



4 chemin du Calquet
31057 Toulouse Cedex 1 - France
Tél.: +33 5 62 74 40 00
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CERTIFICATE OF ANALYSIS

RONAXAN NF

COMMERCIAL LOT: RXT0671AB

PRESENTATION: CPR 100MG 10

FILLED PRODUCT LOT NUMBER: RXT0671A

MANUFACTURING DATE: 04-Jun-2019

EXPIRY DATE: 05/2022

TESTS	THRESHOLDS	RESULTS
APPEARANCE	ROUND, BICONVEXE LIGHT YELLOW TO YELLOW SCORED TABLET	ROUND, BICONVEXE LIGHT YELLOW TO YELLOW SCORED TABLET
WEIGHT VARIATION (WV)	CONFORMS TO PH. EUR. 2.9.40 / USP <905>	CONFORMS TO PH. EUR. 2.9.40 / USP <905>
ACCEPTANCE VALUE (n= 10 ou 30)	R ≤ 15.0 %	2.2 %
NUMBER OF UNITS		10
DISSOLUTION	CONFORMS (30 MIN)	CONFORMS (30 MIN)
Q	R= 85 %	85 %
AVERAGE (N=6)	R ≥ 90 %	102 %
IDENTIFICATION OF DOXYCYCLINE	RT IDENTICAL TO THE REFERENCE (HPLC)	RT IDENTICAL TO THE REFERENCE (HPLC)
ASSAY OF DOXYCYCLINE (HPLC)	0.095 ≤ R ≤ 0.105 g/tab	0.101 g/tab
6-EPIDOXYCYCLINE	R ≤ 2.5 %	0.5 %
METACYCLINE	R ≤ 2.5 %	<0.3 %
OTHER IMPURITIES	R ≤ 1.0 %	<0.5 %

WE CERTIFY THIS PRODUCT MEETS THE REQUIREMENTS OF THE COMPETENT AUTHORITIES

Signature / Function
Jérôme LORET / Qualified Person





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