

Certificate of Analysis

Consignee:	Laboratoire TVM F-63370 Lempdes - France Rue des Bardines	Your Contact:	SYSEUR
		Phone:	Quality ++ 49 30 33 0 93-0
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Product: Twelve Eye Drops [10 ml]
Batch number: 891

Product No.: 0781B2FR
Date of manufacture: 14.09.2021
Release date: 18.11.2021
Expiry date: 08.2023

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
pH-Value (Ph. Eur. current Ed., 2.2.3.)	7.1 - 7.6	7.2
Osmolality (Ph. Eur. current Ed., 2.2.35.)	250 - 300 mosmol/kg	281 mosmol/kg
Viscosity (Ph. Eur. current Ed., 2.2.8.)	≥ 2 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 %)	1.52 mg/ml
Assay Vitamin B12 (HPLC)	0.035 - 0.045 mg/ml (87,5 - 112,5 %)	0.039 mg/ml
Sterility (Ph. Eur. current Ed., 2.6.1.)	sterile	complies
Antimicrobial effectiveness testing (DIN EN ISO 14730)	must comply	complies

Analysis date: 04.11.2021

No.: 21002378

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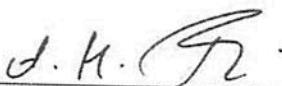
Citigroup Global Markets Deutschland AG
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Place of analysis: Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH
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The product was tested according to the current procedure and complies with the specifications.

18.11.2021

Date


Head Quality Control

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