

CERTIFICATE OF ANALYSIS



SANOFI AVENTIS S.A Spain
Ctra. C-35 (La Batlloria-Hostalric) Km. 63,09
Tel. 93.864.19.00 Fax. 93.864.19.50
17404 Riells i Viabrea (GIRONA) SPAIN

Site: RIELLS

HCHLOROQUINE 200MG 60CPR GB

Item: RIE_587955 Manufacturing date: 23-MAY-2019 00:00:00.00
Batch: 9R1AR Expiry date: APR-2022
Customer batch: OF number: RR04539006
Method reference: RIE-MET-00369 v.17.0
Certificate version: 15

TESTS

SPECIFICATIONS

RESULTS

CHARACTERS

. APPEARANCE

FILM COATED BICONVEX TABLET WITH
FLAT SIDES

COMPLIES

. COLOUR

WHITE

COMPLIES

IDENTIFICATION

. HYDROXYCHLOROQUINE SULPHATE (IR)

COMPLIES

COMPLIES

. HYDROXYCHLOROQUINE SULPHATE (HPLC)

COMPLIES

COMPLIES

TESTS

. AVERAGE MASS

298.9 330.3 MG

315.3

. UNIFORMITY OF MASS

Ph. Eur.

COMPLIES

DISSOLUTION

DISSOLVED HYDROXYCHLOROQUINE

COMPLIES

96

SULPHATE AFTER 30 MIN (Q=75%) (UV)

DEGRADATION PRODUCTS:

. IMPURITY SSR24772

NMT 0.50 %

Not applied

. IMPURITY SSR10022

NMT 0.50%

Not applied

. ANY UNESPECIFIED DEGRADATION PRODUCT

NMT 0.20 %

Not applied

. TOTAL DEGRADATION PRODUCTS

NMT 1.0%

Not applied

. MICROBIOLOGICAL QUALITY:

Not applied

-Total aerobic microbial count (TAMC)

NMT 10³ CFU/G

-Total combined yeasts/moulds

NMT 10² CFU/G

microbial count (TYMC)

-Specified micro-organisms (E.Coli)

ABSENCE/G

ASSAY

. HYDROXYCHLOROQUINE SULPHATE (HPLC)

190.0 210.0 MG/TAB

194.5

This batch has been manufactured in reference to the dossier in force and according to the cGMP

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Qualified person decision:	Released
	3-JUL-2019 13:17:44.00
	Pilar Flores

This certificate of analysis has been electronically signed from a validated LIMS