



LUPIN

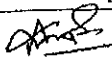
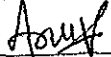

CERTIFICATE OF ANALYSIS
WORKING STANDARD

Material	: LEVONORGESTREL USP	Version No.	: 00
Working Standard No.	: QC1/WS/IN/L001/05	Vendor Batch No.	: P3000034
Material Code	: 307617	Expiry Date	: DEC-2017
Mfg. Date	: JAN-2013	Effective Date	: 25/09/2015
Mfg. By	: Lupin Ltd.	Use Before Date	: 22/09/2016
Standardized against	: USPRS Lot No. G0L474	Storage Condition	: 2°C to 8°C
Specification No.	: FPB-307617-USA-02		

Sr. No.	TESTS	OBSERVATIONS	SPECIFICATIONS
01	Description	White crystalline powder.	White or practically white, odorless 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 should be concordant with the IR spectrum of the standard obtained in the same manner.
03	Loss on drying	0.30 % w/w	Not more than 0.5% w/w
04	Assay (By HPLC ,on dried basis)	100.0 %	Between 98.0% and 102.0%
05	Assay (By HPLC ,on as is basis)	99.7 %	For Information

Note: Odor test is not performed.

Remarks: 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
 25/09/15	 28/09/15	 25/09/15

Lupin Limited

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