

Kalchem International

Chemicals & Compounding Supplies

Product: NF Lactose Hydrate Mod.Spry Dry Fast Flo **WL10404316** **CAS No.:** 64044-51-5

Lot Number: 8515120761


Description: White crystalline powder, spray-dried mixture of crystalline and amorphous lactose. (JP Lactose Monograph Description: Granulated Powder)

NF Monograph Analysis	Foremost Laboratory Result	Specification
Microbial		
Enterobacteriaceae-Bile Tolerant Organism	Absent	Absent
Escherichia coli	Absent	Absent
Total Aerobic Microbial Count	< 1	100 CFU/g maximum
Total Combined Mold and Yeast	< 1	50 CFU/g maximum
Gen App/Organoleptic		
Absorbance @ 400nm	0.00	0.04 @ 400nm maximum
Clarity and Color of Solution	Clear & Colorless	Clear & Nearly Colorless
Identification Tests		
Identification A	*Meets Specification	* Complies With Specification
Identification B	*Meets Specification	* Complies With Specification
Physical & Chemical		
Acidity/Alkalinity	0.0	0.4 mL 0.1N NaOH maximum
Acidity/Alkalinity Color	Solution = Colorless	Solution is Colorless
Heavy Metals	*Meets Specification	* Complies With Specification
Loss on Drying	0.3	1.0 % maximum
PLAI Absorbance @ 210-220nm	0.04	0.25 @ 210-220 nm maximum
PLAI Absorbance @ 270-300nm	0.01	0.07 @ 270-300 nm maximum
Residue on Ignition	0.00	0.10 % maximum
Specific Rotation	55.2	54.4-55.9 deg_angle
Water	4.8	4.5-5.5 %
Non NF Analysis		
Appearance of Solution - EP method	Acceptable	Acceptable
Density-Bulk g/ml	0.62	0.50 g/mL minimum
Density-Tapped g/ml	0.72	0.60 g/mL minimum
Pseudomonas	Negative per 10g	Negative per 10g
Salmonella per 100g	Negative per 100g	Negative per 100g
Staphylococcus aureus	Negative per 10g	Negative per 10g
Particle Size-RoTap		
Particle Size % on #060/250um	0.0	2.0 % maximum
Particle Size % on #140/106um	45.7	20.0 % minimum
Particle Size % on #200/75um	76.2	50.0 % minimum

*Specified Limit Guaranteed: This Lot Not Tested

The above lot number has been manufactured, processed, held in accordance with United States cGMP's and tested according to procedures as stated in the NF lactose monohydrate monograph and conforms to the same monograph specifications. This lot meets the current USP/NF, BP, EP, and JP lactose monohydrate/lactose granulated powder monograph and subsequent supplements at the time of manufacture. This lot number conforms to FDA guidelines regarding BSE/TSE. The USA is the origin of the bovine used in producing this lot number. We have no knowledge of any other impurity in this lot number which is present at a level of 0.1 % or greater. This lot number complies with the ICH Guideline on Residual Solvents (CPMP/ICH/283/95) in that no class 1, 2, 3, or any other solvents are used in our process or likely to be present in the lactose. Storage conditions: Protect from moisture and excessive heat.

Signed by:



14-DEC-2015

Quality Control Supervisor

Date

Abby Lundgren

Kalchem International, Inc
224 South Main Street - Lindsay, OK 73052
Toll Free 888-298-9905 | FAX: 405-756-2373