PRODUCT SPECIFICATION SHEET

Uracyst®

(Sterile Sodium Chondroitin Sulfate Solution 2.0%)

Format: 4x20mL in Glass Vial, 1x20mL in a glass vial

Device Description:

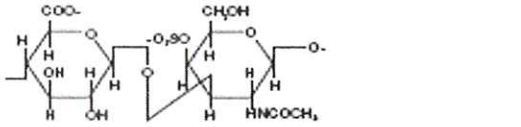
Uracyst® is a 2.0% sterile solution of a highly purified sodium chondroitin sulfate molecule, a natural copolymer based on two disaccharides. It is pH neutral in a phosphate buffered saline solution.

Device Classification:

Class III – in Europe
Class IV – in Canada

Chemical Structure:

Chondroitin is an acidic mucopolysaccharide and is one of the glycosaminoglycans (GAGs). Its repeating disaccharide unit is made of a glucuronic acid and a galactosamine with one sulfate group in ß (1-3') linkage.



Glucuronic acid N-acetyl galactosamine sulfate

Physical and Chemical Parameters:

TEST AND METHOD	SPECIFICATION
Appearance (Visual)	**Clear, colourless to slightly yellow, slightly viscous liquid**
Identification (Sodium Chondroitin by IR (based on USP/EP))	**Presence of major peak for sodium chondroitin**
pH (based on USP)	**7.0 – 7.5**
Osmolality (based on USP)	**270 - 350 mOsm/kg**
Sodium Chloride Content (based on USP – Sodium Chloride Assay)	**7.0 - 8.0 mg/mL**
Net Content (Current USP <698>)	**Average content of 10 vials NLT 20.0 mL**
Assay (TM-609650)	**90.0 – 110.0 % of label claim**

Microbiological Parameters:

TEST AND METHOD	SPECIFICATION
Particulate Matter (Current USP <788>, EP <2.9.19>)	**>= 10 um: NMT 6000 per container**
	>= 25 um: NMT 600 per container
Bacterial Endotoxin Test (Current USP <85>, EP <2.6.14>)	**≤ 8.4 EU/mL**
Sterility (Current USP <71>, EP <2.6.1>)	**No growth - Meets USP / EP requirements**

Storage Conditions:

Store at 2 – 25 ° C. **DO NOT FREEZE.**

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Shelf Life:

36 Months

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