Shilpa Pharma Lifesciences Limited

Unit-1: Plot No. 1A & 1A 'P', 1B, 2, 2A, 2B, 3A to 3E, 4A, 5A, 4B & 5B, Deosugur Industrial Area, Deosugur-584 170, Raichur District, Karnataka State, India.

CIN: U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Name of the Material	: THALIDOMIDE		
Production Batch No.	: TD3 210014	Drug License No.	: KTK/25/256/89
Batch Quantity	: 21.02 Kg	Sample Quantity	: 80 g
Mfg. Date	: NOV-2021	Approved on	: 29.12.2021
Retest Date	: OCT-2025	Ref A.R. No.	: 40000061760

S.No.	Tests	Results	Specifications
01.	Description *USP*	White powder	A white to off white powder.
02.	Solubility *USP*	Confirms	Soluble in Dimethyl formamide and in pyridine.
03.	Identification		
	▪ By Infra-red spectrophotometer *USP197K*	Confirms	The Infrared absorption spectrum of the sample should be concordant with the spectrum obtained from standard.
	▪ By HPLC *USP621*	Confirms	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC test.
	▪ By XRD *In-house*	Confirms	Thalidomide (α-form)should exhibit the XRD pattern characterized by 2θ values at 11.3°(±0.2°); 14.3°(±0.2°) 19.2°(±0.2°);22.8°(±0.2°);26.1°(±0.2°) and 30.4°(±0.2°).
04.	Water content by coulometer *USP921Method Ic*	0.03%	Not more than 0.50% w/w
05.	Residue on ignition *USP 281*	0.05%	Not more than 0.10% w/w
06.	Assay By HPLC *USP 621*	99.5%	Between 98.0% to 101.5% w/w(On anhydrous basis)
07.	Related Substances By HPLC *USP 621*		
	▪ Phthalic acid	Not detected	Not more than 0.10% w/w (LOQ: 0.03%)
	▪ Any individual impurity	0.02%	Not more than 0.10% w/w
	▪ Total impurities	0.03%	Not more than 0.30% w/w
08.	Glutamine Content by HPLC *USP 466*	Not detected	Not more than 0.1% w/w (LOQ: 0.03%)
09.	Residual Solvent By GC *In-house*		
	▪ Methanol	Below LOQ	Not more than 3000 ppm (LOQ:51 ppm)
	▪ Acetone	284 ppm	Not more than 5000 ppm (LOQ:15 ppm)
	▪ Toluene	Below LOQ	Not more than 890 ppm (LOQ:16 ppm)
	▪ N,N Dimethylformamide	229 ppm	Not more than 880 ppm (LOQ:203 ppm)
	▪ Dimethyl sulfoxide	Below LOQ	Not more than 5000 ppm (LOQ:800 ppm)
10.	Microbial enumeration tests *USP 61*		
	▪ Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 cfu/g
	▪ Total combined molds & yeasts counts	Less than 10 cfu/g	Not more than 100 cfu/g
	Tests for specified microorganisms *USP 62*		
	▪ *Escherichia coli*	Absent	Should be absent
	▪ *Bile-Tolererant Gram negative Bacteria*	Absent	Should be absent
	▪ *Salmonella*	Absent	Should be absent
	▪ *Pseudomonas aeruginosa*	Absent	Should be absent
	▪ *Staphylococcus aureus*	Absent	Should be absent
	▪ *Clostridia*	Absent	Should be absent
	▪ *Candida albicans*	Absent	Should be absent
11.	Imidazole content By HPLC *In-house*	Below LOQ	Not more than 0.10% w/w (LOQ : 0.010%)

Storage conditions: Preserve in tight Containers, protected from light. Store at controlled room temperature (20°C to 25°C)

Remarks: The material complies with the above respective Specifications of USP/IH. * LOQ: Limit of Quantitation.

	Prepared by	Checked by	Approved by
Name	D.Lokeswara Rao	Rajendra S.Nikam	O.Maheswara Reddy
Designation	Sr.Executive-QC	Asst.Manager-QC	Dy.Manager-QA
Sign & Date	D.L 02/08/22	02/08/22	02/08/22

Shilpa Pharma Lifesciences Limited

Unit-1: Plot No. 1A & 1A 'P', 1B, 2, 2A, 2B, 3A to 3E, 4A, 5A, 4B & 5B, Deosugur Industrial Area, Deosugur-584 170, Raichur District, Karnataka State, India.

CIN: U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Name of the Material	: THALIDOMIDE		
Production Batch No.	: TD3 210013	Drug License No.	: KTK/25/256/89
Batch Quantity	: 20.80 Kg	Sample Quantity	: 80 g
Mfg. Date	: NOV-2021	Approved on	: 29.12.2021
Retest Date	: OCT-2025	Ref A.R. No.	: 40000061630

