NutraNorth

CERTIFICATE OF ANALYSIS

Manufactured for	**MACKISEN**				
Name of product:	**R-Alpha Lipoic Acid**			**NPN**	**80131279**
Packaging Lot # :	**M2500548/1**	**Master Packaging Record #**		**Expiry Date :**	**08/2028**
		MPR	**MA-N279-60-V0**		
Manufacturing Lot # :	**M2500548**	**Master Manufacturing Record #:**		**MFG Date:**	**09/2025**
		MMR	**MA-N279-V0**		
Storage Conditions:	Store at room temperature (R.T), in closed dry containers and Keep away from high temperature & moisture.				
Physical Description:	Off White Color powder in clear Veggie "2" capsules.		60 count in Bottle-150 cc-38/400 White HDPE Round with Cap-38-400 white HIS P/P,ribbed,plain liner.		

Physical Tests:

		Specifications				
TESTES	**Results**	**Low**	**Target**	**High**	**Strength**	**Method**
Average Wt. of Capsules	317	297	330	363	mg	USP <2091>
Wt. variation of Capsules	confirms	Conforms as per USP weight variation +/- 10 %				USP <2091>
Odour & Taste	confirms	Characteristic, Conforms to Standard				Visual, Olfactory
Disintegration	04 min	NMT 30			min	USP <2040>
IDENTITY	confirms	Conforms to standard				FTIR

Quantity / Potency :	**Results**		**Low**	**Target**	**High**	**Strength**	**Method**
By Qualitative Analysis							
R-Alpha Lipoic Acid	104.08	mg	90.00	100.00	125.00	mg	JPL-134 HPLC
NON-MEDICINAL INGREDIENTS	Microcrystalline Cellulose 101, Empty Clear Vegetable Capsule Size "2"						

Purity:

MICRO:	**Results**	**Limits**	**Method**
Total Plate Count	50 c.f.u / g	< 3,000 c.f.u / g	USP <2021/2022>
Total Yeast	<10 c.f.u / g	< 300 c.f.u / g	USP <2021/2022>
Total Mold	<10 c.f.u / g	< 300 c.f.u / g	USP <2021/2022>
E.Coli	Not Detected	Not Detected	USP <2021/2022>
Salmonella Spp	Not Detected	Not Detected	USP <2021/2022>
Staphylococcus Aureus	Not Detected	Not Detected	USP <2021/2022>
HEAVY METALS:	**Results**	**Limits - 2 capsules / day**	**Method**
Arsenic	<0.0001 mcg / kg b.w/day	< 0.14 mcg / kg b.w./day	ICP-MS
Cadmium	<0.0001 mcg / kg b.w/day	< 0.09 mcg / kg b.w./day	ICP-MS
Lead	0.0006 mcg / kg b.w/day	< 0.14 mcg / kg b.w./day	ICP-MS
Total Mercury	<0.0001 mcg / kg b.w/day	< 0.29 mcg / kg b.w./day	ICP-MS

Prepared by: M.Pradeep Mar/16/2026

Approved by: Bhargava.A Mar/16/2026

Quality Assurance

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CERTIFICATE OF ANALYSIS

Manufactured for	**MACKISEN**				
Name of product:	**R-Alpha Lipoic Acid**			**NPN**	**80131279**
Packaging Lot # :	**M2500548/2**	**Master Packaging Record #**		**Expiry Date :**	**08/2028**
		MPR	**MA-N279-120-V0**		
Manufacturing Lot # :	**M2500548**	**Master Manufacturing Record #:**		**MFG Date:**	**09/2025**
		MMR	**MA-N279-V0**		
Storage Conditions:	Store at room temperature (R.T), in closed dry containers and Keep away from high temperature & moisture.				
Physical Description:	Off White Color powder in clear Veggie "2" capsules.		120 count in Bottle-250 cc-45/400 White HDPE Round with Cap-45-400 white HIS P/P,ribbed,plain liner.		

Physical Tests:

TESTES	Results	Specifications Low	Target	High	Strength	Method
Average Wt. of Capsules	317 mg	297	330	363	mg	USP <2091>
Wt. variation of Capsules	confirms	Conforms as per USP weight variation +/- 10 %				USP <2091>
Odour & Taste	confirms	Characteristic, Conforms to Standard				Visual, Olfactory
Disintegration	4 min	NMT 30			min	USP <2040>
IDENTITY	confirms	Conforms to standard				FTIR

Quantity / Potency :	**Results**		**Low**	**Target**	**High**	**Strength**	**Method**
By Qualitative Analysis							
R-Alpha Lipoic Acid	104.08	mg	90.00	100.00	125.00	mg	JPL-134(HPLC)
NON-MEDICINAL INGREDIENTS	Microcrystalline Cellulose, Empty Clear Vegetable Capsules size "2"						

Purity:

MICRO:	**Results**	**Limits**	**Method**
Total Plate Count	50 c.f.u / g	< 3,000 c.f.u / g	USP<2021>/AOAC
Total Yeast	<10 c.f.u / g	< 300 c.f.u / g	USP<2021>/AOAC
Total Mold	<10 c.f.u / g	< 300 c.f.u / g	USP<2021>/AOAC
E.Coli	Not Detected	Not Detected	USP<2022>/AOAC
Salmonella Spp	Not Detected	Not Detected	USP<2022>/AOAC
Staphylococcus Aureus	Not Detected	Not Detected	USP<2022>/AOAC
HEAVY METALS:	**Results**	**Limits - 2 capsules / day**	**Method**
Arsenic	< 0.0001 mcg / kg b.w./day	< 0.14 mcg / kg b.w./day	ICP-MS
Cadmium	< 0.0001 mcg / kg b.w./day	< 0.09 mcg / kg b.w./day	ICP-MS
Lead	0.0006 mcg / kg b.w./day	< 0.14 mcg / kg b.w./day	ICP-MS
Total Mercury	< 0.0001 mcg / kg b.w./day	< 0.29 mcg / kg b.w./day	ICP-MS

Prepared by: M. Pradeep Mar 16 2026

Approved by: Bhargava Mar 16 2026

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