

## XANTURAL<sup>®</sup> 180 XANTHAN GUM

Document No.: 456-X

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<b>Description</b>	<b>XANTURAL 180</b> is an 80-mesh (180 µm) xanthan gum product suitable for use as a pharmaceutical excipient.
<b>Features</b>	<ul style="list-style-type: none"> <li>• high solution viscosity under low-shear conditions</li> <li>• low solution viscosity under high-shear conditions</li> <li>• non-thixotropic</li> <li>• transparent solutions</li> <li>• compatible with high concentrations of salts and humectants</li> </ul>
<b>Benefits</b>	<ul style="list-style-type: none"> <li>• prevents phase separation in suspensions and emulsions</li> <li>• ensures products are free-flowing throughout their shelf-life</li> <li>• can be used with most ingredients</li> </ul>
<b>Typical Applications</b>	<ul style="list-style-type: none"> <li>• oral suspensions</li> <li>• syrups</li> </ul>
<b>Typical Use Level</b>	0.1 to 0.5%
<b>Dispersion/Hydration</b>	To prepare a solution, <b>XANTURAL 180</b> powder should be added carefully to well stirred water - ideally before any other ingredients - and stirring continued until a smooth, clear solution is obtained. To facilitate dispersion of the powder, a high-shear mixing device can be used.
<b>Standard Packaging</b>	Packed in 25-kg double walled corrugated boxes with polyethylene liners (21 CFR §177.1520). All packaging material complies with relevant UK, EU and US food contact legislation.
<b>Ingredient/Labeling</b>	Xanthan gum, NF/Ph.Eur./JPE CAS No. 11138-66-2 Kosher approved; Halal approved
<b>Regulatory Information</b>	<p><b>XANTURAL 180</b> is manufactured using USP &lt;1078&gt; "Good Manufacturing Practices Guidelines for Bulk Pharmaceutical Excipients."</p> <p><b>XANTURAL 180</b> is tested to ensure compliance with USP &lt;467&gt; Residual Solvents, USP &lt;61&gt; and &lt;62&gt; microbiological testing, and with the purity criteria defined in the monographs for xanthan gum in the current editions of the <i>National Formulary</i>, <i>European Pharmacopoeia</i> and <i>Japanese Pharmaceutical Excipients</i>.</p>
<b>Storage Conditions/ Shelf Life</b>	Store in a roofed and well-ventilated area in the unopened original package. Functional properties of the product are guaranteed to conform with the stated sales specifications for <b>1095 days</b> from the date of manufacture when stored under these conditions. Product quality should be re-evaluated prior to use if this "Best Before" date has been exceeded.
<b>Quality System</b>	Manufactured according to a Quality System registered to ISO 9001:2008.

**Specifications**

<u>Property</u>	<u>Requirement</u>	<u>Test Method</u>
Particle Size	Tyler Standard Screen Scale	KTM004
- 80 mesh (180 µm)	Not less than 95% through	
Loss on Drying	Not more than 15.0%	KTM003
Appearance	White to tan, uniform in appearance	
Viscosity		KTM017
- 1% gum in 1% KCl (60 rpm)	1200 – 1600 mPa · s (cP)	
Viscosity Ratio	1.02 – 1.45	KTM017
Solution pH		KTM005
- 1% gum in DI water	6.0 – 8.0	
Transmittance		KTM087
- 1% gum in DI water (600 nm)	Not less than 85%	
Clarity of Solution	Guaranteed to comply with JPE	
Identification	Passes	KTM015
Pyruvic Acid	Not less than 1.5%	KTM524
Assay	4.2 – 5.0% CO <sub>2</sub>	KTM503
	91.0 – 108.0% xanthan gum	
Ash	6.5 – 16.0%	KTM255
Heavy Metals	Not more than 20.0 mg/kg (ppm)	KTM514
Lead	Not more than 2.0 mg/kg (ppm)	KTM514
Arsenic	Not more than 2.0 mg/kg (ppm)	KTM514
Mercury	Not more than 1.0 mg/kg (ppm)	KTM514
Cadmium	Not more than 1.0 mg/kg (ppm)	KTM514
Isopropyl Alcohol	Not more than 500 mg/kg (ppm)	KTM520
Identification Test A	Guaranteed to comply with EP	
Organic Volatile Impurities	Guaranteed to comply with USP<467>	
Other Polysaccharides	Guaranteed to comply with EP	
Bacteria*		KTM800
- 48 hour	Not more than 500 cfu/g	
- 5 day	Not more than 1,000 cfu/g	
Fungal (Yeast and Mold) Count	Not more than 100 cfu/g	KTM803
Coliform	Negative by Most Probable Number (MPN)	KTM801
<i>Escherichia coli</i>	Absent in 25 g	KTM802
<i>Salmonella</i> spp.	Absent in 25 g	KTM804
<i>Staphylococcus aureus</i>	Absent in 1.0 g	KTM806
<i>Pseudomonas aeruginosa</i>	Absent in 1.0 g	KTM807
Total Aerobic Plate Count	Not more than 2,000 cfu/g	USP <61>
Total Yeasts and Molds	Not more than 200 cfu/g	USP <61>
<i>Escherichia coli</i>	Absent in 1 g	USP <62>
<i>Salmonella</i>	Absent in 10 g	USP <62>
<i>Staphylococcus aureus</i>	Absent in 1 g	USP <62>
<i>Pseudomonas aeruginosa</i>	Absent in 1 g	USP <62>
Bile Tolerant Gram Negative Bacteria	Absent in 1 g	USP <62>
<i>Candida albicans</i>	Absent in 1 g	USP <62>
Clostrida	Absent in 2 g	USP <62>

\* Total viable mesophilic aerobic count

**METHODS OF TESTING** (For test methods not listed, follow the applicable compendium. Full details of test methods are available upon request.)

### Particle Size (KTM004)

Shake 50 g product on an 80 mesh (180 µm) Tyler Standard Screen for 10 minutes using a Cenco-Meinzer sieve shaker.

### Loss on Drying (KTM003)

Spread 3-5 g product evenly on a tared weighing pan and weigh accurately. Dry in an oven at 105°C for 2½ hours. Cool in a desiccator and reweigh.

### Appearance

Qualitative evaluation.

### Viscosity (KTM017)

Slowly add a dry blend of 2.5 g product and 2.5 g KCl to 245 mL deionized water in a 400-mL beaker while stirring at 800 rpm using a low-pitched propeller-type stirrer. After stirring for 2 hours at 800 rpm, adjust the temperature of the solution to 25°C (77°F), and measure the viscosity using the LV model of the Brookfield viscometer at 60 rpm with a #3 LV spindle.

### Solution pH (KTM005)

Slowly add 3 g product to 297 mL deionized water in a 400-mL beaker while stirring at 800 rpm using a low-pitched, propeller-type stirrer. After stirring for 30 min, measure the pH of this solution using a pH meter.

### Transmittance (KTM087)

Slowly add 2 g product to 198 mL deionized water in a 400-mL beaker while stirring at 800 rpm using a low-pitched, propeller-type stirrer. After stirring for 2 hours, centrifuge the solution at 3,000-4,000 rpm for 10 minutes. Measure the transmittance using a Bausch and Lomb Spectronic 215, or other suitable spectrometer, at 600 nm. Use deionized water as the 100% transmittance standard.

**NOTE:** CP Kelco reserves the right to use company test methodology.

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