



NF Lactose – 315

Monohydrate, modified spray-dried

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

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)
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	+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>	Negative	Negative
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	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)
Appearance and flavor	White, crystalline powder, slightly sweet	

STORAGE CONDITIONS

Protect from moisture and excessive heat.

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.