

# CERTIFICATE OF ANALYSIS

**Manufacturer** : LMC Lysozyme Manufacturing Company B.V.  
Energieweg 9, 8071 DA Nunspeet, The Netherlands  
T. +31(0)341 474551



LMC-B.V.

Lysozyme Manufacturing Company

**Product** : WORKING STANDARD LYSOZYME HCL  
**Lot #** : 260422  
**Manufacturing date** : 26-4-2022  
**Expiry date** : 26-4-2025

Acceptance tests	Acceptance criteria	Result
<b>Description:</b>		
Appearance	White powdered solid	Complies
<b>Assay (calculated on the anhydrous substance):</b>		
Microbiological (turbidimetric)	≥ 97,0%	102,5
Microbiological activity	≥ 41000 FIP U/mg	43333
Chemical (spectrophotometric)	98.0 - 101.5%	100,5
<b>Physical-chemical tests:</b>		
pH (2% aqueous solution)	3.2 - 3.8	3,4
Loss on drying (LOD)	≤ 5.0%	4,5
Colour of solution:		
Abs at 360 nm	≤ 0.150	0,068
Abs at 380 nm	≤ 0.120	0,043
Abs at 410 nm	≤ 0.080	0,023
Transmittance:		
at 540 nm, 20% solution as is	≥ 90%	98,6
at 540 nm, 10% solution as is	≥ 95%	99,4
at 540 nm, 10% pH 9 solution	≥ 70%	96,5
Related substances (HPLC)		
Impurity A	< 0,50%	0,21
Impurity B	< 1,5%	0,30
Sum of impurities	≤ 2.5%	0,51
Electrophoresis		
SDS page	Each single stain ≤ intense than reference stain 2%	conform
<b>Microbiological tests:</b>		
Total Aerobic Microbial Count (TAMC)	≤ 10 <sup>3</sup> cfu/g	<10
Total Yeast & Moulds Count (TYMC)	≤ 10 <sup>2</sup> cfu/g	<10
Test for specified microorganisms:		
- <i>Enterobacteriaceae</i>	≤ 10 <sup>2</sup> cfu/g	<10
- <i>Salmonella</i>	Absent/25 g	Absent
- <i>Escherichia coli</i>	Absent/1 g	Absent
- <i>Staphylococcus aureus</i>	Absent/1 g	Absent
- <i>Pseudomonas aeruginosa</i>	Absent/1 g	Absent

**Reference Standard:** Lysozyme HCl FIP Standard lot. H-076  
**Transport conditions:** Room temperature (<30°C) is allowed during transport  
**Storage conditions:** Keep in original closed amber, glass vial with rubber stopper at 5±3°C  
Shelf-life after first opening: 8 weeks

**Name** A. Hagens  
**Function** QA Officer  
**Date of release** 19-5-2022