

OTR3

RECORD FORM

CERTIFICATE OF ANALYSIS –
CLERAPLIQ RELEASERéf. : QC_ENR_029
Version : 02
Date d'application :
27/10/2021
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PRODUCT NAME	CLERAPLIQ	ARTICLE CODE	CLPQ-STND
PRODUCT BATCH NUMBER	0102429A	NUMBER OF UNITS PRODUCED	5 000
STABILITY TIME POINT	☒ AT RELEASE		
STORAGE CONDITION	N.A.		
REFERENCE BATCH NUMBER	1786P3302P2837		
MANUFACTURING DATE	07/2024	EXPIRY DATE	07/2027
DATE OF ANALYSIS	05/09/2024	ANALYSIS NUMBER	243605CLP002_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	4.7
	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	0.02
	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	289
	Sterility	Sterile	Ph. Eur. 2.6.1	Conform

CONCLUSION

☒ CONFORM☐ NOT CONFORM

ISSUE DATE (DD/MM/YYYY)	09/09/2024		
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Released by Denis BARRITAULT, CEO & QP

09-sept.-2024 | 14:29:04 CEST

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Denis BARRITAULT
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