ALKEM LABORATORIES LIMITED,
167/2, Mahatma Gandhi Udyog Nagar,
Dabhel, Daman - 396210.

ALKEM

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name: Duloxetine Capsules 60 mg

Generic Name	Duloxetine Delayed Release Capsules USP 60 mg	**Product Code**	ECRW01
Batch No.	19141608	**Batch Size**	650000 Capsules
Specification No.	SR/FPS/14/098(R)-01	**Qty. Sampled**	200 Capsules
Manufacturing Date	03/2019	**Expiry Date**	02/2021
A.R. No.	03FP19001221	**Pack**	3 x 10's

S. No.	TEST	SPECIFICATION	RESULT
1	**Description**	White to off white enteric coated pellets filled in size "0" hard gelatin capsules, green body & blue-cap printed "Dulox" on cap and "60 mg" on body in white ink.	Off white enteric coated pellets filled in size "0" hard gelatin capsules, green body & blue-cap printed "Dulox" on cap and "60 mg" on body in white ink.
2	**Identification**		
2.1	**By IR**	The peaks at wave numbers of about 1578 cm-1, 1266 cm-1 and 1236 cm-1 in standard preparation are present in sample preparation.	The peaks at wave numbers of about 1578 cm-1, 1266 cm-1 and 1236 cm-1 in standard preparation are present in sample preparation.
2.2	**By HPLC**	The retention time of the principal peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	The retention time of the principal peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.
3	**Average Weight**	398.7 mg ± 7.5 %.	409.6 mg
4	**Uniformity of dosage units (by content uniformity)**	The acceptance value (AV) of 10 dosage units less than (by content uniformity) or equal to 15 .0.	AV:9.9
5	**Dissolution (by HPLC)**		
5.1	**In Acid Stage**	No individual unit exceeds 10% release in 120 minutes.	Minimum: 1 % Maximum: 1 % Average: 1 %
5.2	**In Buffer Stage**	Not less than 75% (Q) of the labeled amount of Duloxetine (C18H19NOS) is dissolved in 60 minutes.	Minimum: 96 % Maximum: 100 % Average: 98 %
6	**Loss on drying (w/w, at 105° for 4 hours)**	Not more than 3.0 %.	1.68 %
7	**Assay by (HPLC, w/w)**	Not less than 95.0% and not more than	

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Vipul.Kapdi	Approved By	suresh.sharma
Checked On	30-04-2019 15:32	Approved On	30-04-2019 15:47
Printed by: Mukesh.Thakur		Printed on: 30-04-2019 16:18	
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S. No.	TEST	SPECIFICATION	RESULT
		110.0% of the labeled amount of Duloxetine (C18H19NOS)	100.5 %
8	**Organic impurities (By HPLC, w/w)**		
8.1	**Duloxetine related compound - H**	Not more than 0.15 %.	Not Detected
8.2	**Any individual unspecified degradation product**	Not more than 0.15 %.	0.011 %
8.3	**Total Impurities**	Not more than 0.3 %.	0.07 %
9	**Residual solvents (By GC)**		
9.1	**Isopropyl alcohol**	Not more than 5000 ppm.	864 ppm
9.2	**Dichloromethane**	Not more than 600 ppm.	Not Detected

Test Plan Remarks: --

Remarks: APPROVED (Sample Conforms to above Specification)

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