

OTR3

RECORD FORM

CERTIFICATE OF ANALYSIS – CLERAPLIQ RELEASE

Réf. : QC_ENR_029
Version : 02
Date d'application :
27/10/2021
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PRODUCT NAME	CLERAPLIQ	ARTICLE CODE	C-CLERAPLIQ
PRODUCT BATCH NUMBER	0102229	NUMBER OF UNITS PRODUCED	49 854
STABILITY TIME POINT	☒ AT RELEASE		
STORAGE CONDITION	N.A.		
REFERENCE BATCH NUMBER	652-024-Ly		
MANUFACTURING DATE	07/2022	EXPIRY DATE	07/2025
DATE OF ANALYSIS	09/09/2022	ANALYSIS NUMBER	223609CLP002_01

Tests performed by laboratory: OTR3, 61 avenue du Général de Gaulle, 94010 Créteil FRANCE at all time points (release, stability and end of shelf life).				
	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	4.9
	Concentration	90 – 110 µg/mL	QC_POS_004 – QC HPLC assay	93
	Δ Retention Time	NMT 0.15 min	QC_POS_004 – QC HPLC assay	0.03
	Sulphation index	0.9 – 1.1	QC_POS_005 – QC DMMB assay	1.0

Additional tests performed by OTR3's subcontractors in the case of initial and/or end time points (release, end of shelf life)				
	TEST	STANDARD	METHOD	RESULT
Additional tests	Osmolality	270-330 mOsm/kg	Ph. Eur. 2.2.35	290
	Sterility	Sterile	Ph. Eur. 2.6.1	Conform

CONCLUSION		☒ CONFORM	☐ NOT CONFORM
ISSUE DATE (DD/MM/YYYY)	12/09/2022		
EDITED BY (Name, Signature)	Laurine COIEFFEY	DocuSigned by: <i>Laurine Coieffey</i> 8435CF86D16F4E1...	
APPROVED BY (Name, Signature)	Özgül TEZGEL	DocuSigned by: <i>Özgül TEZGEL</i> 6E3190A01397486...	

Released by D. BARRITAUULT on 16/09/2022

DocuSigned by:

Denis BARRITAUULT

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