anew
BIOPEPTIDES

Certificate of Analysis

Product Name: Anew – Thymosin Alpha 1 500 mcg Buccal Patch (Dietary Supplement; 20 ct per box)

Batch. No.	NPRC-2605	**A. R. No**	NP-AR-260512	**Batch Size**	25,000 Patches (1,250 boxes × 20 patches/box)
Mfg. Date	Aug-2026	**Exp. Date**	Feb-2027	**Date of Release**	09-Aug-2026

S. No.	Test	Specification	Result
1	Description	White to off-white colored, square shape buccal patch	White to off-white colored, square shape buccal patch
2	**Physical Integrity (Visual / Stereo-microscope inspection at 10× magnification)**		
	a) Tri-Layer Structure (TD-IntelGel™)	Three distinct layers visible (bio adhesive backing, lyophilized peptide hydrogel matrix, mucoadhesive interface); no delamination, splitting, air pockets, or layer separation	Complies
	b) Muco-SmartSeal® Edge Integrity	Continuous, intact peripheral seal around the full edge perimeter; no gaps, breaks, discontinuities, or seal-flow defects	Complies
3	**Identification**		
	a) Thymosin Alpha 1) (By RP-HPLC)	The retention time of the principal peak in the test solution corresponds to that of the Thymosin Alpha 1 reference standard chromatogram as obtained in the assay.	Complies
4	Average Weight (mg)	100.00 ± 7.5 % (Between 92.50 to 107.50 mg)	100.12 mg
5	Moisture Content (% w/w, Karl Fischer, USP <921>)	Between 3.00 to 6.00 %	4.18 %
6	Patch Dissolution Time (in simulated salivary fluid pH 6.8, 37 °C, mechanical agitation)	Between 2.5 and 3.5 minutes (150 – 210 seconds; ≈ 3.0 min target ± 17 %)	2.9 minutes (174 seconds)
7	Surface pH (1 patch dissolved in 5 mL purified water, 25 °C; USP <791>)	Between 5.0 and 7.0	6.31
8	Uniformity of Dosage Units (USP <905>)	Acceptance value (AV) Not More Than 15.0	AV = 5.8 (Complies)
9	**Assay: Each Buccal Patch contains**		
	a) Thymosin Alpha 1 500 mcg (By RP-HPLC, gradient elution with TFA-modified mobile phase, UV detection at 220 nm, against Thymosin Alpha 1 reference standard)	Between 90.0 % to 110.0 % of the label claim (i.e. 450 mcg to 550 mcg of Thymosin Alpha 1 per patch)	99.4 % (497 mcg per patch)
10	**Related Substances (By RP-HPLC with photodiode-array detection at 220 nm; Ph. Eur. <2034> 'Substances for Pharmaceutical Use' Table 2034-2 and USP <1503> 'Quality Attributes of Synthetic**		

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	Peptide Drug Substances' — synthetic peptides are outside the scope of ICH Q3A/Q3B; peptide-specific thresholds: reporting > 0.1 %, identification > 0.5 %, qualification > 1.0 %)		
	a) Methionine sulfoxide variant — Met(O)-Thymosin Alpha 1 (specified; oxidation at Met-6; +16 Da; $[M+4H]^{4+}$ shift +4.0 m/z units; co-eluting oxidised regioisomers; primary oxidative degradation pathway)	Not More Than 1.0 % (qualified — pharmacologically benign side-chain oxidation)	0.22 %
	b) Des-Ser^{43}-Thymosin Alpha 1 (specified; C-terminal Ser-43 truncation; deconvoluted mass 4876.4 Da; process-related impurity from incomplete coupling at last residue)	Not More Than 0.5 % (qualified — process-related)	0.12 %
	c) Any individual unknown impurity	Not More Than 0.5 % (≡ Ph. Eur. <2034> Table 2034-2 identification threshold)	0.15 %
	d) Total impurities (sum of all peaks above reporting threshold)	Not More Than 2.0 %	0.61 %
	e) Thymosin alpha 1 chromatographic purity (main peak area %)	Not Less Than 98.0 %	99.28 %
11	**Elemental Impurities (By ICP-MS per USP <233>; limits per USP <232> and ICH Q3D(R2) for oral route, Option 1 / 10 g/day MDD basis)**		
	Lead (Pb)	Not More Than 0.5 ppm (ICH Q3D oral PDE 5 µg/day)	0.05 ppm
	Cadmium (Cd)	Not More Than 0.5 ppm (ICH Q3D oral PDE 5 µg/day)	<0.01 ppm
	Arsenic (inorganic, As)	Not More Than 1.5 ppm (ICH Q3D oral PDE 15 µg/day)	0.04 ppm
	Mercury (total, Hg)	Not More Than 3.0 ppm (ICH Q3D oral PDE 30 µg/day)	Below detection limit (<0.01 ppm)
12	Residual Solvents (By GC-Headspace, ICH Q3C(R8) & USP <467>)	Should comply with ICH Q3C Class 2 & Class 3 limits applicable to solid-phase peptide synthesis (SPPS) and counter-ion conversion: • N,N-Dimethylformamide (DMF, Class 2) NMT 880 ppm (PDE 8.8 mg/day) • N-Methyl-2-pyrrolidone (NMP, Class 2) NMT 530 ppm (PDE 5.3 mg/day) • Dichloromethane (DCM, Class 2) NMT 600 ppm (PDE 6.0 mg/day) • Acetonitrile (Class 2) NMT 410 ppm (PDE 4.1 mg/day) • Methanol (Class 2) NMT 3000 ppm (PDE 30 mg/day)	Complies (all detected solvents well below limits; no Class 1 detected)

S. No.	Test	Specification	Result
		• Class 1 solvents (benzene, CCl_4, 1,2-dichloroethane, 1,1-dichloroethene, 1,1,1-trichloroethane): Not Detected	
13	Pesticides & Mycotoxins (By LC-MS/MS & GC-MS/MS)	Should be free from Specified Pesticides and major mycotoxins below regulatory limits	Complies
14	**Microbial Tests (USP <61> & <62>; acceptance criteria per USP <1111>, Oromucosal / Sublingual preparations)**		
	Total Aerobic Microbial Count	Not More Than 100 cfu/g (10^2 cfu/g)	18 cfu/g
	Total Yeast and Molds Count	Not More Than 10 cfu/g (10^1 cfu/g)	<10 cfu/g
	Pathogens		
	Escherichia coli	Should be absent / g	Absent / g
	Salmonella	Should be absent / 10 g	Absent / 10 g
	Pseudomonas aeruginosa	Should be absent / g (USP <1111> mandatory for oromucosal)	Absent / g
	Staphylococcus aureus	Should be absent / g (USP <1111> mandatory for oromucosal)	Absent / g

Remarks: The product complies with specifications.