SYMED LABS LIMITED

UNIT-II, Plot No.25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M),
Medchal-Malkajgiri District – 500 055, Telangana State, INDIA. Tel:+ 91 40 23635060
URL: http//www.symedlabs.com, CIN: U24231TG1998PLC029961

Certificate of Analysis

Product	:	THALIDOMIDE	Reference	:	In-House
Batch No.	:	2AK(m)0050625	Batch Quantity	:	60.85 Kg
Date of Manufacture	:	Jun' - 2025	Date of analysis	:	31/07/2025
Expiry date	:	May -2030	A.R. No.	:	02FP25002398
Storage conditions	:	Preserve in tight containers and store at controlled room temperature.			

S.No.	Test	Specification	Results
1.	Description	A white to off white powder	A white powder
2.	Solubility	Soluble in Dimethylformamide and Pyridine.	Complies
3.	a) Identification by IR	The IR absorption spectrum of the test sample should be similar to the Thalidomide working standard.	Matches with the spectrum of standard
	b) Identification by HPLC	The retention time of Thalidomide peak of the sample solution corresponds to that of standard solution as obtained in the assay	Matches with the retention time of standard
4.	Water content by Coulorometric titration	Not more than 0.5%w/w	0.03 %w/w
5.	Optical Rotation	Between (–) 0.10° and (+) 0.10°	(+) 0.00°
6.	Sulphated Ash	Not more than 0.2 %w/w	0.03 %w/w
7.	Limit of Glutamine (Ordinary impurities by TLC)	Not more than 0.1%	Less than 0.1%
8.	Organic Impurities	Any individual impurity : Not more than 0.1%	0.02 %
		Total impurities : Not more than 0.3%	0.04 %
9.	Assay On anhydrous basis (by HPLC)	Not less than 98.0%w/w and not more than 101.5%w/w	99.8 %w/w
10.	Microbial enumeration tests		
	a) Total Aerobic Microbial Count	Not more than 1000 cfu/g	Less than 10 cfu/g
	b) Total Combined Yeasts and Moulds Count	Not more than 100 cfu/g	Less than 10 cfu/g
	c) Tests for Specified Microorganisms		
	i) Escherichia Coli	Should be absent/g	Absent
	ii) Pseudomonas aeruginosa	Should be absent/g	Absent
	iii) Salmonella species	Should be absent/10g	Absent
	iv) staphylococcus aureus	Should be absent/g	Absent
	v) Bile tolerant gram negative bacteria	Should be absent/g	Absent

Corp. Office: Plot No. 290, Srivalli's Corporate, Road No.6, Kakatiya Hills, Madhapur,Hyderabad-81 Telangana, INDIA.Tel: +91 40 23635000,Fax: +91 40 23549428

SYMED LABS LIMITED

UNIT-II, Plot No.25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M),
Medchal-Malkajgiri District – 500 055, Telangana State, INDIA. Tel:+ 91 40 23635060
URL: http//www.symedlabs.com, CIN: U24231TG1998PLC029961

Certificate of Analysis

Product	: **THALIDOMIDE**	Reference	: In-House
Batch No.	: 2AK(m)0050625	Batch Quantity	: 60.85 Kg
Date of Manufacture	: Jun' - 2025	Date of analysis	: 31/07/2025
Expiry date	: May -2030	A.R. No.	: 02FP25002398
Storage conditions	: Preserve in tight containers and store at controlled room temperature.		

S.No.	Test	Specification	Results
11.	Residual solvents by GC		
	Ethanol	Not more than 5000 ppm	Not detected (LOQ=60.0 ppm)
	Toluene	Not more than 890 ppm	Not detected (LOQ=9.2 ppm)
	DMF	Not more than 880 ppm	317.5 ppm

The product **conforms** to the above specifications.

Approved Signatory (QC)
Name : K.Ravi Kumar
Designation : Asst.Manager
Date 04/08/25

Authorized signatory (QA)
Name : K.Sunil Kumar
Designation : Asst.Manager
Date 04/08/25

Corp. Office: Plot No. 290, Srivalli's Corporate, Road No.6, Kakatiya Hills, Madhapur,Hyderabad-81 Telangana, INDIA.Tel: +91 40 23635000,Fax: +91 40 23549428