



Foremost® NF Lactose

Product Code 312

Description: Monohydrate, Crystalline, 200 mesh, Impalpable

| 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 #140 (106 micron) | 0.0-1.0 % | 1.0 % (maximum) |
| On USS #200 (75 micron) | 0.0-5.0 % | 6.0 % (maximum) |
| On USS #325 (45 micron) | 20-30 % | Not applicable |
| PHYSICAL CHARACTERISTICS | | |
| Bulk Density | 0.53g/mL | 0.45 g/mL (minimum) |
| Tapped Density | 0.81g/mL | 0.70 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 312 conforms to the current versions of the NF/USP, EP, and JP monographs.

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