PRODUCT DATA SHEET

CPKelco
A HUBER COMPANY

XANTURAL® 11K XANTHAN GUM

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Description

XANTURAL 11K is an agglomerated xanthan gum product suitable for use as a pharmaceutical excipient.

Features

- large particle size
- 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

- little or no dust formed when handled
- can be dispersed in water easily
- prevents phase separation in suspensions and emulsions
- ensures products are free-flowing throughout their shelf-life
- can be used with most ingredients

Typical Applications

- oral suspensions
- syrups

Typical Use Level

0.1 to 0.5%

Dispersion/Hydration

XANTURAL 11K should be added to water, ideally before any other ingredients. The water should be stirred strongly enough to create a vortex, and the **XANTURAL 11K** powder added quickly, in a steady stream, into the wall of the vortex. Stirring is continued until a smooth, clear solution is obtained.

Standard Packaging

Packed in 25-kg Leverpak drums (or their equivalent) with polyethylene liners (21 CFR §177.1520). All packaging materials comply with relevant UK, EU, and United States food contact legislation.

Ingredient/Labeling

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

Regulatory Information

XANTURAL 11K is manufactured using USP <1078> "Good Manufacturing Practices Guidelines for Bulk Pharmaceutical Excipients."

XANTURAL 11K 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.

XANTURAL® 11K XANTHAN GUM

Specifications

Property	Requirement	Test Method
Particle Size	Tyler Standard Screen Scale	KTM004
- 14 mesh (1.18 mm)	Not less than 98% through	
- 80 mesh (180 μm)	Not more than 12% 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>
Salmonella	Absent in 10 g	USP <62>
Staphylococcus aureus	Absent in 1 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

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 14 and 80 mesh (1.18 mm and 180 µm) Tyler Standard Screens for 2 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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