

OTR3

RECORD FORM

CERTIFICATE OF ANALYSIS –
CLERAPLIQ RELEASE

Réf : QC_ENR_029
Version : 03
Date d'application :
25/11/2024
Page 1 sur 1

PRODUCT NAME	CLERAPLIQ	ARTICLE CODE	C-CLERAPLIQ
PRODUCT BATCH NUMBER	0102615	NUMBER OF UNITS PRODUCED	22 750
TIME POINT	☒ AT RELEASE		
STORAGE CONDITION	N.A.		
REFERENCE BATCH NUMBER	1786P3509P3211		
MANUFACTURING DATE	04/2026	EXPIRY DATE	04/2029
DATE OF ANALYSIS	19/05/2026	ANALYSIS NUMBER	262119CLP001_01

Tests performed by laboratory: OTR3, 61 avenue du Général de Gaulle, 94010 Créteil FRANCE				
	TEST	STANDARD	METHOD	RESULT
Appearance	Appearance	Clear	Visual check	Conform
Identification	HPLC	Conforms to the spectrum of the internal reference	QC_POS_004 – QC HPLC assay	Conform
Tests	pH	≥ 4.5	QC_POS_007 – QC pH assessment	4.8
	Concentration	90 – 110 µg/mL	QC_POS_004 – QC HPLC assay	94
	Δ Retention Time	NMT 0.15 min	QC_POS_004 – QC HPLC assay	0.01
	Sulphation index	0.9 – 1.1	QC_POS_005 – QC DMMB assay	1.0

Additional tests performed by OTR3's subcontractors				
	TEST	STANDARD	METHOD	RESULT
Additional tests	Osmolality	270-330 mOsm/kg	Ph. Eur. 2.2.35	287
	Sterility	Sterile	Ph. Eur. 2.6.1	Conform

CONCLUSION	☒ CONFORM	☐ NOT CONFORM
ISSUE DATE (DD/MM/YYYY)	20/05/2026	
EDITED BY (Name, Signature)	Laurine COIEFFEY	DocuSigned by: <i>Laurine Coieffey</i> 543ECF86D16F4E1...
APPROVED BY (Name, Signature)	Alan MOUGEOLLE	Signé par : <i>Alan MOUGEOLLE</i> 545451D554E04D9...

Released by Denis BARRITAULT, CEO & QP
21/05/2026

DocuSigned by:
Denis BARRITAULT
545451D554E04D9...