



Foremost[®] NF Lactose

Product Code 310

Description: Monohydrate, Crystalline, 80 mesh, Regular

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 #80 (180 micron)	0.0-1.0 %	2.0 % (maximum)
On USS #140 (106 micron)	15-30 %	Not applicable
On USS #200 (75 micron)	35-45 %	30-60 %
PHYSICAL CHARACTERISTICS		
Bulk Density	0.66g/mL	No Specification
Tapped Density	0.92g/mL	No Specification
% 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 protein.

CONFORMANCE

NF lactose monohydrate 310 conforms to the current versions of the NF/USP, EP, and JP monographs.

This information is presented in good faith but it is not warranted as to accuracy of results. Also, freedom from patent infringement is not inferred. This information is offered solely for your investigation, verification, and consideration. (04/14)