



**K alchem International, Inc**  
Compounding Chemicals You Can Trust

<b>PRODUCT:</b>	<b>LACTOSE MONOHYDRATE POWDER, NF</b>	<b>EXPIRATION DATE:</b>	<b>12/2022</b>
<b>FINISHED LOT NO:</b>	<b>A28898</b>	<b>MFG DATE:</b>	
<b>CAS#</b>	<b>10039-26-6</b>	<b>SPECIFICATIONS:</b>	<b>NF</b>

## Certificate of Analysis

<b>TEST CRITERIA</b>	<b>SPECIFICATIONS</b>	<b>RESULTS</b>
<b>CHARACTERISTICS</b>	<b>White or creamy white powder</b>	<b>Pass</b>
<b>ODOR</b>	<b>Odorless</b>	<b>Pass</b>
<b>IDENTIFICATION A</b>	<b>Positive</b>	<b>Pass</b>
<b>IDENTIFICATION B</b>	<b>Positive</b>	<b>Pass</b>
<b>WATER DETERMINATION</b>	<b>4.5 - 5.5%</b>	<b>4.9%</b>
<b>SPECIFIC ROTATION @ 20°C</b>	<b>+54.5- + 55.9°</b>	<b>+55.3°</b>
<b>Clarity/Color of solution</b>	<b>To Pass</b>	<b>Pass</b>
<b>Residue on Ignition</b>	<b>NMT 0.1%</b>	<b>&lt;0.1%</b>
<b>Loss on Drying</b>	<b>NMT 0.5%</b>	<b>0.1%</b>

<b>PROTIEN AND LIGHT ABSORBING IMPURITIES</b>		
<b>ABSORB 0.1% @ 270-300nm</b>	<b>NMT 0.07</b>	<b>0.00</b>
<b>ABSORB 0.1%, 1cm @ 210-220nm</b>	<b>NMT 0.25</b>	<b>0.03</b>
<b>ACIDITY OR ALKALINITY</b>	<b>To Pass</b>	<b>Pass</b>
<b>HEAVY METALS</b>	<b>NMT 5 ppm</b>	<b>NMT 5 ppm</b>
<b>TOTAL AEROBIC MICROBIAL COUNT</b>	<b>NMT 100 cfu/g</b>	<b>&lt;100 cfu/g</b>
<b>TOTAL COMBINED YEAST AND MOLD</b>	<b>NMT 50 cfu/g</b>	<b>&lt;10 cfu/g</b>
<b>ESCHERICHIA COLI</b>	<b>Absent</b>	<b>Absent</b>
<b>CONCLUSION: Product is in conformity with the requirements of the Current USP</b>		

**DATE OF RELEASE:** \_\_\_\_\_ **ANALYSIS #** \_\_\_\_\_

**APPROVED BY/ DATE:** \_\_\_\_\_

**Kalyn R Tabor, Quality Control**