



Certificate of Analysis

Product Name: Thymalfasin
Batch No.: HDC20240225
Manufacturing Date: Feb 25th, 2024
Report Date: Feb 26th, 2024

CAS No.: 69440-99-9
Batch Quantity: 558.826g
Retest Date: Feb 24th, 2026
Standard: In-house

Test Items	Specifications	Test Results
Appearance	White or almost white powder or loose lump	Conforms
Solubility	Insoluble in acetonitrile, ether and chloroform, slightly soluble in water, soluble in trifluoroacetic acid	Conforms
Specific optical rotation	-100.0° to -110.0° (anhydrous and acetic acid-free substance)	-108.6°
Identification	(1) The chemical identification reaction of the substance should be blue-purple (Positive reaction)	Conforms
	(2) The retention time of the principal peak of the test solution corresponds to that of the reference solution, as obtained in the Assay	Conforms
	(3) The molecular weight measured by mass spectrometry should be 3108.3±1	3108.2
Amino acid analysis	Aspartic acid: 3.4 ~ 4.6	4.02
	Glutamic acid: 5.4 ~ 6.6	5.72
	Serine: 2.4 ~ 3.6	2.43
	Threonine: 2.4 ~ 3.6	2.74
	Alanine: 2.7 ~ 3.3	2.95
	Valine: 2.4 ~ 3.6	2.54
	Leucine: 0.8 ~ 1.2	0.99
	Isoleucine: 0.8 ~ 1.2	1.01
Lysine: 3.4 ~ 4.6	4.32	
Appearance of solution	The solution should be clear and colorless. If turbid, it should not be thicker than that of reference suspension 1	Conforms
Acetic acid	Not more than 5.0%	Not detected
Related substances	Impurity I: Not more than 1.0%	0.09%
	Impurity II: Not more than 1.0%	0.27%
	Impurity III: Not more than 1.0%	0.48%
	Unspecified impurity: Not more than 0.5%	0.07%
	Total impurities: Not more than 3.0%	1.1%
Water	Not more than 5.0%	1.2%
Assay	95.0% ~ 105.0% (anhydrous and acetic acid-free substance)	99.9%
Bacterial endotoxin	Less than 5 EU/mg	Conforms



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Microbial Limits	TAMC: Not more than 100 CFU/g	Conforms
	TYMC: Not more than 50 CFU/g	Conforms
Residual Solvents	Methanol: Not more than 3000 ppm	Not detected
	Ether: Not more than 1000 ppm	Not detected
	Acetonitrile: Not more than 410 ppm	3 ppm
	Methylene chloride: Not more than 600 ppm	Not detected
	DMF: Not more than 880 ppm	3 ppm
	Trifluoroacetic acid: Not more than 5000 ppm	Not detected
Conclusion	The testing results of this batch are complied with the Standard of In-house.	

Storage Conditions: Preserved in airtight containers at a temperature of 2-8C, protected from sunlight and moisture.