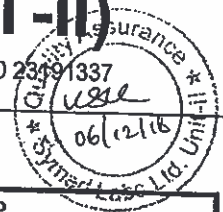


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SYMED LABS LIMITED (UNIT-II)

Plot No.25/B, Phase-III, IDA, Jeedimetla, Hyderabad – 500 055, Telangana, INDIA.Tel:+ 91 40 23491337
 URL: <http://www.symedlabs.com>, CIN: U24231TG1998PLC029961

Certificate of Analysis



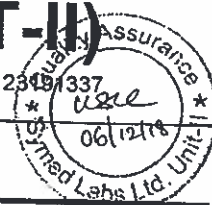
Product : ESZOPICLONE Reference : USP
 Batch No. : 2ESZ0100918 Batch Quantity : 11.80 Kg
 Date of Manufacture : Sep' - 2018 Date of analysis : 10/09/2018
 Expiry date : Aug' -2023 A.R. No. : 02FP18001413
 Storage conditions : Preserve in tight containers. Store at controlled room temperature.

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 second 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 diffractogram 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	0.33%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%	0.06%
	ii) Impurity-B	Not more than 0.10%	Not detected (LOQ = 0.0052%)
	iii) Impurity-C	Not more than 0.10%	Not detected (LOQ = 0.0065%)
	iv) Any other impurity	Not more than 0.10%	0.01%
	v) Total impurities	Not more than 0.30%	0.08%

SYMED LABS LIMITED (UNIT-II)

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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	99.9%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	989 ppm
	iv) MIBK	Not more than 4490 ppm	Not detected (LOQ = 75.0 ppm)
#10.	Particle Size(By Malvern)		
	D(0.10)	Not more than 10 μ m	3.65 μ m
	D(0.50)	Not more than 20 μ m	16.67 μ m
	D(0.90)	Between 30 μ m and 50 μ m	40.91 μ m
*11.	BOSE-V content by HPLC	Not more than 500 ppm	Not detected

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:02FP18001412.

Approved Signatory (QC)

Name : Ch.Sairam

Designation: Asst.Manager

Date

Authorized Signatory (QA)

Name : Y.Prameela Jyothi

Designation: Sr.Executive

Date

06/12/18