HETERO LABS LIMITED

Unit-V, TSIIC Formulation SEZ,S. No. 439,440,441 & 458,
Polepally Village, Jadcherla,Mahaboob Nagar - 509301,
Telangana State , INDIA.

CERTIFICATE OF ANALYSIS

Product Name: Escitalopram Comprimidos Recubiertos 10 mg			
Product Code	4021481	**A.R. No.**	S5FP20001456
Specification No.	FPS/3003580-1-05	**Batch No.**	EST20003A
Mfg. Date	01/2020	**Packing Size / Type**	3X10'S BLISTER PACK
Exp. Date	12/2022	**Date Of Release**	18-03-2020 15:51

S. No.	TEST	RESULT	SPECIFICATION
1	**Description (Visual inspection)**	White, oval, scored, biconvex film coated tablets debossed with 'J' on one side and '2' on the other side.	White to off white, oval, scored, biconvex film coated tablets debossed with 'J' on one side and '2' on the other side.
2	**Identification**		
2.1	**By HPLC (Ph. Eur. 2.2.29 & In-House)**	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the Assay.	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the Assay.
2.2	**By UV (Ph. Eur. 2.2.25 & In-House)**	The UV absorption spectrum of sample solution exhibits maxima at the same wavelength as that of standard solution.	The UV absorption spectrum of sample solution should exhibit maxima at the same wavelength as that of standard solution.
3	**Average weight (Mass) (In-House)**	128.71 mg	128.12mg ± 4.0% (122.99mg – 133.24mg)
4	**Water content (By KF) (Ph. Eur. 2.5.12, Method A)**	4.79 %m/m	Finished limit:Not more than 7.0%m/m , Stability limit:Not more than 8.0%m/m
5	**Dissolution (By UV) (Ph. Eur. 2.9.3, 2.2.25 & In-House)**	Tablet -1 : 100 % Tablet -2 : 99 % Tablet -3 : 98 % Tablet -4 : 101 % Tablet -5 : 99 % Tablet -6 : 101 % Average:99 %	Not less than 80% (Q) of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.
6	**Uniformity of Dosage units (Content uniformity, By UV) (Ph. Eur. 2.9.40, 2.2.25 & In-House) Acceptance value (L1)**	7.5	Not more than 15.0
7	**Related compounds (By HPLC) (Ph.Eur.2.2.29 & In-House)**		
7.1	**Citalopram Related compound-A**	Below LOQ (LOQ = 0.010%m/m)	Finished limit:Not more than 0.2%m/m , Stability limit:Not more than 0.3%m/m
7.2	**Citalopram Related compound-B (3-hydroxy Citalopram)**	0.05 %m/m	Finished limit:Not more than 0.30%m/m , Stability limit:Not more than 0.50%m/m

Remarks: APPROVED (Sample Conforms to above Specification)
Stability Specification:SSS/3003580-1-05

Checked By	maheswarapu.prashanth	Approved By	Mummadi.Viswanatha Reddy
Date	18-03-2020 17:11	Date	18-03-2020 17:14

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7.3	**Citalopram Related compound-C (3-oxocitalopram)**	0.11 %m/m	Finished limit:Not more than 0.30%m/m , Stability limit:Not more than 0.50%m/m
7.4	**Citalopram Related compound-E (Citalopram N-oxide)**	0.00 %m/m	Not more than 0.2%m/m
7.5	**Maximum single unknown impurity**	Below Disregard Limit (DRL = 0.05%m/m)	Not more than 0.20%m/m
7.6	**Total impurities**	0.16 %m/m	Finished limit:Not more than 1.0%m/m , Stability limit:Not more than 2.0%m/m
8	**Assay (By HPLC) (Ph. Eur. 2.2.29 & In-House) Each film coated tablet contains**		
8.1	**Escitalopram oxalate equivalent to Escitalopram (C20H21FN2O), in mg**	9.95	Not less than 9.50 and Not more than 10.50
8.2	**(%) Labeled amount**	99.5	Not less than 95.0 and Not more than 105.0
9	**Microbiological examination (Ph. Eur. 2.6.12 & 2.6.13)**		
9.1	**Microbial enumeration tests**		
9.1.1	**Total aerobic microbial count**	Less than 10 cfu per g	Not more than 1000 cfu per g.
9.1.2	**Total combined yeast and molds count**	Less than 10 cfu per g	Not more than 100 cfu per g.
9.2	**Test for specified Microorganisms**		
9.2.1	**Bile-Tolerant Gram Negative Bacteria**	Absent	Should be absent
9.2.2	**Escherichia coli**	Absent	Should be absent
9.2.3	**Salmonella**	Absent	Should be absent
9.2.4	**Staphylococcus aureus**	Absent	Should be absent
9.2.5	**Pseudomonas aeruginosa**	Absent	Should be absent
10	**Identification of colourant (In-House) Titanium dioxide**	A pale yellow colour to orange colour develops immediately.	A pale yellow colour to orange colour should develop immediately.
11	**Breakability (Subdivision of tablets) (Ph. Eur. General monographs 0478)**	Complies	Not more than 1 individual mass is outside the limits of 85 per cent to 115 per cent of the average mass and no individual mass is outside the limits of 75 per cent to 125 per cent of the average mass.

Remarks: APPROVED (Sample Conforms to above Specification)
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