



Holden Medical Laboratories Pvt. Ltd.
Plot No: C35, C36 & C37, Malegaon, M.I.D.C.
Sinnar, Nashik- 422113, INDIA

FINISHED PRODUCT – CERTIFICATE OF ANALYSIS

Format No: HML_QC_FPCOA_19_04_04
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Product Name	: Fluconazole Capsules 150 mg	A. R. No.	: FG/442/20-21
Batch No.	: HE20K10	Mfg. Date	: Nov.20
Batch Size	: 2.00 Lac Capsules	Exp. Date	: Oct. 23
Received Date	: 05/12/20	Pack Size	: 1X2 Capsules
Released Date	: 16/12/20	Sample Quantity	: 100X1X2 Capsules
SR. NO.	TESTS	RESULTS	LIMITS
1	DESCRIPTION	Size "2" Turquoise-Turquoise hard gelatin capsule containing white powder, such 2 capsules are packed in Aluminium / PVC blister & such 1 blister is further packed in printed carton along with leaflet.	Size "2" Turquoise-Turquoise hard gelatin capsule containing white powder, such 2 capsules are packed in Aluminium / PVC blister & such 1 blister is further packed in printed carton along with leaflet.
2	IDENTIFICATION	Complies by HPLC	By HPLC
3	AVG. WT.	0.3416 gm	0.343 gm \pm 7.5 %
4	AVG WT OF INNER CONTENT	0.2777 gm	0.280 gm \pm 7.5 %
5	UNIFORMITY OF WT.	Complies.	Within \pm 7.5 % of Avg. Wt.
6	RELATED SUBSTANCES		
	INDIVIDUAL IMPURITY	Maximum individual impurity: 0.142%	NMT 1.0%
	TOTAL IMPURITY	0.204%	NMT 2.0%
7	DISINTEGRATION TIME	1 minute 57 seconds	NMT 30 minutes.
8	DISSOLUTION	91.99% to 97.04%	NLT 80.0% in 45 minutes
9	LOSS ON DRYING	1.43% w/w	NMT 5.0% w/w
10	UNIFORMITY OF DOSAGE UNITS	L1: 1.42	L1 (Maximum allowed acceptance value) : NMT 15.0
11	MICROBIAL TEST	40 CFU/gm 20 CFU/gm Absent Absent	Total Viable Count: NMT 10^3 CFU/gm Total Fungal Count: NMT 10^2 CFU/gm Escherichia coli: Should be absent Salmonella abony: Should be absent
12	ASSAY		

Ingredient	Label Claim	Result	Percentage	Limit
Fluconazole USP	150 mg/Capsule	148.19 mg/capsule	98.79 %	90.0 % to 110.0 %

Storage/Precautions: Store in a dry place below 30°C. Protect from light.

Quality Control Remarks: The above sample **Complies** / **Does-not-Comply** as per In-house Standards.

U.V.
16/12/20
Analysed By
Ms. U.V. Ghule
QC Officer/ Executive

U.V.
16/12/20
Checked By
Mrs. M.R. Shirsath
QC Executive/ Assistant QC Manager

U.V.
16/12/20
Approved By
Ms. V.V. Shinde
QC Manager

BATCH RELEASE CERTIFICATE

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Confirmation Statement by Qualified Person (QP):**Product Name: Fluconazole Capsules 150 mg****Batch No: HE20K10**

I hereby confirm that the manufacturing stages referred in the Technical Quality Agreement have been carried out in full compliance with the GMP requirements and the terms described in the agreement for ensuring compliance with the requirements of the Marketing Authorisation (s). As Manufacturer we are certifying and releasing the batch for distribution.

Name, designation and signature with date of qualified person confirming the manufacturing and releasing the batch.

Mrs. Aparna Potdar
Qualified person (QP)

AP
16/12/20



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