



Manufacturers & Exporters of Pharmaceuticals
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QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : STOP EJAC	A.R. No. : F/486/12
Packing : 10x10 TAB	Rel. Dt. : 21-07-2012
Generic Name : DAPOXETINE TABLETS 60 MG	T.R. Slip No. : CSPTP12496
Product Code : STOP01	T.R. Slip Dt. : 21-07-2012
Batch No. : T-212001	Analysis Date : 21-07-2012
Actual Batch Size : 52000 TAB	Mfg. Dt. : JUL-2012
Packing Batch Size : 52000 TAB	Exp. Dt. : JUN-2015
Sample Size : 50 TAB	Test Packing : 50 TAB
Released Qty : 52000 TAB	Mfg. Lic No. : G/1325
Remarks : pass	Test As Per : IH
	Location : GORWA01
	Make : CENTURION

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A blue coloured, Round shaped, Biconvex, Film coated Tablet.	A blue coloured, Round shaped, Biconvex, Film coated Tablet.
2	IDENTIFICATION	Complies	Must Complies as per IHS.
3	AVERAGE WEIGHT	294.63 mg	299.00 mg \pm 5.00 %
4	UNIFORMITY OF WEIGHT	Complies	Complies Within \pm 7.5 %
5	THICKNESS	4.19 mm	4.20 mm \pm 0.2 mm
6	DIAMETER	9.65 mm	9.60 mm \pm 0.2 mm
7	DISINTEGRATION TIME	5 Min. 45Sec. in Water : Medium at 37°C	NMT 30 Min.
8	ASSAY	101.4 %	Each Film Coated Tablet Contains: Depoxetine Hcl Eq. to Depoxetine 60 mg [Limit :90 % to 110 %]



Conclusion : The above sample complies as per IH
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the reasons given above.

Analysed By QC CHEMIST	Approved By KRISHNA PANCHAL QC IN CHARGE
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