



TOPSCIENCE 众山



Medical Device Grade Chondroitin Sulfate Sodium

Material Submission Code:
005707-00507-7063

Master Files Registration Number:
M2024112-000, M2024308-000, M2024310-000

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

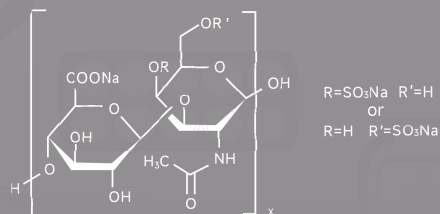
Tel: +86-532-80821298

E-mail: sales@trongenbio.com

Website: www.topscience.cn



INCI NAME: CHONDROITIN SULFATE SODIUM
MOLECULAR FORMULA: $H(C_{14}H_{19}NNa_2O_{14}S)_xOH$
RECOMMENDED DOSAGE: 0.1%~4%
SOLUBILITY: SOLUBLE IN WATER



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 ($\geq 98.0\%$), exceeding pharmacopeia standards.



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

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 | $A_{420nm} \leq 0.35$ | 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) ($\leq 2\%$) | Ph.Eur. |
| Protein | $\leq 0.1\%$ (dried substance) | In house |
| Chlorides | $\leq 0.1\%$ | ChP |
| Sulfates | $\leq 0.24\%$ | ChP |
| Residue on ignition | 20.0%~30.0% (dried substance) | ChP |
| Heavy metals | ≤ 20 ppm | Ph.Eur. |
| Loss on drying | $\leq 12.0\%$ | Ph.Eur. |
| Assay | $\geq 98.0\%$ (dried substance) | Ph.Eur. |
| Residual solvents: Ethanol | $\leq 0.5\%$ | 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

- 100g/bottle, 1kg/bag; inner packaging is either DURAN glass bottles or pharmaceutical-grade low-density polyethylene bags with aluminum foil lining.
- In an airtight container, protected from light and humidity, 2~8°C.