TOPSCIENCE众山

Medical Grade Chondroitin Sulfate Sodium

Material Submission Code:
005707-00507-7063

Master Files Registration Number:
M2024112-000

SHANDONG TOPSCIENCE BIOTECH CO., LTD.

Address: #98 Lanshan West Road, Lanshan District, Rizhao, Shandong, China

Tel: +86-532-80821298

E-mail: sales@topscience.cn

Website: www.topscience.cn

QINGDAO TRONGEN BIOTECH CO., LTD.

Address: #330 Songling Road, Laoshan District, Qingdao, Shandong, China

Tel: +86-532-80821298

E-mail: sales@trongenbio.com

Website: www.topscience.cn

MOLECULAR FORMULA: $H(C_{14}H_{19}NNa_2O_{14}S)_xOH$

SOLUBILITY: Soluble in water

RECOMMENDED DOSAGE: 0.1%~4%

PRODUCT ADVANTAGES

Fish Source: Utilizes pharmaceutical-grade chondroitin sulfate sodium extracted from shark cartilage, which is highly compatible with the human body, resulting in low adverse reactions and easy absorption.

Enzymatic Hydrolysis Technology: Employing proprietary enzymes for hydrolysis, which is harmless to the human body and effectively removes excess protein while preserving product activity.

Ultrafiltration Technology: Significantly removes protein, impurities, and heavy metals from the hydrolyzed protein, thus purifying chondroitin sulfate sodium.

Precipitation Technology: Utilizes complex precipitation techniques to eliminate residual protein and impurities, resulting in a high product purity (≥98.0%), exceeding pharmacopeia standards.

Protein: Protein Content ≤0.1%, significantly lower than the standards of Ph.Eur. (≤3.0%) and USP (≤6.0%).

PRODUCT SPECIFICATIONS

Items	Specifications	Methods
Appearance	White or almost white powder	Visualization
Visible particles	There should be no obvious foreign objects detected during the inspection of visible particles	ChP
Identification A. Infrared absorption B. Reaction(b) of sodium	Complies with Ph.Eur. reference spectrum of sodium chondroitin sulfate sodium (marine) CRS Positive	Ph.Eur.
pH	5.5~7.5	Ph.Eur.
Specific optical rotation	-12~-19 (dried substance)	Ph.Eur.
Clarity and color of solution	A_{420nm}≤0.35	USP
Related substances	Any secondary band in the electropherogram obtained with the test solution is not more intense than the band in the electropherogram obtained with reference solution(b)(≤2%)	Ph.Eur.
Protein	≤0.1% (dried substance)	In house
Chlorides	≤0.1%	ChP
Sulfates	≤0.24%	ChP
Residue on ignition	20.0%~30.0% (dried substance)	ChP
Heavy metals	≤20 ppm	ChP
Loss on drying	≤12.0%	Ph.Eur.
Assay	≥98.0% (dried substance)	Ph.Eur.
Residual solvents: Ethanol	≤0.5%	In house
Bacterial endotoxins	<0.05 EU/mg	ChP

APPLICATIONS

Suitable for class II and III medical devices in the medical field.

PACKAGE AND STORAGE

1. 100g/bottle, 1kg/bag; inner packaging is either DURAN glass bottles or pharmaceutical-grade low-density polyethylene bags with aluminum foil lining.

2. In an airtight container, protected from light and humidity, 2-8°C.