



ANALYSIS CERTIFICATE

FDA Labeler Code No. 053296

PRODUCT: MIRTAPAZINE EP

Certificate of Analysis No. : 17A0337/01

Lot No. : A-170320

Quantity. : 0 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
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Description

White or almost white

Conforms

powder, slightly

hygroscopic to hygroscopic.

Identification

I.R.

Conforms

Optical Rotation

-0.10° to + 0.10°

0 °

-0.00°

Water

NMT 3.5%

0.22 %

Sulfated ash

NMT 0.1%

Less than 0.05 %

Related Substances. Impurity A

NMT 0.1%

Less than 0.05 %

Related Substances. Impurity B

NMT 0.1%

Less than 0.05 %

Related Substances. Impurity C

NMT 0.1%

Less than 0.05 %

Related Substances. Impurity D

NMT 0.1%

Less than 0.05 %

Related Substances. Impurity E

NMT 0.1%

Less than 0.05 %

Related Substances. Impurity F

NMT 0.1%

Less than 0.05 %

Related Substances. Any unspecified impurity

NMT 0.10%

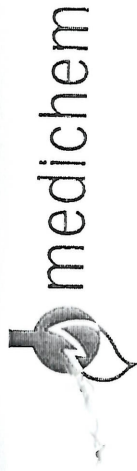
Less than 0.05 %

Printed date: July 21, 2017

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ANALYTICAL DATA		SPECIFICATIONS	RESULTS	NOTES
Related Substances. Total impurities		NMT 0.2%	Less than 0.05 %	
Assay		99.0-101.0% (anhydrous substance)	99.9 %	
Residual solvents. Ethyl acetate		NMT 2000 ppm	Less than 100 ppm	
Residual solvents. Toluene		NMT 200 ppm	Less than 100 ppm	

Manufacturing Date June 22, 2017
Re-Test date June 22, 2022


Analyst


21-07-17
Head of Quality Control

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