Foremost® NF Lactose

Product Code 314WG

Description: Lactose Monohydrate, Crystalline

Lactose occurs as a white crystalline powder obtained from whey. Crystalline lactose monohydrate contains one molecule of water of hydration. It is soluble in water and very slightly soluble in alcohol and insoluble in chloroform and in ether.

Lactose, a reducing sugar is a disaccharide composed of one molecule of glucose and one molecule of galactose.

NF lactose monohydrate is used as an excipient in the pharmaceutical industry. Lactose exhibits little reactivity with most drugs and in the monohydrate form is stable for many years. It is routinely used as an excipient in the manufacture of tablets and capsules.

Chemical Name:
4-O-ß-D galactopyranosl-D-glucopyranose
Chemical Formula:
$C_{12}H_{22}O_{11}. H_2O$
Molecular Weight:
360.32

PHISICAL CHARACTERISTICS	TYPICAL	SPECIFICATION
Bulk Density	0.53g/mL	0.45 g/mL (min)
Tapped Density	0.81g/mL	0.70 g/mL (min)
% 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.

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

CONFORMANCE
NF Lactose monohydrate 314WG conforms to the current versions of the USP/NF, EP, and JP monographs.

CHEMICAL ANALYSIS	TYPICAL	SPECIFICATION
Acidity or alkalinity	0.1 mL	0.4 mL of 0.1 N NaOH (max)
Clarity and color @ 400 nm	0.01	0.04 (max)
Heavy metals, µg/g	<5.0	5.0 (max)
Loss on drying, %	0.1	0.5 (max)
Protein and light-absorbing impurities		
at 210-220 nm	0.05	0.25 (max)
at 270-300 nm	0.01	0.07 (max)
Residue on ignition, %	0.02	0.1 (max)
Specific rotation	+55.2°	+54.4° to +55.9°
Water, %	5.0	4.5 to 5.5

MICROBIOLOGICAL STANDARDS	TYPICAL	SPECIFICATION
Total aerobic microbial count	<10 cfu/g	100 cfu/g (max)
Escherichia coli	Negative	Negative
Total combined molds and yeasts count	<10 cfu/g	50 cfu/g (max)
Staphylococcus aureus	Negative	Negative
Pseudomonas aeruginosa	Negative	Negative
Salmonella species	Negative	Negative

POWDER FINENESS *(CUMULATIVE)*	TYPICAL	SPECIFICATION
On USS #80 (180 micron)	0%	0% (max)
On USS #140 (106 micron)	0.0-1.0 %	7.0 % (max)
On USS #200 (75 micron)	0.0-5.0 %	1-15.0 % (max)