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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 4023191337
URL: http//www.symedlabs.com, CIN: U24231TG1998PLC029961

Quality Assurance + Quality Control Symed Labs Ltd 21/02/2020

Certificate of Analysis

Product	: ESZOPICLONE	Reference	: USP
Batch No.	: 2ESZ0030220	Batch Quantity	: 11.69 Kg
Date of Manufacture	: Feb'- 2020	Date of analysis	: 20/02/2020
Expiry date	: Jan' -2025	A.R. No.	: 02FP20000352
Storage conditions	: Preserve in tight containers. Store at controlled room temperature.		

S.No	Test	Specification	Result
1.	Description	A white or light yellow crystalline solid	A white crystalline solid
2.	Identification		
	2.1) By IR	The IR absorption spectrum of the test sample Should be similar to the IR absorption spectrum of Eszopiclone working standard.	Matches with the spectrum of standard
	2.2) By HPLC	The retention time of the major peak of the test sample solution corresponds to that of the Eszopiclone working standard peak of the resolution solution, as obtained in the Chiral purity by HPLC.	Matches with the retention time of standard
	2.3) By XRD	The Diffractogram of Eszopiclone Test sample should match with the Eszopiclone Standard sample.	Matches with the difractogram of Standard
3.	Solubility	Soluble in methylene chloride and in dilute HCl; practically insoluble in water and slightly soluble in alcohol (95% Ethanol).	Complies
4.	Loss on drying	Not more than 0.50%w/w	0.17%w/w
5.	Residue on ignition	Not more than 0.10%w/w	0.04%w/w
6.	Related substances by HPLC		
	i) Impurity-A	Not more than 0.10%	0.04%
	ii) Impurity-B	Not more than 0.10%	Not detected (LOQ = 0.0052%)
	iii) Impurity-C	Not more than 0.10%	0.01%
	iv) Any other impurity	Not more than 0.10%	0.01%
	v) Total impurities	Not more than 0.30%	0.06%

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Quality Assurance * Unit-II * Symed Labs Ltd. 21/02/2020

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S.No	Test	Specification	Result
7.	Assay by HPLC (On dried basis)	Between 98.5%w/w and 101.0%w/w	99.0%w/w
8.	Chiral purity by HPLC	R- isomer should not be more than 0.10%	0.07%
9.	Residual solvents by GC		
	i) Acetone	Not more than 5000 ppm	Not detected (LOQ = 8.0 ppm)
	ii) Methanol	Not more than 3000 ppm	Not detected (LOQ = 21.0 ppm)
	iii) IPA	Not more than 5000 ppm	589 ppm
	iv) MIBK	Not more than 4490 ppm	Not detected (LOQ = 75.0 ppm)
*10.	BOSE-V content by HPLC	Not more than 500 ppm	Not tested
#11.	Particle size	D(0.10): Not more than 10µm	3.47 µm
		D(0.50): Not more than 20µm	17.46 µm
		D(0.90): Between 30µm and 50 µm	44.22 µm

The product **conforms** to the above specifications.
LOQ = Limit of Quantitation.
* The test should be performed for 1st batch of the year and there after every 10th batch in the calendar year.
# As per the customer requirement. Reference A.R.No:02FP20000351.

Approved Signatory (QC)
Name : P.Venkata Reddy
Designation: Manager
Date P. Venkata Reddy 21/02/20

Authorized Signatory (QA)
Name : Y.Prameela jyothi
Designation: Sr.Executive
Date 21/02/2020

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