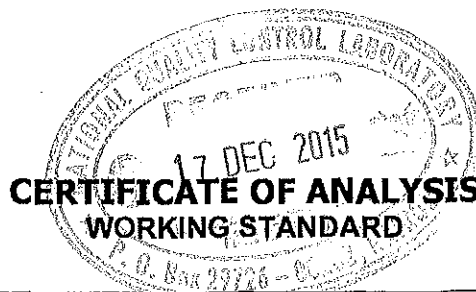


WRS
N16-1



LUPIN



CERTIFICATE OF ANALYSIS
WORKING STANDARD

Material	: NORETHINDRONE USP	Version No.	: 00
Working Standard No.	: QC1/WS/IN/N003/04	Vendor Batch No.	: 124136003
Material Code	: 307635	Expiry Date	: NOV-2017
Mfg. Date	: DEC-2012	Effective Date	: 30/09/2015
Mfg. By	: Lupin Ltd.	Use Before Date	: 25/09/2016
Standardized against	: USPRS Lot No.:L0F237	Storage Condition	: 2°C to 8°C
Specification No.	: FPB-307635-USA-03		

Sr. No.	TESTS	OBSERVATIONS	SPECIFICATIONS
01	Description	White crystalline powder	White to creamy white odourless crystalline powder.
02	Identification (By IR)	IR spectrum of the test is concordant with the IR spectrum of the standard obtained in the same manner.	IR spectrum of the test is concordant with the IR spectrum of the standard, obtained in the same manner.
03	Loss on Drying (At 105°C in vacuum for 3 hrs.)	0.24% w/w	Not more than 0.50 % w/w
04	Assay (By HPLC, on dried basis)	99.2%	Between 98.0% to 101.0%
05	Assay (By HPLC, on as is basis)	99.0 %	For Information

Note: i) Odour test is not performed in Description.

Remark: The material complies / Does not comply as per above specification and can be/can not be used as Working Standard.

Prepared by	Checked by	Approved by
 30/09/15	 30/09/15	 30/09/15

Lupin Limited

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