

MIRTAZAPINUM 100 g

Lot No.: 23B21-APR23073

Autorisation :	1890R06228	Date Of Analysis :	12/12/2022
Analytical Reference :	Ph. Eur. 10.8 [07/2009 :2338] Corr. 9.0	Production Number :	010323-GS22164
CNK :	4683-314	Expiry Date :	08/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder, slightly hygroscopic to hygroscopic	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification	The spectrum complies with the spectrum obtained with mirtazapine CRS	Complies
TESTS	SPECIFICATION	RESULT
Optical rotation	- 0.10° to + 0.10° (anhydrous substance)	0.00°
Related substances		
Impurity A	≤ 0.1%	< 0.05%
Impurity B	≤ 0.1%	< 0.05%
Impurity C	≤ 0.1%	< 0.05%
Impurity D	≤ 0.1%	< 0.05%
Impurity E	≤ 0.1%	< 0.05%
Impurity F	≤ 0.1%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.2%	< 0.05%
Water	≤ 3.5%	2.6%
Sulfated ash	≤ 0.1%	0.02%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0 % to 101.0 % (anhydrous substance)	100.3%
Manufacturer identification code: S/GS/174		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: