WRS FI-1



<u>Certificate of Analysis</u> <u>Working Standard</u>

Name of the Raw Material

: Fluconazole USP

W/S No.

: QC/WS/051 ·

Date of Preparation

: 17.06.15

Use Before

: 16.06.16

Evaluated against USPRS

Lot No.: H1L308

Sr.	Test	Result	Specification
No.			
1.	Description	White crystalline powder.	A white to almost White crystalline powder.
2.	Identification : IR	The IR absorption spectrum of substance is concordant with the reference spectrum of Fluconazole RS.	The IR absorption spectrum of substance should be concordant with the reference spectrum of Fluconazole RS.
3.	Related Substances Fluconazole related compound A Fluconazole related compound B Fluconazole related compound C Specified impurity Any other individual impurity Total unknown impurities Total impurities	Not detected Not detected Not detected Not detected 0.378 % 0.081 % 0.29 % 0.675 %	Not more than 0.2 % Not more than 0.1 % Not more than 0.2 % Not more than 1.0 % Not more than 0.1 % Not more than 0.3 % Not more than 1.5 %
4,	* Loss on drying	0.41 %	Not more than 0.5 %
5.	* Assay	99,38 %	Between 98.0 % and 102.0 % on dried substances.
6.	* Potency	98.98 %	••

^{*} Average Result of Triplicate Analysis.

Conclusion: The sample complies with the specification.

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Prepared By

Q.C. Manager

1 4 JAN 2016