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 : TEMOZOLOMIDE EP			
Commercial Batch No. : Will be assigned after approval			
Production Batch No. : TPM2220019			Drug License No. : KTK/25/256/89
Batch quantity : 20.52 Kg			Dispatch Quantity: 240 g
Mfg. Date : MAR-2022			Approved on : 26.03.2022
Retest Date : FEB-2025			Ref. A.R No. : 40000067435
S.No.	**Tests**	**Results**	**Specifications**
01.	Appearance *Ph.Eur.1.4*	Slightly pink powder	White or slightly brown or slightly pink powder.
02.	Solubility *Ph.Eur.1.4*	Confirms	Slightly soluble in water, soluble in dimethyl sulfoxide very slightly soluble in ethanol(96 percent) and practically insoluble in toluene.
03.	Identification		
	▪ By FTIR *Ph.Eur.2.2.24*	Confirms	The Infrared absorption spectrum of the Temozolomide should concordant with the spectrum obtained from Temozolomide standard.
	▪ By HPLC *Ph.Eur.*2.2.29	Confirms	The principal peak in the chromatogram obtained with the test solution (b) is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (d) in the assay.
	▪ By XRD *In-house*	Confirms	The X-ray diffractogram of the sample should confirm with polymorph form 1A.
04.	Related Substances By HPLC *Ph.Eur.2.2.29*		
	▪ Impurity-A(Sum of the peaks)	Not detected	Not more than 0.15% w/w
	▪ Impurity-B	Not detected	Not more than 0.15% w/w
	▪ Impurity-D	Not detected	Not more than 0.10% w/w
	▪ Impurity-E	Not detected	Not more than 0.10% w/w
	▪ Each unspecified impurity	Not detected	Not more than 0.10% w/w
	▪ Total impurities	Not detected	Not more than 0.5% w/w
05.	Water content *Ph.Eur.2.5.32*	0.10%	Not more than 0.4% w/w
06.	Sulphated Ash *Ph.Eur.2.4.14*	0.05%	Not more than 0.1% w/w
07.	Assay By HPLC On anhydrous substances *Ph.Eur.2.2.29*	99.8%	Between 98.0% w/w to 102.0% w/w
Storage: Store at 2°C to 8°C, protected from light and moisture.			
Remarks: The above material complies with the respective specification EP/IH.			

	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. Lok 06/09/22	06/09/22	06/09/22

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S.No.	**Tests**	**Results**	**Specifications**
08.	Residual Solvents By GC *In-house*		
	▪ Acetonitrile	Below LOQ	Not more than 150 ppm (LOQ: 35 ppm)
	▪ Ethyl acetate	Not detected	Not more than 1000 ppm (LOQ: 31 ppm)
	▪ Acetone	Below LOQ	Not more than 2000 ppm (LOQ: 40 ppm)
	▪ Total residual solvents	Below LOQ	Not more than 2000 ppm
09.	Microbial Enumeration tests		
	A)Total viable aerobic count *Ph.Eur.2.6.12*		
	▪ Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 cfu/g
	▪ Total yeasts and molds count	Less than 10 cfu/g	Not more than 100 cfu/g
	B) Specified Microorganisms *Ph.Eur.2.6.13*		
	▪ *Escherichia coli*	Absent	Should be absent
	▪ *Pseudomonas aeruginosa*	Absent	Should be absent
	▪ *Staphylococcus aureus*	Absent	Should be absent
	▪ *Salmonella*	Absent	Should be absent
	▪ *Bile-Tolerant Gram negative Bacteria*	Absent	Should be absent
	▪ *Clostridia*	Absent	Should be absent
	▪ *Candida albicans*	Absent	Should be absent
Storage: Store at 2°C to 8°C, protected from light and moisture.			
Remarks: The above material complies with the respective specification EP/IH.			* LOQ : Limit of Quantitation

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