



Foremost® NF Lactose

Product Code 313

Description: Monohydrate, Crystalline, 325 mesh, Impalpable C

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, %	0.2	0.5 (maximum)
Protein and light-absorbing impurities at 210-220 nm	0.05	0.25 (maximum)
at 270-300 nm	0.01	0.07 (maximum)
Residue on ignition, %	0.02	0.1 (maximum)
Specific rotation	+55.0° to +55.3°	+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 #200 (75 micron)	0.0-1.0 %	1.0 % (maximum)
On USS #325 (45 micron)	2.0-8.0 %	10.0 % (maximum)
On USS #400 (37 micron)	15-25 %	Not applicable
PHYSICAL CHARACTERISTICS		
Bulk Density	0.44 g/mL	0.35 g/mL (minimum)
Tapped Density	0.72g.mL	0.65 g/mL (minimum)
% Lactose (d.b.)	99 % (+)	
Appearance	White, crystalline powder	White, crystalline powder
Flavor and odor	Slightly sweet	Slightly sweet

STORAGE CONDITIONS

Protect from moisture and excessive heat.

EXPIRATION DATE

Sealed container can be stored at least 36 months without undergoing decomposition or degradation

ALLERGEN CLASSIFICATION

Contains lactose, does not contain milk or whey proteins.

CONFORMANCE

NF Lactose monohydrate 313 conforms to the current versions of the NF/USP, EP, and JP monographs.