



Foremost® NF Lactose
Modified, Spray Dried
Product Code 315

Description: A spray-dried mixture of crystalline and amorphous lactose

IDENTIFICATION	TYPICAL	SPECIFICATION
Lactose Determination Method A	Matches scan	Reference IR scan
Lactose Determination Method B	Matches chromatogram	Reference Chromatogram
CHEMICAL ANALYSIS	TYPICAL	SPECIFICATION
Acidity or alkalinity	0.1 mL	0.4 mL of 0.1 N NaOH (maximum)
Clarity and color @ 400 nm	0.01	0.04 (maximum)
Heavy metals, µg/g	Less than 5.0	5.0 (maximum)
Loss on drying, %	0.3	1.0 (maximum)
PLAI at 210-220 nm	0.05	0.25 (maximum)
PLAI at 270-300 nm	0.01	0.07 (maximum)
Residue on ignition, %	0.02	0.1 (maximum)
Specific rotation	+54.8° to +55.2°	+54.4° to +55.9°
Water, %	4.8 to 5.2	4.5 to 5.5
MICROBIOLOGICAL STANDARDS	TYPICAL	SPECIFICATION
Total aerobic microbial count	Less than 10 cfu/g	100 cfu/g (maximum)
<i>Escherichia coli</i>	Absent	Absent
Total combined molds and yeasts count	Less than 10 cfu/g	50 cfu/g (maximum)
<i>Staphylococcus aureus</i>	Negative	Negative
<i>Pseudomonas aeruginosa</i>	Negative	Negative
<i>Salmonella</i> species/100g	Negative	Negative
POWDER FINENESS (CUMULATIVE)	TYPICAL	SPECIFICATION
On USS #30 (600 micron)	0 %	0 % (maximum)
On USS #140 (106 micron)	30-60 %	20 % (minimum)
On USS #200 (75 micron)	55-75 %	50 % (minimum)
PHYSICAL CHARACTERISTICS	TYPICAL	SPECIFICATION
Bulk Density	0.67 g/mL	0.60 g/mL (minimum)
Tapped Density	0.78 g/mL	0.70 g/mL (minimum)
% Lactose (d.b.)	99 % (+)	
Appearance and flavor	White, crystalline powder, slightly sweet	

STORAGE CONDITIONS	PACKAGE STYLE
Protect from moisture and excessive heat.	Multiwall kraft paper bag with inserted polyethylene liner 25 kg 35 Gallon fiber drum with inserted polyethylene liner. 95kg

RE-EVALUATION DATE
Sealed container can be stored at least eighteen months without undergoing decomposition or degradation.

ALLERGEN CLASSIFICATION
Contains lactose, does not contain milk or whey proteins.

CONFORMANCE
NF Lactose monohydrate modified spray dried 315 conforms to the NF/USP, EP, and JP monographs.

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