PRODUCT DATA SHEET

CPKelco
A HUBER COMPANY

Document No.: 454-X

XANTURAL® 75 XANTHAN GUM

Description
XANTURAL 75 is a fine particle size xanthan gum product suitable for use as a pharmaceutical excipient.

Features
- fast hydration on contact with water
- high solution viscosity under low-shear conditions
- low solution viscosity under high-shear conditions
- non-thixotropic
- transparent solutions
- compatible with high concentrations of salts and humectants

Benefits
- provides a sustained release effect at low concentrations in tablets
- prevents phase separation in suspensions

Typical Applications
- hydrophilic matrix sustained release tablets
- reconstitutable oral suspensions

Typical Use Level
5 to 25% in tablets and reconstitutable powder blends

Dispersion/Hydration
If it is desired to prepared a solution of **XANTURAL 75,** the powder should be added carefully to well stirred water and stirring continued until a smooth, clear solution is obtained. Lumping can be prevented by pre-blending **XANTURAL 75** with other powder ingredients.

Standard Packaging
Packed in 25-kg open mouth bags, and in 125-kg Leverpak drums (or their equivalent) with polyethylene liners, and 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.

Ingredient/Labeling
Xanthan gum, NF/Ph.Eur./JPE
CAS No. 11138-66-2
Kosher approved; Halal approved

Regulatory Information
XANTURAL 75 is manufactured using USP <1078> "Good Manufacturing Practices Guidelines for Bulk Pharmaceutical Excipients."

XANTURAL 75 is tested to ensure compliance with USP <467> Residual Solvents, USP <61> and <62> microbiological testing, and with the purity criteria defined in the monographs for xanthan gum in the current editions of the *National Formulary, European Pharmacopeia* and *Japanese Pharmaceutical Excipients.*

Storage Conditions/ Shelf Life
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 **1095 days** 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.

Quality System
Manufactured according to a Quality System registered to ISO 9001.

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Specifications

Property	Requirement	Test Method
Particle Size	Tyler Standard Screen Scale, Ro-Tap	KTM146
- 80 mesh (180 μm)	Not less than 100% through	
- 200 mesh (75 μm)	Not less than 92% 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_2 91.0 – 108.0% xanthan gum	KTM503
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>	
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
Escherichia coli	Absent in 25 g	KTM802
Salmonella spp.	Absent in 25 g	KTM804
Staphylococcus aureus	Absent in 1.0 g	KTM806
Pseudomonas aeruginosa	Absent in 1.0 g	KTM807
Total Aerobic Plate Count	Not more than 1,000 cfu/g	USP <61>
Total Yeasts and Molds	Not more than 100 cfu/g	USP <61>
Escherichia coli	Absent in 1 g	USP <62>
Staphylococcus aureus	Absent in 1 g	USP <62>
Salmonella	Absent in 10 g	USP <62>
Pseudomonas aeruginosa	Absent in 1 g	USP <62>
Bile Tolerant Gram Negative Bacteria	Absent in 1 g	USP <62>
Candida albicans	Absent in 1 g	USP <62>
Clostrida	Absent in 2 g	USP <62>

* Total viable mesophilic aerobic count

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

Particle Size (KTM146)
Shake 50 g product on 80 and 200 mesh (180 and 75 μm) Tyler Standard Screens for 20 minutes using a Ro-Tap 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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