

GENU® pectin (citrus) type USP/100

File no.: 0001130-46

Revision date: May 28, 2018

Description	GENU® pectin (citrus) type USP/100 is a high ester pectin extracted from citrus peel.
Features in application	<ul style="list-style-type: none">• No sugar or other inert agent used for standardization• Medium particle size• Light colored powder• Thickening hydrocolloid in pharmaceutical products• Stabilizing hydrocolloid in pharmaceutical products
Typical Applications	<ul style="list-style-type: none">• Wound care• Ostomy devices• Emulsions and suspensions
Typical Use Level	05. – 33%
Standard packaging	Packed in 20 kg paper bags. All packaging material complies with FDA and EU food contact legislation.
Regulatory Compliance	<p>Manufactured under food cGMP</p> <p>GENU® pectin (citrus) type USP/100 is tested to ensure compliance with USP <467> Residual Solvents, USP <61> and <62> microbial testing, and with the purity criteria defined in the monograph for pectin in the current edition of the <i>United States Pharmacopeia</i>.</p> <p>The identity, purity and microbial criteria relevant for the hydrocolloid can be found in Pectin Identity and Purity, Healthcare 0000019</p>
Labeling information	<p>GENU® pectin (citrus) type USP/100 Pectin, CAS: 9000-69-5 Degree of Esterification: 55-65% Methoxy Groups: 6.7-12.0% Not for retail sale</p>

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Specifications (Reported on Certificate of Analysis)	Property	Specification	CP Kelco Control Method
	Degree of Esterification , %	55 – 65	0006011
	Methoxy Groups, %	6.7 – 12.0	0006011
	Galacturonic acid, %	Not less than 74.0	0006011
	pH of 1% solution	3.6 – 4.1	0006041
	Sugar and organic acid, mg/25 ml	Not more than 20.0	0006014
	Arsenic, As, ppm	Not more than 3.00	0006083
	Lead, Pb, ppm	Not more than 5.00	0006083
	Loss on drying, %	Not more than 10.0	0006012
	Whiteness, L-value	76 - 85	0006007
	Particle size, 0.150 mm, %	Not more than 5.0	0006013
	Particle size, 0.180 mm, %	Not more than 1.0	0006013
	Total Aerobic Plate Count, CFU/g	Not more than 300	USPCP61
	Total Yeasts/Molds, CFU/g	Not more than 100	USPCP61
	Salmonella	Absent/10 g	USPCP62
	E. coli	Absent/1 g	USPCP62
	Staphylococcus aureus	Absent/1 g	USPCP62
	Pseudomonas aeruginosa	Absent/1 g	USPCP62
	Bile Tolerant Gram Negative Bacteria	Absent/1 g	USPCP62
	Candida albicans	Absent/1 g	USPCP62
	Clostridia	Absent/2 g	USPCP62
Other characteristics	Sulfur Dioxide, ppm: Less than 10 ppm Residual Solvents <467>: Less than 0.5% Free-flowing powder Flavor*: Essentially flavorless Odor*: Essentially odor free *) <i>Pectin is produced from natural raw materials, thus batch to batch variation of color, flavor and odor may occur.</i>		
Shelf Life/Best before	When stored in a roofed and well ventilated location in the unopened original package, the product may be stored up to 1095 days (36 months) from date of manufacture. Shelf Life/Best Before period is the guaranteed period through which we guarantee the purity and identity		
Additional Documents	Additional documents available upon request. customer.request@cpkelco.com		
Production facilities	Possible production facilities of CP Kelco: CP Kelco, Grossenbrode, Germany CP Kelco, Limeira, Brazil CP Kelco, Lille Skensved, Denmark		

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