



# Qingdao Wantuming Biological Products Co., Ltd

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## CERTIFICATE OF ANALYSIS Chondroitin Sulfate Sodium USP 40

<b>Solvents Used</b>	<i>Water &amp; Ethanol</i>	<b>Country Of Origin</b>	<i>China</i>
<b>Sterillization Status</b>	<i>Non Irradiation/ETO</i>	<b>Standards</b>	<i>USP 40</i>
<b>Manufacturing Date</b>	<i>2018/8/10</i>	<b>Batch No.</b>	<i>CS201808010</i>
<b>Expiration Date</b>	<i>2021/8/9</i>	<b>Batch Quantity</b>	<i>1000kg</i>

ITEMS	SPECIFICATION	RESULT	TEST METHOD
Appearance	White or almost white powder	White powder	<i>In House Method</i>
I.D.-A Infrared absorption	Compare with the CRS	Corresponding	<i>USP 40 &lt;197K&gt;</i>
I.D.-B General Sodium	Gives reaction of sodium	Positive	<i>USP 40 &lt;191&gt;</i>
I.D.-C Disaccharide Composition	$\Delta$ Di-4S / $\Delta$ Di-6S is NLT 1.0	> 1.0	<i>USP 40 &lt;P6900&gt;</i>
I.D.-D Specific Rotation	Between -20.0° to -30.0°	Meet requirement	<i>USP 40 &lt;781S&gt;</i>
Content by CPC Titration	90.0%-105.0% (dried basis)	98.21%	<i>USP 40 &lt;P6900&gt;</i>
Content by HPLC	NLT 90.0% (dried basis)	97.67%	<i>In House Method</i>
Content by Enzymatic HPLC	NLT 83.0% (dried basis)	97.90%	<i>USP 40 &lt;P6901-6902&gt;</i>
Residue On Ignition	20.0%-30.0%	26.73%	<i>USP 40 &lt;281&gt;</i>
Chloride	NMT 0.50%	<0.50%	<i>USP 40 &lt;221&gt;</i>
Sulfate	NMT 0.24%	<0.24%	<i>USP 40 &lt;221&gt;</i>
Electrophoretic Purity	NMT 2%	<2%	<i>USP 40 &lt;P6901-6902&gt;</i>
Limit Of Protein	NMT 6.0% (dried basis)	2.27%	<i>USP 40 &lt;P6901&gt;&amp;&lt;857&gt;*</i>
Total Bacterial Count	NMT 1000 cfu/g	120 cfu/g	<i>USP 40 &lt;2021&gt;</i>
Yeasts & Molds	NMT 100 cfu/g	15 cfu/g	<i>USP 40 &lt;2021&gt;</i>
Salmonella	Absence	Not detected	<i>USP 40 &lt;2022&gt;</i>
Escherichia Coli.	Absence	Not detected	<i>USP 40 &lt;2022&gt;</i>
Heavy Metals	NMT 20 ppm	<20 ppm	<i>USP 40 &lt;231&gt; Method II*</i>
As	NMT 3 ppm	Pass	<i>In House Method</i>
Cd	NMT 2 ppm	Pass	<i>In House Method</i>
Hg	NMT 0.3 ppm	Pass	<i>In House Method</i>
Pb	NMT 0.5 ppm	Pass	<i>In House Method</i>
Nonspecific Dissaccharides	NMT 10.0%	0.31%	<i>USP 40 &lt;P66901-6902&gt;</i>
Clarity And Color Of Solution	NMT 0.35 at 420nm	0.095	<i>USP 40 &lt;P6902&gt;&amp;&lt;857&gt;*</i>
Optical Rotation	-20.0° to -30.0°	-27.65°	<i>USP 40 &lt;781S&gt;</i>
pH	5.5-7.5	6.9	<i>USP 40 &lt;791&gt;</i>
Loss On Drying	NMT 10.0%	8.72%	<i>USP 40&lt;731&gt;</i>
Residue of Solvents	NMT 5000 ppm (Ethanol)	741 ppm	<i>USP 40 &lt;467&gt;</i>
Particle Size	NLT 95% through 80 mesh	98.62%	<i>USP 40 &lt;786&gt;</i>
Bulk Density	0.6g/mL-0.85g/mL	Pass	<i>USP 40 &lt;616&gt; Method I</i>
Tapped Density	0.65g/mL-0.95g/mL	Pass	<i>USP 40 &lt;616&gt; Method I</i>

Storage: Preserve in tight containers.

Expiry Date: 36 months if store under the conditions above and stay in original packaging.

Packing: 25kg net. Polyethylene bag with cardboard drum.

**CONCLUSION: CONFORM TO THE REQUIREMENTS OF USP 40.**

INSPECTOR:

*Qian Zhan*

QC DIRECTOR:

*Jin Fan.*