

PHARMACEUTICAL CHONDROITIN SULFATE PH. EUR.

ABOUT

ScanDroitin™ Chondroitin Sulfate, Ph.Eur. is a natural and pure choice for the sourcing of top-quality ingredients in your finished formulations. Pharmaceutical grade chondroitin sulfate by ZPD is strictly manufactured under Good Manufacturing Practice (GMP) and without the use of organic solvents.

ZPD support you with technical expertise and competences until your registration is fully completed.

ScanDroitin™

FEATURES AND OVERVIEW

- Suitable for pharmaceuticals, animal nutrition ingredients and technical applications
- DMF AP & RP available
- Recommended serving 800 - 1200 mg daily

Purity:

95 % - 105 %

Sample size:

50 grams

Retest:

36 Months

Pharmacopeia:European Pharmacopeia
Version 11**Origins available:**

Bovine

Packaging:25 Kg double PE bags in
fiber drum**MOQ:**

25 Kg

Physical appearance:White or almost white
hygroscopic powder

CERTIFICATES

- Accreditation certificate of foreign drug manufacturer in Japan
- Certificate of GMP compliance of a manufacturer
- European food authorization in accordance to EC/853/2004
- FDA Certificate of Registration
- Registration of feed company in accordance to EC/183/2005

SERVICES

- Full traceability
- Manufactured without the use of organic solvents
- Direct compressibility
- Customized solutions
- Enhanced support for product registration
- Readily available stock services

Chondroitin sulfate is a natural substance extracted only from animal sources. It is subject to multiple purification processes to obtain a pharmacopeia-determined purity of the CS molecule. Achieving high purity levels begins with the sourcing of uncontaminated animal cartilage, which is paramount to making sure the quality is also consistently high.

Raw materials

At ZPD A/S only raw materials of the highest quality are accepted for use in the production of chondroitin sulfate. All bovine material are stated BSE free and much time is spent on sourcing and selecting the best possible material for the extraction process.

Consistent production quality

From our production, ZPD A/S values consistently high quality in order to provide the finest possible chondroitin sulfate for our clients. Extraordinary analyses have been made to establish e.g. the consistency of the products produced (intern data). Figure 1 illustrates the general content of chondroitin sulfate of five different commercial batches of our bovine, chondroitin sulfate ph. eur. product, analyzed by three separate, highly specific methods of analysis compared to a European standard.

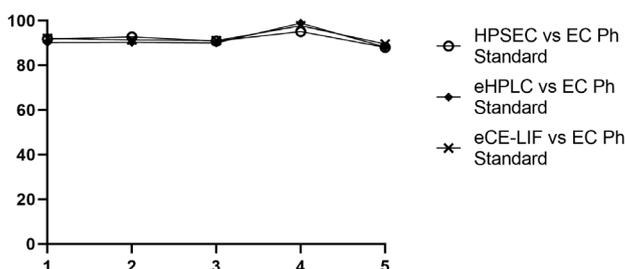


Figure 1 Percentage content of chondroitin sulfate: This simple, graphical illustration represents the percentage content of chondroitin sulfate found in five commercial batches of bovine chondroitin sulfate ph. eur.

Product purity

Chondroitin sulfate from ZPD A/S as minimum live up to standards of pharmacopeia. Additionally, steps have been taken towards exploration of natural related substances such as keratan sulfate, dermatan sulfate and heparan sulfate, whose presence may influence quality and functional capacity of the product¹.

Commercial chondroitin sulfate products of bovine origin were externally analyzed by specific analyses.

As seen from analysis results in Table 1, only trace amounts of these related substances were found in the product, supporting the high production and product standards.

References

1. Volpi, N., (2019), Chondroitin Sulfate Safety and Quality, Molecules, 24, 1447

EXPERT OPINION

“Chondroitin Sulfate from ZPD has been rigorously tested to be of very high quality. Based on my findings for purity and consistency, it is without doubt product of very high standard, with zero-to-very-low naturally related substances and artificial pollution, which are not detectable in general monographs for Chondroitin Sulfate (i.e. Keratan sulfate, Dermatan sulfate, Heparan sulfate, Hyaluronic acid and Nucleic acids). The related substances are naturally occurring in the raw material and it is mainly efficient sourcing and comprehensive production process, that control the level of unwanted molecules.

ZPD has shown to successfully produce Chondroitin Sulfate of very high purity, consistency and safety.”

Prof. Nicola Volpi, PhD

Table 1 Related substances: Chondroitin sulfate of bovine origin was analyzed for potential content of natural related substances, co-purified from the raw material. As seen from the contents found, only trace amounts of each was found, adding to the quality of the product.

Related Substances	Trace Amount
Keratan sulfate	< 0.1% w/w
Dermatan sulfate	< 1.0% w/w
Heparan sulfate	< 0.1% w/w
Hyaluronic acid	< 0.5% w/w