Holden Medical Laboratories Pvt. Ltd.
C35, C36 & C37, MIDC, Malegaon, Sinnar, Nashik -422113.
QUALITY CONTROL DEPARTMENT

RAW MATERIAL – CERTIFICATE OF ANALYSIS

Format No.: HML_QC_ RMCOA_14_04_01
Effective Date: 01/04/14
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Name of Raw Material	:	Fluconazole USP	**A.R. No.**	:	RM/229/20-21
Batch No.	:	AFLNC1020125	**Invoice No. / Date**	:	199/20/10/20
Qty. Received	:	02 X 25 Kg 02 X 25 Kg	**Manufacturer**	:	Virupaksha organics Pvt.Ltd
Mfg. Date	:	Sep-20	**Supplier**	:	Inland Pharma
Retest Date	:	Aug-25	**Sample Qty.**	:	47.5 gm
Released Date	:	02/11/20	**Sampled by**	:	MPK

TESTS		RESULTS	LIMITS
Description	:	White, crystalline powder.	White or almost white, crystalline powder.
Solubility	:	Freely soluble in methanol; soluble in alcohol and in acetone; sparingly soluble in isopropanol& in chloroform ;slightly soluble in water ;very slightly soluble in toluene	Freely soluble in methanol; soluble in alcohol and in acetone; sparingly soluble in isopropanol& in chloroform ;slightly soluble in water ;very slightly soluble in toluene
Identification **A] By IR** **B]By HPLC**	 : :	 Complies Complies	 A]Infrared Absorption spectrophotometry. B]The retention time of the major peak of the sample solution corresponds to that of the Standard solution ,as obtained in the Assay
Organic impurities:Procedure 1: **Fluconazol related compound A** **Fluconazol related compound B** **Fluconazol related compound C** **Specified impurity** **Any other individual unspecified impurity** **Total unknown Impurities** **Total Impurities**	 : : : : : : :	 Not detected Not detected Not detected Not detected 0.0224 % 0.0350% 0.0350 %	 NMT 0.2% NMT 0.1% NMT 0.2% NMT 1.0% NMT 0.1% NMT 0.3% NMT 1.5%
Loss On Drying at 105 °C	:	0.03 % w/w	NMT 0.5% w/w
Residue on ignition	:	0.04 % w/w	NMT0.1 % w/w
Assay	:	99.32 %	98.0% to 102.0% on dried basis.

REMARKS: The above sample **complies** with USP standards

Analysed by
Date: 02/11/20

Checked by
02/11/20

Approved by
02/11/20

Note: If signature & entries in blue ink it indicates that it is an original document.