

PHARMASTER Z.I. de Krafft 67150 Erstein - France	CERTIFICATE of ANALYSIS / СЕРТИФИКАТ ИСПЫТАНИЯ: Quixx aloe nasal spray 30 ml Спрей назальный Квикс® алоэ
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Berlin Chemie Item Code Код изделия "Берлин-Хеми" (Berlin Chemie):	F119785	coa@berlin-chemie.de
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Analysis method No. № метода испытаний:	MAL005 rev07	Product code Код продукта:	223
Test no. / № испытания:	18/04/24-188	Batch No. / № серии:	242014
Manufacturing date Дата изготовления:	16/04/2024	Expiry date Срок годности:	04/2027

	RESULTS / РЕЗУЛЬТАТЫ	SPECIFICATIONS / СПЕЦИФИКАЦИИ
CHARACTERISTICS / ХАРАКТЕРИСТИКИ Aspect / Внешний вид Colour / Цвет Smell / Запах pH / Значение pH Osmolality / Осмоляльность	Clear solution Slightly yellow solution Characteristic odour 7.2 294 mosmol/kg	Clear solution / Прозрачный раствор Colourless or slightly yellow solution / Бесцветный или слегка желтый раствор Characteristic odour / Характерный запах 5.0 to 8.0 270 to 320 mosmol/kg / 270 – 320 мосмоль/кг
Test / Испытание Aloe vera (Limit test) / Алоэ вера (Предельное испытание)	Pass	Pass / Проходит испытание
Total halogens (in NaCl) / Содержание галогенов (в пересчете на NaCl)	9.1 g/l	8.0 to 10.0 g/l / 8,0 – 10,0 г/л
MICROBIOLOGY / МИКРОБИОЛОГИЧЕСКИЕ ИССЛЕДОВАНИЯ ТАМС / ОКАМ ТУМС / ОКДПГ Staphylococcus aureus Pseudomonas aeruginosa	< 1 CFU/ml < 1 CFU/ml Absence/ml Absence/ml	According to current European Pharmacopoeia chapter 5.1.4 / В соответствии с действующим изданием Европейской фармакопеи, ч. 5.1.4. ≤ 10 ² CFU/ml / ≤ 10 ² КОЕ/мл ≤ 10 ¹ CFU/ml / ≤ 10 ¹ КОЕ/мл Absence/ml/ Отсутств./мл Absence/ml/ Отсутств./мл

COMMENTS / КОММЕНТАРИИ	N/A	Record No. 20/05/2024 Calvin GOENET Quality Assurance Pharmacist
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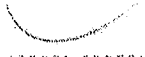
DECISION OF THE CONTROL LABORATORY / КОММЕНТАРИИ			
Laboratory technicians Лаборанты	Laboratory Manager Руководитель лаборатории	Date / Дата: 03/05/2024 Initials / Подпись:	Date / Дата: 03/05/2024 Initials / Подпись:
PASS / СООТВ. FAIL / НЕ СООТВ.	Date / Дата: 03/05/2024 Initials / Подпись:	Laboratoires PHARMASTER Fabrice MANGEL LAB DE CONTRÔLE CONFORME	Date / Дата: 03/05/2024 Initials / Подпись:

BAU0228/2/a_UA

Revision index: 04 dated 28.08.2018

Initials:

Вн. ак. № 111
 от 18.06.2024

 PHARMASTER <small>LABORATOIRE</small>	<h2>QUALITÉ MICROBIOLOGIQUE DES PRODUITS FINIS</h2>
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Selon la Pharmacopée Européenne en vigueur, chapitre 5.1.4
 According to current edition of European Pharmacopeia, chapter 5.1.4

Nom du produit <i>Product name</i>	QUIXX SOFT 30mL	Code produit <i>Product code</i>	223
N° de lot <i>Batch number</i>	242014		
Demande d'analyse <i>Analysis order</i>	18/04/24-187		
Méthode d'analyse <i>Analysis method</i>	IK016		
Date d'analyse <i>Analysis date</i>	23/04/2024		

DÉNOMBREMENT DES GERMES AÉROBIES TOTAUX (DGAT) ET DES LEVURES ET MOISSISSURES TOTALES (DMLT)
Total Aerobic Microbial Count (TAMC) and Total Yeast and Mould Count (TYMC)

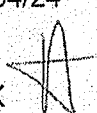
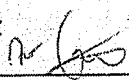
Spécifications <i>Specifications</i> (UFC / mL de produit) <i>(CFU / mL of product)</i>	DGAT / TAMC ≤ 10 ²	DLMT / TYMC ≤ 10 ¹
Résultats / Results (UFC / mL de produit) <i>(CFU / mL of product)</i>	DGAT / TAMC <1 UFC / mL	DLMT / TYMC <1 UFC / mL

