

CERTIFICATE of ANALYSIS

Page 1/1

Product name: EUFINDOL COMPRIMIDOS RECUBIERTOS 50 mg
Batch no.: 9J093A
Manufacturing date: 09.2019
Expiry date: 08.2024
Package size: 100
Analysis order N°: LAN 71220-05
Batch size: 2,000,000 pieces
Appearance primary packaging: Blister

Article No.: 26003CL

TESTS	SPECIFICATIONS	RESULTS
Appearance	White, round and biconvex film coated tablets	Corresponds
Dimensions		
Diameter	7 mm	7.1 mm
Thickness	3.9 - 4.2 mm	4.1 mm
Average mass	150.0 mg $\pm$ 7.5 %	151.6 mg
Uniformity of mass	Acc. to Ph. Eur. 2.9.5	Corresponds
Breaking strength	40 - 100 N	85 N
Disintegration time	Not more than 30 minutes	< 5 min.
Loss on drying	Not more than 5.0 %	3.9 %
Purity		
Single impurities	Not more than 0.2 %	0.0 %
Total impurities	Not more than 1.0 %	0.0 %
Cis-isomer	Not more than 0.3 %	< 0.03 %
Identification of tramadol hydrochloride	HPLC	Corresponds
Identification of tramadol hydrochloride	TLC	Corresponds
Identification of chloride	Positive	Corresponds
Identification of titanium dioxide	Positive	Corresponds
Assay of tramadol hydrochloride	50.0 mg $\pm$ 5 %	49.5 mg
Dissolution	Not less than 80 % (Q= 75 %) after 30 minutes	97 %
Microbiological limit tests*	Acc. to Ph. Eur.	Not tested

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

*Microbiological testing is done every 10th batch

Date of release: 05.11.19

Compiled by:



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Dr. J. Frank

Qualified person