

# QA RELEASE

Sign & Date Aaale/10/11/2022  
Stamp Identification No.: N-A/QAR/001



## CERTIFICATE OF ANALYSIS

<b>Product</b>	: Mirtazapine Hemihydrate Ph.Eur.	<b>Customer Name</b>	: Fac Secundam Artem NV (Magis Pharma), Belgium
<b>Batch No.</b>	: MH2209006	<b>Mfg. Month</b>	: 09/2022
<b>Batch Quantity</b>	: 258.30 Kg	<b>Exp. Month</b>	: 08/2027
<b>Dispatch Quantity</b>	: 10.00 Kg	<b>Date Analysed</b>	: 22/10/2022
<b>Analytical Report No.</b>	: ARFP2200815	<b>Specification No.</b>	: S-FP-MH-02-10
<b>Reference</b>	: Ph.Eur.	<b>Status</b>	: Initial
<b>Mfg. Site</b>	: Plot No.-1 to 5, 31 to 35, 48 to 51, 26 & K/201, Lakhmapur, Tal. Dindori, Dist. Nashik-422 202, Maharashtra, India		
<b>Storage</b>	: Store in a well closed container between 15°C - 30°C.		

S.No.	TEST	RESULT	SPECIFICATION
1.0	Appearance	White powder, slightly hygroscopic.	White or almost white powder, slightly hygroscopic to hygroscopic.
2.0	Solubility	Complies	Practically insoluble in water, freely soluble in anhydrous ethanol.
3.0	Identification by		
	3.1) IR	Complies	IR spectrum of sample shall match with IR spectrum of standard.
4.0	Optical Rotation (Anhydrous substance)	+ 0.002°	Between -0.10° and +0.10°
5.0	Related Substances by HPLC		
	5.1) Impurity A	Not detected	Not more than 0.1%
	5.2) Impurity B	Not detected	Not more than 0.1%
	5.3) Impurity C	Not detected	Not more than 0.1%
	5.4) Impurity D	Not detected	Not more than 0.1%
	5.5) Impurity E	Not detected	Not more than 0.1%
	5.6) Impurity F	Not detected	Not more than 0.1%
	5.7) Unspecified Impurities	BQL (LOQ is 0.020%)	Not more than 0.10%
	5.8) Total impurities	0.00%	Not more than 0.2%
6.0	Water Content	2.61% w/w	Maximum 3.5% w/w
7.0	Sulfated Ash	0.05% w/w	Maximum 0.1% w/w
8.0	Assay (Anhydrous substance)	100.0%	99.0% to 101.0%
9.0	Residual solvents by GC		
	9.1) Methanol	1225 ppm	Not more than 2000 ppm
	9.2) Di-isopropyl Ether	BQL (LOQ is 175 ppm)	Not more than 500 ppm
	9.3) Ethyl acetate	Not detected	Not more than 500 ppm
	9.4) Toluene	BQL (LOQ is 39 ppm)	Not more than 100 ppm
10.0	Benzene content by HS GC	Not detected	Not more than 2 ppm

The product CONFORMS to the above specification.

USP IMP A/EP Imp. A : (14bRS)-2-Methyl-1,2,3,4,10,14b-hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine 2-oxide. (Mirtazapine N-oxide)

USP IMP B/EP Imp. B : [2-[(2RS)-4-Methyl-2-phenylpiperazin-1-yl]pyridin-3-yl]methanol. (Acyclomirtazapine alcohol)

USP IMP C/EP Imp. C : (14bRS)-2-Methyl-3,4,10,14b-tetrahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepin-1(2H)-one. (1-Ketomirtazapine)

USP IMP D/EP Imp. D : (14bRS)-1,2,3,4,10,14b-hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine. (Desmethyilmirtazapine)

USP IMP E/EP Imp. E : (2RS)-4-Methyl-1-(3-methylpyridin-2-yl)-2-phenylpiperazine. (Acyclomirtazapine methyl Derivative)

USP IMP F/EP Imp. F : (14bRS)-2-Methyl-1,3,4,14b-tetrahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepin-10(2H)-one. (10-Ketomirtazapine)

BQL = Below Quantification Limit

LOQ = Limit of Quantification

Prepared by (QC)

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10/11/2022

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### PLANT:

Plot No. - 1 to 5, 31 to 35, 48 to 51, 26 &  
K/201, Lakhmapur, Tal. Dindori,  
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### PLANT:

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