RECHERCHE DES GERMES SPÉCIFIÉS / TEST FOR SPECIFIED MICRO-ORGANISMS

Spécifications <i>Specifications</i> (/ mL de produit) <i>(/ mL of product)</i>	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>
	Absence / Absence	Absence / Absence
Résultats / Results (/ mL de produit) <i>(/ mL of product)</i>	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>
	Absence / mL	Absence / mL

Accordé le 16/05/2024

Calvin GOEHRY
 Quality Assurance
 Pharmacist

DECISION DU LABORATOIRE DE CONTROLE / DECISION OF CONTROL LABORATORY		
	Technicien/Technician	Responsable du Laboratoire <i>Laboratory manager</i>
CONFORME / PASS NON-CONFORME FAIL	Date/Date: 30/04/24 Visa/Initials: NK 	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Labo des PHARMASTER de la BAUDOUIN Responsable Microbiologie Pharmacie CONFORME </div> Date/Date: 30 AVR. 2024 Visa/Initials: 

**CERTIFICATE of ANALYSIS:
 QUIXX SOFT / QUIXX ALOE
 30 ML NASAL SPRAY**

Berlin Chemie Item Code:	F154092	coa@berlin-chemie.de	
Analysis method No.	MAL005 rev07	Product code	223
Test No.	18/04/24-188	Batch No.	242014
Manufacturing date	16/04/2024	Expiry date	04/2027

	RESULTS	SPECIFICATIONS
CHARACTERS		
Aspect	Clear solution	Clear solution
Colour	Slightly yellow solution	Colourless to slightly yellow solution
Smell	Characteristic odour	Characteristic odour
pH	7.2	5.0 to 8.0
Osmolality	294 mosmol /kg	270 to 320 mosmol /kg
TEST		
Aloe vera (Limit test)	Pass	Pass
Total halogens (in NaCl)	9.1 g / L	8.0 to 10.0 g / L
MICROBIOLOGY QUALITY		According to the current European Pharmacopoeia chapter 5.1.4
TAMC	< 1 CFU / mL	≤ 10 ² CFU / mL
TYMC	< 1 CFU / mL	≤ 10 ¹ CFU / mL
<i>Staphylococcus aureus</i>	Absence / mL	Absence / mL
<i>Pseudomonas aeruginosa</i>	Absence / mL	Absence / mL

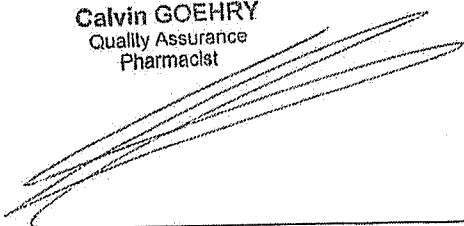
COMMENTS	N/A	Accordé 16/05/2024 Calvin GOEHRY Quality Assurance Pharmacist
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DECISION OF THE CONTROL LABORATORY			
Laboratory technicians		Laboratory Manager	
<input checked="" type="radio"/> PASS <input type="radio"/> FAIL	Date : 03/05/2024 Initials : <i>FC</i>	Date : 03/05/2024 Initials : <i>[Signature]</i>	Laboratoires PHARMA MASTER Fabrice MANGEL LAB DE CONTRÔLE CONFORME

DOSSIER DE LOT

Batch record

Quixx SOFT_Spray nasal 30ml - Zone 2-Ligne 7
Quixx SOFT_30ml nasal spray - Area 2-Line 7

CLIENT / Customer : Berlin-Chemie	CODE PRODUIT : 223 Product code
N° DE LOT / Batch number : 242014	NOMBRE THEORIQUE D'UNITES : 33 113 Batch size (units)
PEREMPTION : Expiry date : <u>2027-04</u> (Date de fabrication + 3 ans) (Manufacturing date + 3 years)	NOMBRE D'UNITES EXPEDIEES : Quantity delivered (units)
QUANTITE MISE EN ŒUVRE : Batch size volume <u>1000 Litres</u>	Modèle : Version <u>Vente Tchèque : 12 000</u>
N° DE COMMANDE CLIENT : Customer order No. <u>429027</u>	Modèle : Version <u>Vente Ukraine : 19 660</u>
	Modèle : Version <u>- : -</u>
	Echantillons AQ Client Customer QA samples <u>-</u>
	Total : Total <u>31 660</u>
	Lot soldé le : Batch completed <u>17/04/2024</u>
ACCEPTATION Acceptance	LIBERATION Release
	Accord de 16/05/2019 Calvin GOEHRY Quality Assurance Pharmacist 
OBSERVATIONS :	
Lot enchaîné Linked batch	<input checked="" type="checkbox"/> Oui / Yes <input type="checkbox"/> Non / No
N° des lots enchaînés : Batch No. of linked batches	<u>242013 / 242014 / 242015</u>
La production a été réalisée conformément aux exigences des Bonnes Pratiques de Fabrication, au dossier de marquage CE et la norme ISO 13485. Manufacturing was carried out in accordance to the Good Manufacturing Practices, the CE mark technical file and the ISO 13485.	