

Year : 2024-2025

FORM 39 RULE 150E (f)
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product	: ANABROOK-10 TAB	Control No	: FP/0576/24
Generic	:	Slip No	: 0576
Packing	: 10STRIP x 10TAB BOX	Testing Date	: 19-11-2024
Batch No	: 15822	Test Packing	: 2x25 TAB
Batch Size	: 100000 TAB	Test Quantity	: 50.0000 TAB
Mfg. Date	: Nov2024	Test As Per	: IHS
Exp. Date	: Apr2027	Release Date	: 26-11-2024
Mfg.Lic. No:	G/28/1157		

TEST	RESULT	SPECIFICATIONS
DESCRIPTION	A WHITE COLOURED ROUND SHAPED BICONVEX UNCOATED TAB WITH HAVING BOTH SIDE PLAIN	A WHITE COLOURED ROUND SHAPED BICONVEX UNCOATED TAB WITH HAVING BOTH SIDE PLAIN
WEIGHT OF 20 TABLETS	4023.0 MG	4000 MG $\pm$ 5% W/W
AVERAGE WEIGHT OF 20 TAB	201.2 MG	200 MG $\pm$ 7.5% W/W
UNIFORMITY OF WEIGHT	COMPLIES	200 MG $\pm$ 7.5% W/W
DISINTERGRATION TIME	01 MIN 26 SEC	NMT 15 MIN
THICKNESS	4.00 MM	3.80 MM TO 4.20 MM
HARDNESS	MIN: 5.0 KG/CM ² MAX: 7.5 KG/CM ²	NLT 3 KG/CM ²
FRIABILITY	0.30%	NMT 1% W/W
IDENTIFICATION	COMPLIES	THE PRINCIPAL PEAK IN THE CHROMATOGRAM OBTAINED WITH THE TEST SOLUTION CORRESPONDS TO THAT IN THE CHROMATOGRAM OBTAINED WITH THE REF.SOLUTION
UNIFORMITY OF CONTENT	MIN:86.10% MAX:99.08% AVG:92.61%	85.0% TO 115.0%
ASSAY		

REMARKS : The Product conform to IHS

Release Dt: 26-Nov-2024

Analysed By : ALPESH

Person Incharge of Testing:

DWARAKESH HEALTHCARE

3222, PHASE-IV, G.I.D.C., VATVA, AHMEDABAD-382 445

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TEST	RESULT		SPECIFICATIONS
EACH UNCOATED TAB CONTAIN OXANDROLONE USP 10 MG	9.81MG	98.10%	90.0% TO 110.0%

REMARKS : The Product conform to IHS

Release Dt: 26-Nov-2024

Analysed By : ALPESH

Person Incharge of Testing:

(Q.A./Q.C. Incharge)