

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



**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Product Name: Duloxetine Capsules 30mg

Generic Name	Duloxetine Delayed Release Capsules USP 30mg	Product Code	ECRW11
Batch No.	19142425	Batch Size	1600000 Capsules
Specification No.	SR/FPS/14/099(R)-01	Qty. Sampled	200 Capsules
Manufacturing Date	05/2019	Expiry Date	04/2021
A.R. No.	03FP19002105	Pack	3 x 10's

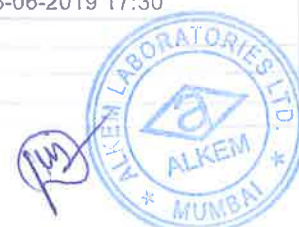
S. No.	TEST	SPECIFICATION	RESULT
1	Description	White to off white enteric coated pellets filled in size "2" hard gelatin capsules, white-body & blue-cap printed "Dulox" on cap in white ink and "30 mg" on body in black ink.	Off white enteric coated pellets filled in size "2" hard gelatin capsules, white-body & blue-cap printed "Dulox" on cap in white ink and "30 mg" on body in black 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	199.35 mg \pm 7.5 %.	210.12 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:6.8
5	Dissolution (by HPLC)		
5.1	In Acid Stage	No individual unit exceeds 10 % release in 120 minutes.	Minimum: 0 % Maximum: 0 % Average: 0 %
5.2	In Buffer Stage	Not less than 75%(Q) of the labeled amount of Duloxetine (C ₁₈ H ₁₉ NOS) is dissolved in 60 minutes.	Minimum: 94 % Maximum: 101 % Average: 99 %
6	Loss on drying (w/w, at 105° for 4 hours)	Not more than 3.0 %.	1.41 %

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rajesh.Kumar Bangre	Approved By	suresh.sharma
Checked On	28-06-2019 17:18	Approved On	28-06-2019 17:30
Printed by: Mukesh.Thakur		Printed on: 28-06-2019 17:37	
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S. No.	TEST	SPECIFICATION	RESULT
7	Assay by (HPLC, w/w)	Not less than 95.0% and not more than 110.0% of the labeled amount of Duloxetine (C ₁₈ H ₁₉ NOS).	101.7 %
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 %.	0.022 %
8.3	Total Impurities	Not more than 0.3 %.	0.09 %
9	Residual solvents (By GC)		
9.1	Isopropyl alcohol	Not more than 5000 ppm.	840 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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