

CERTIFICATE OF ANALYSIS



CLEVOR EYE-DROPS VET 3X0.6 ML PLHURO

Product Number: 154114
 Batch Number: 1931359
 Order Number: 81025421

Customers Batch Number: XG134
 Date of Manufacture: 14.05.2019
 Date of Expiration: 11.2021
 Storage: Below +25 °C
 Specification: 10015905-01 (Mat:154114): 28.11.2019

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY 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
Partic.matter, presence of visib. partic	visual	free from visible particles	free from visible particles	VERPACKUNGSTE HOLOPACK
Colour, ampoule	visual	complies with the specimen	complies with the specimen	VERPACKUNGSTE HOLOPACK
Shape, ampoule	visual	complies with the specimen	complies with the specimen	VERPACKUNGSTE HOLOPACK
Cleanliness, ampoule	visual	clean	clean	VERPACKUNGSTE HOLOPACK
Dimensions, ampoule	visual	complies with the specimen	complies with the specimen	VERPACKUNGSTE HOLOPACK
Identification	HPLC	positive	positive	VERPACKUNGSTE HOLOPACK
Assay	HPLC	95,0 % - 105,0 %	99,0 %	VERPACKUNGSTE HOLOPACK
Impurity B	HPLC	nmt 1,0 %	0,2 %	VERPACKUNGSTE HOLOPACK

Manufacturing license number: PIMFA/2019/000732

Orion Corporation
 ORION PHARMA

DNO 090017f8246c6b6

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CLEVOR EYE-DROPS VET 3X0.6 ML PLHURO

Product Number: 154114
 Batch Number: 1931359
 Order Number: 81025421

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Impurities, any unspecified	HPLC	nmt 1.0 %	0,0 %	HOLOPACK VERPACKUNGSTE
Impurities, total	HPLC	nmt 2.0 %	0,2 %	HOLOPACK VERPACKUNGSTE
Uniformity of dosage units	mass var	conforms to USP and Ph.Eur.	conforms to USP and Ph.Eur.	HOLOPACK VERPACKUNGSTE
Uniformity of dosage units, AV	mass var	nmt 15.0	3,6	HOLOPACK VERPACKUNGSTE
pH	USP	3,8 - 4,5	4,0	HOLOPACK VERPACKUNGSTE
Sterility	113205-1	sterile	sterile	VERPACKUNGSTE Espoo

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 30.04.2020 09:20:19 by a Qualified Person Mirna Jaakkola

Orion Corporation Manufacturing license number: FIMEA/2019/000732

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BATCH CERTIFICATE



CLEVOR EYE-DROPS VET 3X0.6 ML PLHURO

Product Number: 154114
Batch Number: 1931359
Order Number: 81025421

Customers Batch Number: XG134
Date of Manufacture: 14.05.2019
Date of Expiration: 11.2021

Quantity: 1026 PCE

Manufacturing site: HoloPack Verpackungstechnik GmbH
Bahnhofstrasse 18 D-74429 SULZBACH-LAUFEN, BADEN-WUERTTEMBERG
GMP Compliance of Manufact. site: DE_BW_01_GMP_2019_0107

Quality control site: Orion Corporation, Espoo plant
Orionintie 1 FI-02200 ESPOO
GMP Compliance of Quality Ctrl site: 003953/06.02.00/2017

Quality control site: HoloPack Verpackungstechnik GmbH
Bahnhofstrasse 20, D-73453 Abtsgmuend-Untergroeningen, Baden-Wuerttemb
GMP Compliance of Quality Ctrl site: DE_BW_01_GMP_2019_0109

Packaging site: Orion Corporation, Espoo plant
Orionintie 1 FI-02200 ESPOO
GMP Compliance of Packaging site: 003953/06080200/2017

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 30.04.2020 09:20:19 by a Qualified Person Minna Jaakkola

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DNO 090017ff8246c6h6

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CLEVOR OLDATOS SZEMCSEPP 30MG/ML
Gysz: XG134 Lej: 2021-11-30
Kisz: 3x0,6 ML Me: Doboz
SZÉKELY KFT részére

Szállító:
Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
Tel: +36-1-414-6476
e-mail: qa@mpx.hu



CERTIFICATE OF ANALYSIS

Written by: **Pauli Harshada**

Date dd.mm.yyyy (UTC)	Justification	Electronically signed by
31.07.2020 12:50:42	Approved	Jaakkola Minna (minnja)

Signature page

eSigned

DSO 09001708246e36

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