KERRY

KalChem
INTERNATIONAL
Compounding Chemicals You Can Trust

MATERIAL	20617678	SHEFFIELD LACTOSE SD FAST FLO 316 25KG	
CUSTOMER MATERIAL			
CUSTOMER			
SALES ORDER		CUSTOMER REF. NO	
PRINT DATE	05/09/2023*	SHIP QUANTITY	
		COUNTRY OF ORIGIN	USA

BATCH	0007019652	BEST BEFORE DATE/EXPIRY DATE	04/22/2026*
		PRODUCTION DATE	04/23/2023*

INSPECTION CHARACTERISTICS	RESULT	UNITS	SPECIFICATION	METHOD
Absorbance at 400nm	0.00	A	<= 0.04	NF, CLARITY AND COLOR OF SOLUTION
Color and Clarity of Solution	Conform		Conform	NF, CLARITY AND COLOR OF SOLUTION
Acidity/Alkalinity	0.1	ml	<= 0.4	NF, ACIDITY OR ALKALINITY
Acidity/Alkalinity Color	Conform		Conform	NF, ACIDITY OR ALKALINITY
PLAI, Absorbance at 210 to 220nm	0.04	A	<= 0.25	USP <857>
PLAI, Absorbance at 270 to 300nm	0.01	A	<= 0.07	USP <857>
Appearance of Solution, EP	Conform		Conform	EP, VISUAL INSPECTION

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Water	5.1	%	4.5 ... 5.5	USP <921>, Method I
Residue on Ignition	0.0	%	<= 0.1	USP <281>
Loss on Drying	1.0	%	<= 1.0	USP <731>
Specific Rotation	55.0	Degree	54.4 ... 55.9	USP <781S>
Identification A	Pass		Pass	USP <197K>
Identification B	Pass		Pass	USP <201>
Heavy Metals	< 5	ppm	<= 5	JP <1.07>
Total Aerobic Microbial Count	1	CFU/g	<= 100	USP <61>
Total Yeast and Mold	1	CFU/g	<= 50	USP <61>
Bile Tolerant Organisms	Not Detected			USP <62>
Pseudomonas	Not Detected			USP <62>
Staphylcoccus aureus	Not Detected			USP <62>
Escherichia coli	Not Detected			USP <62>
Salmonella	Not Detected			USP <62>
Rotap Particle Size, % on #060/250um	0.2	%	<= 2.0	USP <786>, ROTAP
Rotap Particle Size, % on #140/106um	61.7	%	>= 20.0	USP <786>, ROTAP
Rotap Particle Size, % on #200/75um	83.3	%	>= 50.0	USP <786>, ROTAP
Bulk Density	0.56	g/mL	>= 0.50	USP <616>

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Tapped Density	0.64	g/mL	>= 0.60	USP <616>

~Re-evaluation Date: 18 months from DOM for 315 and 12 months from DOM for 316. This lot meets the current USP/NF, BP, EP, CP and JP monographs. This lot number has been manufactured, processed and held in accordance with cGMP's and tested according to procedures as stated in applicable compendia against monograph specifications. 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. White or almost white, odorless, crystalline powder. Freely soluble in water, practically insoluble in ethanol Storage conditions: Protect from moisture and excessive heat. Protect from freezing.

This certificate has been produced electronically for a product which meets specification. Signed on Behalf of Kerry by.

The product described in this certificate has been manufactured and tested in accordance with our standard procedures applicable to such product and conforms to the specifications for such product set forth herein.

Unless we have agreed to provide per batch or other testing frequency (in which case conformity has been determined in accordance with our contractual agreement), conformity to specification has been determined based on our risk assessment and our periodic, statistically-based testing program for the product.

All information appearing in this certificate is based upon tests and data we deem reliable. It is the customer's responsibility to determine the suitability of the product for its own use(s) and appropriate shipping, packaging, storage and/or distribution conditions, and no representation, warranty or guarantee, express or implied, is made by us in this certificate as to the suitability or effect of such use(s) or results to be obtained under actual use by customer or other third parties.

*All dates in this document are expressed in the format MM/DD/YYYY