

Navigating the Next Phase of Nitrosamine Compliance for Pharmaceutical Producers.

Our experts have dedicated years of investigation to defining and designing appropriate testing protocols for the detection of nitrosating agents, such as nitrite in excipients, often in the absence of clear regulatory standards. Thanks to these efforts, we are now proud to offer among the industry's largest collection of low nitrite excipients, unlocking safe, adaptable drug development without compromise.

RANGE PRESENTATION

Product Category	Product	Manufacturing sites	Limit of detection in ppb	Limit of Quantification in ppb	Nitrite levels observed (values in ppb)
Polyols	PEARLITOL® mannitol, SD, PF, C grades	Nanning (Cn), Lestrem (FR), Gurnee (IL, USA)	10	25	<25
	LYCASIN® maltitol liquid	Lestrem (FR)	10	25	Not Detected
		Gurnee (IL, USA)			<25
	SweetPearl® maltitol	Lestrem (FR)	10	25	Not Detected
		Gurnee (IL, USA)			<25
	NEOSORB® sorbitol powder	Lestrem (FR)	10	25	<25
		Gurnee (IL, USA)			<25
	NEOSORB® sorbitol liquid	Lestrem (FR)	10	25	<25
Gurnee (IL, USA)		<25			
XYLISORB® xylitol	Lestrem (FR)	10	25	<25	
POLYSORB® 85/70/00 partially dehydrated sorbitol liquid	Lestrem (FR)	10	25	Not Detected	
Native Starches	Wheat Starch TB	Lestrem (FR)	20	50	<50
	Maize Starch B	Lestrem (FR)	20	50	<50
	Extra white Starch	Cassano (IT)	20	50	<80
	Amylo N-400 high amylose maize starch	Benifaio (ES)	20	50	<50
Pregel Starches	LYCATAB® CT partially pregelatinized starch	Crest (Nellore, IND)	30	100	<100
	LYCATAB® CT-LM low moisture partially pregelatinized starch				
	LYCATAB® C partially pregelatinized starch	Lestrem (FR)			



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Modified Starches	CLEARGUM® TA 90 partially hydrolyzed tapioca starch	Lestrem (FR)	20	50	<50
	CLEARGUM® CO 03 octenyl succinate starch	Lestrem (FR)	10	25	<25
Sugars	NUTRIOSE® Soluble Fiber	Lestrem (FR)	10	25	Not Detected
	Dextrose Monohydrate M, F, Anhydrous Dextrose C	Benifaio (ES)	10	25	<25
	GLUCIDEX® 6D, 12D, IT 12P, IT 47, 28E maltodextrin	Lestrem (FR)	10	25	<25
	Glucose Syrup 4779	Lestrem (FR)	10	25	<100
	Glucose Syrup 4779, S02	Lestrem (FR)	10	25	Not Detected
	Glucose Syrup 3072, 6080	Beinheim (FR)	10	25	<80
	KLEPTOSE® Linecaps pea maltodextrin	Lestrem (FR)	10	25	<25
Cyclodextrin	KLEPTOSE® HPB-LB, KLEPTOSE® HPB hydroxypropyl beta-cyclodextrin	Lestrem (FR)	10	25	<25
Co-Processed	PEARLITOL® Flash co-processed mannitol-starch	Lestrem (FR)	10	25	<25
	PEARLITOL® CR-H co-processed mannitol-HPMC	Lestrem (FR)	10	25	Not Detected
Organics acids	Glucono Delta Lactone	Lestrem (FR)	10	25	<25

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PH_OD-LOW-NITRITE-EXCIPIENTS-RANGE-TF-1e.11/02024


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