



CERTIFICATE OF ANALYSIS WORKING STANDARD

Material	: ETHINYL ESTRADIOL USP	Version No.	: 01
Working Standard No.	: QC1/WS/IN/E001/04	Vendor Batch No.	: P4000155
Material Code	: 307656	Expiry Date	: NOV-2019
Mfg. Date	: DEC-2014	Effective Date	: 02/02/2015
Mfg. By	: Lupin Ltd.	Use Before Date	: 30/01/2016
Standardized against	: USPRS Lot No. ROM195	Storage Condition	: 2°C to 8°C
Specification No.	: FPB-307656-USA-04		

Sr. No.	TESTS	OBSERVATION	SPECIFICATIONS
01	Description	White crystalline powder.	White to creamy white crystalline powder.
02	Solubility*	Practically insoluble in water, Soluble in chloroform and in ether. Freely soluble in alcohol.	Practically insoluble in water, Soluble in chloroform and in ether. Freely soluble in alcohol.
03	A. Identification (By IR)	Infrared spectrum of the test is concordant with the Infrared spectrum of the standard, obtained in the same manner.	Infrared spectrum of the test is concordant with the Infrared spectrum of the standard, obtained in the same manner.
	B. By TLC *	The principle spot in the chromatogram obtained with test solution is similar in position, colour, fluorescence and size to the principle spot in the chromatogram obtained with reference solution.	The principle spot in the chromatogram obtained with test solution is similar in position, colour, fluorescence and size to the principle spot in the chromatogram obtained with reference solution.
	C. By UV(50µg/mL in alcohol at 281nm, on dried basis) *	Absorptivities differ by 1.7% of standard.	Absorptivities not differ by more than 3.0% of standard.
04	Completeness of solution(100mg in 5 mL of alcohol) *	Solution is clear and free from undissolved solid.	Solution is clear and free from undissolved solid.
05	Specific rotation (1.25g in 25mL, of pyridine, on dried basis) *	-28.1°	Between -28.0° and -29.5°
06	Melting range*	183.6°-184.0°C No melting observed between 142°C and 146°C and the range between beginning and end of melting does not exceed 2°C.	Between 180° and 186°C No melting should observed between 142°C and 146°C and the range between beginning and of melting does not exceed 2°C.

Prepared by <i>[Signature]</i> 20/07/15	Checked by <i>[Signature]</i> 20/07/15	Approved by <i>[Signature]</i> 20/07/15
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Lupin Limited

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