

Certificate of Analysis

Consignee: DOMES PHARMA SC
F-63370 Lempdes - France
Rue des Bardines

Your Contact:

SYSDUER

Quality
Phone: ++ 49 30 33 0 93-0
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Product: Twelve Eye Drops [10 ml]
Batch number: 232

Product No.: 0781B2FR
Date of manufacture: 15.04.2022
Release date: 17.08.2022
Expiry date: 03.2024

Test Parameters	Specifications	Results of Testing
Appearance (Visual inspection)	limpid, pink solution	complies
Visible particles (Ph. Eur. current Ed., 2.9.20.)	practically free from visible particles	complies
Opalescence (Ph. Eur. current Ed., 2.2.1.)	not more opalescent than reference suspension II	complies
Sub-visible particles $\geq 10 \mu\text{m}$ (Ph. Eur. current Ed., 2.9.53., method 1)	≤ 1000	16
Sub-visible particles $\geq 25 \mu\text{m}$ (Ph. Eur. current Ed., 2.9.53., method 1)	≤ 100	0
pH-Value (Ph. Eur. current Ed., 2.2.3.)	7.1 - 7.6	7.4
Osmolality (Ph. Eur. current Ed., 2.2.35.)	250 - 300 mosmol/kg	276 mosmol/kg
Viscosity (Ph. Eur. current Ed., 2.2.8.)	$\geq 2 \text{ mPa s}$	6 mPa s
Identity Hyaluronic acid sodium salt (HPLC)	positive	complies
Identity Vitamin B12 (HPLC)	positive	complies
Assay Hyaluronic acid sodium salt (HPLC)	1.35 - 1.65 mg/ml (90 - 110 %)	1.57 mg/ml
Assay Vitamin B12 (HPLC)	0.035 - 0.045 mg/ml (87,5 - 112,5 %)	0.038 mg/ml
Sterility (Ph. Eur. current Ed., 2.6.1.)	sterile	complies

No.: 22001541

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Test Parameters	Specifications	Results of Testing
Antimicrobial effectiveness testing (DIN EN ISO 14730)	must comply	complies

Analysis date: 11.08.2022
 Place of analysis: Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH
 Brunsbütteler Damm 165 / 173
 13581 Berlin
 Germany

The product was tested according to the current procedure and complies with the specifications.
 The batch was released.

17.08.2022

Date



Head Quality Control

***** End of Certificate of Analysis *****