

CERTIFICATE OF ANALYSIS

Product Name	Mirtazapine Ph.Eur.	Page 1 of 2
Batch Number	2001104618	A.R.No. 20FPN1434
Mfg. Date	11-May-2020	Date of Release 24/05/2020
Dispatch Quantity	Not Applicable	Retest Date 10-May-2024

S.No.	Test	Specification	Result
1	Description	A white or almost white powder, hygroscopic.	A white powder hygroscopic
2	Solubility	Freely soluble in anhydrous ethanol, practically insoluble in water.	Freely soluble in anhydrous ethanol, practically insoluble in water.
3	Identification By IR	IR spectrum must exhibit maxima at the same wave numbers as the Mirtazapine working standard spectrum.	IR spectrum exhibits maxima at the same wave numbers as the Mirtazapine working standard spectrum.
4	Water (%w/w, by KF, determined on 1.000g)	Not more than 1.0	0.14
5	Sulphated ash (%w/w, determined on 1.0 g)	Not more than 0.1	0.05
6	Optical rotation(°) (α, at D-line of sodium measured at 20°C, c=1, in anhydrous ethanol, on anhydrous basis)	Between -0.10 and +0.10	0.000
7	Assay (By Titrimetry, %w/w, as C ₁₇ H ₁₉ N ₃ , on anhydrous basis)	Not less than 99.0 and Not more than 101.0	99.8
8	Residual solvents (By GC, µg/g) Cyclohexane	Not more than 1000	146

	Prepared By	Checked By	Approved By
Signature			
Date	09/09/2020	09/09/2020	09/09/2020

Format No.: AQA023-F05-01

AUROBINDO PHARMA LTD

Unit I: Survey No.379, 385, 386, 388 to 396, Borpatla (Village), Hatnoora (Mandal), Sanga Reddy (District), Telangana (State), INDIA. PIN : 502 296,
Tel : +91 8458 230 250, 230 251, 230 314, Fax : +91 8458 230 315.

Regd. Off: Plot No. 2, Maitri vihar, Ameerpet, Hyderabad - 500 038. Telangana, INDIA Tel : +91 40 6672 5000 Fax : +91 40 2374 6833, 2374 1080

PAN No. AABCA7366H

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S.No.	Test	Specification	Result
9	Related substances (By HPLC, % w/w)		
	Mirtazapine Related Compound A	Not more than 0.1	Not detected
	[Ph.Eur. Impurity A] [Mirtazapine oxide]		
	Mirtazapine Related Compound B	Not more than 0.1	Below LOQ
	[Ph.Eur. Impurity B] [Mirtazapine penultimate]		
	Mirtazapine Related Compound C	Not more than 0.1	Below LOQ
	[Ph.Eur. Impurity D] [Desmethyl Mirtazapine]		
	Mirtazapine Related Compound D	Not more than 0.1	Not detected
	[Ph.Eur. Impurity E] [Deshydroxy compound]		
10	Mirtazapine Related Compound E	Not more than 0.1	Not detected
	[Ph.Eur. Impurity F] [Oxo Mirtazapine]		
	Any other	Not more than 0.10	Not detected
	Total	Not more than 0.2	0.00
10	Microbiological Quality		
	a. Total aerobic microbial count (TAMC), (cfu/g)	Not more than 1000	Less than 10
	Total combined yeasts /moulds count (TYMC), (cfu/g)	Not more than 100	Less than 10
	b. Escherichia coli	Must be absent	Absent
Additional tests:			
11	Assay (By HPLC, % w/w, as C ₁₇ H ₁₉ N ₃ , on anhydrous basis)	Not less than 99.0 and Not more than 101.0	100.3
12	Particle size (µm, By Malvern particle size analyzer)		
	D (v, 0.5)	Report results	102
	D (v, 0.9)		257
13	Bulk density (g/ml)		
	Untapped	Report results	0.43
	Tapped		0.74

REMARKS: The material complies as per above specification.

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