



Medical Device Grade Chondroitin Sulfate Sodium

Material Submission Code:
005707-00507-7063

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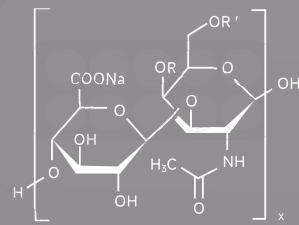


INCI NAME: CHONDROITIN SULFATE SODIUM

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

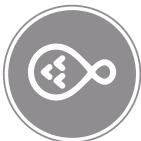
RECOMMENDED DOSAGE: 0.1%~4%

SOLUBILITY: SOLUBLE IN WATER



$R=SO_3Na$ $R'=H$
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PRODUCT ADVANTAGE



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 the 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 SPECIFICATION

| 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 | Complies with Ph.Eur. reference spectrum of sodium chondroitin sulfate sodium (marine) CRS Positive | Ph.Eur. |
| B. Reaction(b) of sodium | | |
| 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 | 20.00%~30.00% (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 |

APPLICATION

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.