

CERTIFICATE OF ANALYSIS

NO. : 066/2014
 PRODUCT : YOHIMBINE HYDROCHLORIDE EP
 DATE OF MFG : 10/02/2014
 QUANTITY : 1.00 Kg.
 DATE OF EXPIRY: 09/02/2019

DATE OF ISSUING : 21/02/2014
 BATCH NO. : 864302502001
 MFG BY :
 BATCH SIZE : 20.00 Kgs.

SAMPLING DATA		
DATE OF SAMPLING : 17/02/2014		SAMPLE QUANTITY: 60 gms.
ANALYSIS RECORD		
QUANTITY ACTUALLY USED IN ANALYSIS : 15 gms PRODUCT SPECIFICATION NO.: 8643/E-Rev.01		
QUANTITY RETAINED AS CONTROL SAMPLE: 45 gms ANALYTICAL PROTOCOL NO. : 8643/E Rev.01		
TESTS	REQUIREMENT/LIMIT	RESULTS
APPEARANCE	White or slightly yellowish crystalline powder.	Slightly yellowish crystalline powder.
SOLUBILITY	Sparingly soluble (1gm in 30 to 100ml) in water, practically insoluble (1gm in more than 10,000ml) in ethanol (96 percent) and in methylene chloride.	Sparingly soluble in water, practically insoluble in ethanol (96 percent) and in methylene chloride.
IDENTIFICATION	A. Infrared absorption spectrophotometry (2.2.24). B. It gives reaction (a) of chlorides (2.3.1).	Complies with Infrared absorption spectrophotometry. It gives reaction (a) of chlorides.
pH (for solution S)	3.5 to 5.5	4.85
SPECIFIC OPTICAL ROTATION (dried substance)	(+101° to +105°	(+103.2°
RELATED SUBSTANCES		
(i) Sum of impurities A & G	NMT 1.0%	0.05%
(ii) impurity F	NMT 0.4%	Less than 0.05%*
(iii) Unspecified impurities (for each impurity)	NMT 0.10%	Less than 0.05%*
(iv) Total impurities	NMT 2.0%	0.05%
LOSS ON DRYING	NMT 0.5%	0.14%
SULPHATED ASH	NMT 0.1%	0.06%
RESIDUAL SOLVENTS		
Chloroform	NMT 60 ppm	Less than 10 ppm**
Methanol	NMT 3000 ppm	304 ppm
Toluene	NMT 890 ppm	Less than 10 ppm**
ASSAY (dried substance)	97.0% to 102.0%	99.3%

* Disregard limit of impurity is 0.05%.

** The limit of detection of Chloroform and Toluene is 10 ppm in sample solution.

On the basis of above tests the material is found to Conform/ ~~does not Conform~~ with the Specification as per European Pharmacopoeia.

PREPARED BY 21/02/14	CHECKED BY 21/02/14	MANAGER Q.C 21/02/14
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