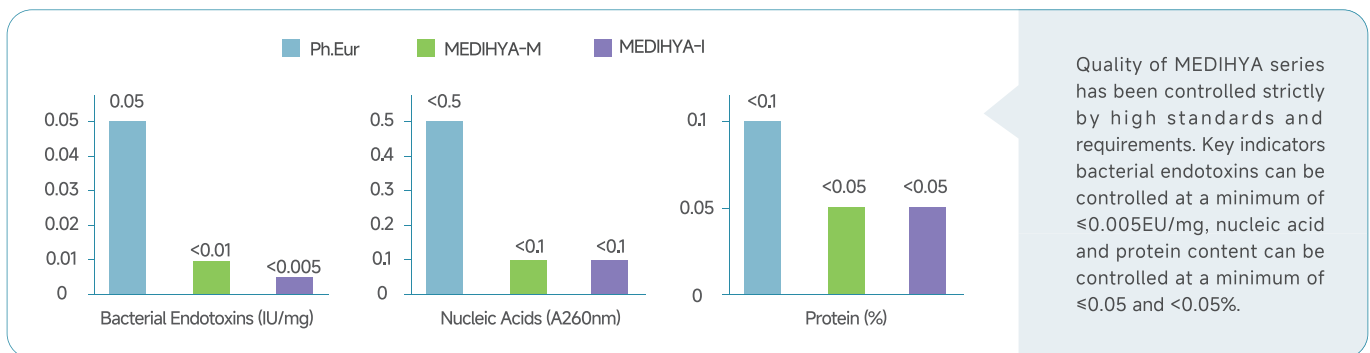


## PRODUCT MESSAGE

	MEDIHYA-I	MEDIHYA-M	MEDIHYA-S	MEDIHYA-T
<b>Description</b>	Medical Device I Grade Sodium Hyaluronate	Medical Device M Grade Sodium Hyaluronate	Medical Device S Grade Sodium Hyaluronate	Medical Device T Grade Sodium Hyaluronate
<b>Intrinsic Viscosity</b>	0.2~4.0 m <sup>3</sup> /kg	0.2~4.0 m <sup>3</sup> /kg	0.2~4.0 m <sup>3</sup> /kg	0.2~4.0 m <sup>3</sup> /kg
<b>Specification</b>	<ul style="list-style-type: none"><li>• Tested according to the latest edition of the Ph. Eur.</li><li>• Bacterial endotoxins &lt;0.005EU/mg</li><li>• Pass sterility test</li></ul>	<ul style="list-style-type: none"><li>• Tested according to the latest edition of the Ph. Eur.</li><li>• Bacterial endotoxins &lt;0.01 EU/mg</li></ul>	<ul style="list-style-type: none"><li>• Tested according to the latest edition of the Ph. Eur.</li><li>• Bacterial endotoxins &lt;0.05 EU/mg</li></ul>	<ul style="list-style-type: none"><li>• Tested according to the latest edition of the Ph. Eur.</li></ul>
<b>Application</b>	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
<b>GMP</b>	Written Confirmation	Written Confirmation	Written Confirmation	—



## QUALITY & SPECIALITY



## EFFICACY STUDY

### Safety Tests

<b>Test project</b>	Test for Pyrogen	Test for In Vitro Cytotoxicity	Test for Skin Sensitization
<b>Conclusion</b>	No pyrogenicity	No potential cytotoxicity	No obvious sensitization reaction observed
<b>Test project</b>	Test for Genotoxicity: In Vitro Mouse Lymphoma tk Assay	Test for Acute Systemic Toxicity	Bacterial Reverse Mutation (Ames) Study
<b>Conclusion</b>	The results were negative	No obvious acute systemic toxicity observed	The vehicle and positive controls performed as anticipated

### 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+Aluminium foil bag.
2. In an airtight container, protected from light and humidity, 2-8°C.