



CERTIFICATE OF ANALYSIS

CLEVOR EYE-DROPS VET 3X0.6 ML PLHURO

Product Number: 154114  
 Batch Number: 1934583  
 Order Number: 80988512  
 Customers Batch Number: XM145  
 Date of Manufacture: 17.09.2019  
 Date of Expiration: 09.2021  
 Storage: Below +25 °C  
 Specification: 10015905-01 (Mat:154114) 28.11.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
Clarity, solution	visual	clear solution	clear solution	HOLOPACK VERPACKUNGSTE
Colour, solution	visual	very slight yellow to yellow	very slight yellow to yellow	HOLOPACK VERPACKUNGSTE
Partic matter, presence of visible particles	visual	free from visible particles	free from visible particles	HOLOPACK VERPACKUNGSTE
Colour, ampoule	visual	complies with the specimen	complies with the specimen	HOLOPACK VERPACKUNGSTE
Shape, ampoule	visual	complies with the specimen	complies with the specimen	HOLOPACK VERPACKUNGSTE
Cleanliness, ampoule	visual	clean	clean	HOLOPACK VERPACKUNGSTE
Dimensions, ampoule	visual	complies with the specimen	complies with the specimen	HOLOPACK VERPACKUNGSTE
Identification	HPLC	positive	positive	HOLOPACK VERPACKUNGSTE
Assay	HPLC	95.0 % - 105.0 %	100.6 %	HOLOPACK VERPACKUNGSTE
Impurity B	HPLC	nmt 1.0 %	< 0.1 %	HOLOPACK VERPACKUNGSTE

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7. pld. Kiadva: 20/04/29

MEDIMPEX GYÓGYSZER ZRT.  
 1158 Bp. Rákospalotai határút 2.  
 Nagyné Kán Éva  
 Minőségbiztosító szakasszisztens  
 Csak a piros színű hiteles



CERTIFICATE OF ANALYSIS

CLEVOR EYE-DROPS VET 3X0,6 ML PLHURO

Product Number: 154114  
 Batch Number: 1934583  
 Order Number: 80938512

TESTS	METHOD	REQUIREMENTS	RESULTS	QILTY CTRL SITE
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Impurities, any unspecified	HPLC	nml 1,0 %	< 0,1 %	HOLOPACK VERPACKUNGSTE
Impurities, total	HPLC	nml 2,0 %	< 0,1 %	HOLOPACK VERPACKUNGSTE

Uniformity of dosage units	mass var	conforms to USP and Ph.Eur.	conforms to USP and Ph.Eur.	HOLOPACK VERPACKUNGSTE
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Uniformity of dosage units, AV	mass var	nml 15,0	3,2	HOLOPACK VERPACKUNGSTE
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pH	USP	3,8 - 4,5	4,1	HOLOPACK VERPACKUNGSTE
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**Sterility** 113205-1 sterile  
 I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 20.01.2020 15:44:20 by a Qualified Person *Minna Jaakkola* Minna Jaakkola 29.01.2020

Minna Jaakkola  
 QP, QA External Supply  
 Orion Corporation

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CLEVOR OLDATOS SZEMCSÉPP 30MG/ML  
 Gysz: XM145  
 Kész: 3x0,6 ML  
 Lej: 21/09/30  
 Me.: Doboz  
 SZÉKELY KFT részére



BATCH CERTIFICATE

CLEVOR EYE-DROPS VET 3X0,6 ML PLHURO

Product Number: 154114  
 Batch Number: 1934583  
 Order Number: 80988512  
 Customers Batch Number: XM145  
 Date of Manufacture: 17.08.2019  
 Date of Expiration: 09.2021  
 Quantity: 3503 PCE

Manufacturing site: Halopak Verpackungstechnik GmbH  
 Bahnhofsstrasse 18 D-74429 SULZBACH-LAUFEN, BADEN-WÜRTTEMBERG  
 GMP Compliance of Quality Cert site: DE\_BW\_01\_GMP\_2019\_0107

Quality control site: Orion Corporation, Espoo plant  
 Orionitie 1 FI-02200 ESPOO

GMP Compliance of Quality Cert site: 003983006;08.02.002/2017

Quality control site: Halopak Verpackungstechnik GmbH  
 Bahnhofstrasse 20, D-73453 Abtsgmuend-Untergroeningen, Baden-Wuertemb

GMP Compliance of Quality Cert site: DE\_BW\_01\_GMP\_2019\_0109

Packaging site: Orion Corporation, Espoo plant  
 Orionitie 1 FI-02200 ESPOO  
 GMP Compliance of Packaging site: 003983006;002/2017

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Electronically approved 20.01.2020 15:44:20 by a Qualified Person Minna Jaakkola

*Minna Jaakkola*  
 Qualified Person  
 Orion Corporation

28.01.2020

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