

BEST PRACTICES ON CHONDROITIN QUALITY IN A GLOBALIZED SUPPLY CHAIN: QUALITY REGIMES, STANDARDS, AND METHODOLOGIES

Jana B. Hildreth¹, Nicola Volpi², Weiguo Zhang¹, Hellen A. Oketch-Rabah³

¹Synutra Pure, Ltd., Rockville, MD, USA, ²University of Modena, Modena, Italy, ³United States Pharmacopeia, Rockville, MD, USA

ABSTRACT

There is modest clinical evidence supporting the safe use of Chondroitin Sulfate (CS) for pain management in arthritis patients. (Singh *et al.*, 2015) In the United States CS is used as a dietary ingredient in dietary supplements intended to support joint health, while in the European Union countries CS is included in treatment regimens for osteoarthritis pain management. Accordingly the United States Pharmacopeia has set CS quality standard for dietary supplement grade CS, while the European Pharmacopoeia's quality standard are for pharmaceutical grade chondroitin sulfate. It has been reported that specific activity of CS depends on the quality: such as chondroitin sulfate structure and properties that determine its bioavailability and efficacy. (Volpi, 2009) Thus CS quality affects therapeutic utility of commercial preparations, particularly products manufactured to meet pharmaceutical standards versus products manufactured to meet food grade standards (dietary supplements). In this poster we discuss various testing methods available that can be used to establish identity, purity, strength, composition and limit of contaminants of CS. To ensure high quality and purity of CS material, we recommend the use of compendial CS standards with complementary analytical procedures as well as adherence to proper quality systems, good laboratory practices and training. These practices will ensure that only high quality CS is used in medicines and dietary supplements so that patients and consumers can benefit appropriately.

References:

- Singh, J. A., Noorbaloochi, S., MacDonald, R. and Maxwell, L. J. (2015) Chondroitin for osteoarthritis. The Cochrane database of systematic reviews, 1, CD005614.
- Volpi, N. (2009) Quality of different chondroitin sulfate preparations in relation to their therapeutic activity. Journal of pharmacy and pharmacology, 61, 1271-1280.