S.No.	Tests	Results	Specifications
01.	Description *USP*	White powder	A white to off white powder.
02.	Solubility *USP*	Confirms	Soluble in Dimethyl formamide and in pyridine.
03.	Identification		
	▪ By Infra-red spectrophotometer *USP197K*	Confirms	The Infrared absorption spectrum of the sample should be concordant with the spectrum obtained from standard.
	▪ By HPLC *USP621*	Confirms	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC test.
	▪ By XRD *In-house*	Confirms	Thalidomide (α-form)should exhibit the XRD pattern characterized by 2θ values at 11.3°(±0.2°); 14.3°(±0.2°) 19.2°(±0.2°);22.8°(±0.2°);26.1°(±0.2°) and 30.4°(±0.2°).
04.	Water content by coulometer *USP921Method Ic*	0.04%	Not more than 0.50% w/w
05.	Residue on ignition *USP 281*	0.05%	Not more than 0.10% w/w
06.	Assay By HPLC *USP 621*	99.3%	Between 98.0% to 101.5% w/w(On anhydrous basis)
07.	Related Substances By HPLC *USP 621*		
	▪ Phthalic acid	Not detected	Not more than 0.10% w/w (LOQ: 0.03%)
	▪ Any individual impurity	0.01%	Not more than 0.10% w/w
	▪ Total impurities	0.01%	Not more than 0.30% w/w
08.	Glutamine Content by HPLC *USP 466*	Not detected	Not more than 0.1% w/w (LOQ: 0.03%)
09.	Residual Solvent By GC *In-house*		
	▪ Methanol	54 ppm	Not more than 3000 ppm (LOQ:51 ppm)
	▪ Acetone	138 ppm	Not more than 5000 ppm (LOQ:15 ppm)
	▪ Toluene	Below LOQ	Not more than 890 ppm (LOQ:16 ppm)
	▪ N,N Dimethylformamide	222 ppm	Not more than 880 ppm (LOQ:203 ppm)
	▪ Dimethyl sulfoxide	Below LOQ	Not more than 5000 ppm (LOQ:800 ppm)
10.	Microbial enumeration tests *USP 61*		
	▪ Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 cfu/g
	▪ Total combined molds & yeasts counts	Less than 10 cfu/g	Not more than 100 cfu/g
	Tests for specified microorganisms *USP 62*		
	▪ *Escherichia coli*	Absent	Should be absent
	▪ *Bile-Tolererant Gram negative Bacteria*	Absent	Should be absent
	▪ *Salmonella*	Absent	Should be absent
	▪ *Pseudomonas aeruginosa*	Absent	Should be absent
	▪ *Staphylococcus aureus*	Absent	Should be absent
	▪ *Clostridia*	Absent	Should be absent
	▪ *Candida albicans*	Absent	Should be absent
11.	Imidazole content By HPLC *In-house*	Below LOQ	Not more than 0.10% w/w (LOQ : 0.010%)

Storage conditions: Preserve in tight Containers, protected from light. Store at controlled room temperature (20°C to 25°C)

Remarks: The material complies with the above respective Specifications of USP/IH. * LOQ: Limit of Quantitation.

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Name	D.Lokeswara Rao	Rajendra S.Nikam	O.Maheswara Reddy
Designation	Sr.Executive-QC	Asst.Manager-QC	Dy.Manager-QA
Sign & Date	D. L 02/08/22	02/08/22	02/08/22

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CIN: U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Name of the Material	: THALIDOMIDE		
Production Batch No.	: TD3 200023	Drug License No.	: KTK/25/256/89
Batch Quantity	: 20.09 Kg	Sample Quantity	: 80 g
Mfg. Date	: OCT-2020	Approved on	: 23.10.2020
Retest Date	: SEP-2024	Ref A.R. No.	: 40000045055

S.No.	Tests	Results	Specifications
01.	Description *USP*	White powder	A white to off white powder.
02.	Solubility *USP*	Confirms	Soluble in Dimethyl formamide and in pyridine.
03.	Identification		
	▪ By Infra-red spectrophotometer *USP197K*	Confirms	The Infrared absorption spectrum of the sample should be concordant with the spectrum obtained from standard.
	▪ By HPLC *USP621*	Confirms	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC test.
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04.	Water content by coulometer *USP921Method Ic*	0.05%	Not more than 0.50% w/w
05.	Residue on ignition *USP 281*	0.06%	Not more than 0.10% w/w
06.	Assay By HPLC *USP 621*	99.7%	Between 98.0% to 101.5% w/w(On anhydrous basis)
07.	Related Substances By HPLC *USP 621*		
	▪ Phthalic acid	Not detected	Not more than 0.10% w/w (LOQ: 0.03%)
	▪ Any individual impurity	0.01%	Not more than 0.10% w/w
	▪ Total impurities	0.02%	Not more than 0.30% w/w
08.	Glutamine Content by HPLC *USP 466*	Not detected	Not more than 0.1% w/w (LOQ: 0.03%)
09.	Residual Solvent By GC *In-house*		
	▪ Methanol	54 ppm	Not more than 3000 ppm (LOQ:51 ppm)
	▪ Acetone	222 ppm	Not more than 5000 ppm (LOQ:15 ppm)
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	▪ Dimethyl sulfoxide	Not detected	Not more than 5000 ppm (LOQ:800 ppm)
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	▪ Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 cfu/g
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	▪ *Escherichia coli*	Absent	Should be absent
	▪ *Bile-Tolererant Gram negative Bacteria*	Absent	Should be absent
	▪ *Salmonella*	Absent	Should be absent
	▪ *Pseudomonas aeruginosa*	Absent	Should be absent
	▪ *Staphylococcus aureus*	Absent	Should be absent
	▪ *Clostridia*	Absent	Should be absent
	▪ *Candida albicans*	Absent	Should be absent
11.	Imidazole content By HPLC *In-house*	0.01%	Not more than 0.10% w/w (LOQ : 0.010%)

Storage conditions: Preserve in tight Containers, protected from light. Store at controlled room temperature (20°C to 25°C)

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