| SIMA PHARMA | Form | SP-PR-LIB-F-013 | Status : APPLICABLE |
|---|---|---|---|
| | *Certificate of Analysis DIVERSEY for ClearKlens Cleansinald RTU VH9S 4x5L* | | Date of application : 13/07/2023 |
| | | | Index : 01 |

| Diversey | **ClearKlens Cleansinald RTU VH9S 4x5L SKU 100848253** |
|---|---|
| **Batch Number** | SPH28082023 |
| **Production date** | 08/2023 |
| **Expiration Date** | 01/2025 |

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

| **ClearKlens Cleansinald VH9S RTU** | | | | |
|---|---|---|---|---|
| **Test** | **Test Method** | **Specification** | **Unit** | **Results** |
| Appearance | PS-CON-I-029 | Clear colorless liquid | N/A | Clear colorless liquid |
| Relative density (20°C) | PS-CON-I-027 | 0.990 – 1.010 | - | 1.001 |
| pH (neat Solution 20°C) | PS-CON-I-040 | 9.0 – 11.4 | - | 10.8 |
| Content of cationic substances (%) | PS-CON-I-034 | 0.070 – 0.090 | % | 0.075 |

| **Water routine test** | | | | |
|---|---|---|---|---|
| Microbiological Quality of WFI Water | Water PPI VRAC European pharmacopoeia | <10 cfu/100ml | CFU / 100mL | <1 |

**Control of the Sterility of the product:**

| **Test** | **Test Method** | **Specification** | **Conformity** | **Reference number** |
|---|---|---|---|---|
| Sterilization | Gamma Irradiation | 25.0 – 45.0 (kGy) | C | FR02S12751857-1-1 2013-1211A |
| Sterility certificate | Membrane filtration sterility testing EP 11.0 2.6.1 | No Growth | C | 23/CBH/STE/227 |

The analysis results above could change over time in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the Safety Data Sheet.

| Diversey | **ClearKlens Cleansinald RTU VH9S 4x5L SKU 100848253** |
|---|---|
| **Batch Number** | SPH28082023 |
| **Production date** | 08/2023 |
| **Expiration Date** | 01/2025 |

*We certify that, except for the exceptions or deviations listed above, the quoted supply has been manufactured and tested in accordance with the requirements of the specifications in force*

| **SIMA-PHARMA Control (Responsible for the production process of the final product) :** | **Stamp and signature** |
|---|---|
| **Name:** E. JACQUIN<br>**Position:** General Manager<br>**Produced on behalf of Diversey at:**<br>Sima Pharma: Z.I. de Rousset / Peynier, 54 Av. de la Plaine, 13790 Rousset, France<br>**Date:** 28/05/23 |  |

***End of certificate of analysis***

For further information, please contact Diversey at pharma@diversey.com

ENR75-TLBB-502 C

MedicalGroup
implant coating experts

Rapport N° : 23/CBH/STE/227
Report N°

Demandeur : SIMAPHARMA
Enquirer. 54, avenue de la Plain ZI de Rousset 13790 ROUSSET

# Rapport d'essai - Essai de stérilité par la méthode de filtration sur membrane
## *Test report - Membrane filtration sterility testing*

selon la Pharmacopée Européenne 11e édition chapitre 2.6.1
*according to the 11th European Pharmacopoeia Edition, chapter 2.6.1*

## ECHANTILLON(S)/SAMPLE(S)

### Informations Client / Customer informartions:

| | | | |
|---|---|---|---|
| Désignation : *Product name* | ClearKlens Cleansinald RTU VH9S S | Numéro de commande : *Order number* | FBC01138 |
| Référence client : *Customer reference* | 100848253 | POE : *SIP* | - |
| Numéro de lot : *Batch number* | SPH28082023 | Matériau(x) : *Material* | - |
| Nombre d'échantillon(s) : *Sample quantity* | 1 | Donnée de stérilisation : *Sterilization date :* | - |
| N° cahier des charges *N° of conditions of contract* | - | | |
| Commentaire(s) : *Comment(s)* | 10 Bidons poolés de 5 L | | |

### Informations Medical Group / Medical Group informations:

| | | | |
|---|---|---|---|
| Date de réception : *Receipt date :* | mercredi 6 septembre 2023 | Date de réalisation : *Testing date* | mardi 12 septembre 2023 |

## PROTOCOLE/PROTOCOL

| | | | |
|---|---|---|---|
| Volume d'échantillon filtré : *Filtred sample volume :* | 500 ml | | |
| Solution neutralisante : *Neutralizing solution :* | DNP + Thiosulfate | Volume de rinçage : *Rinsing volume :* | 3 x 100 ml |
| Nombre de milieux testés : *Number of Environnement tested :* | 2 | Volume d'immersion de la membrane : *Immersion volume of membranes :* | 100 ml |

| Conditions *Conditions* | Milieux de culture *Environnement of culture* | Température d'incubation *Incubation temperature* | Durée d'incubation *Incubation period* |
|---|---|---|---|
| Bactéries aérobies, levures, champignons *Aerobic and fungal* | Bouillon Trypcase Soja *Tryptone soy solution* | 22,5 ± 2,5°C | 14 jours *14 days* |
| Bactéries anaérobies et aérobies Anaerobic and aerobic | Bouillon Thioglycolate avec Résazurine Thioglycolate Resazurine | 32,5 ± 2,5°C | 14 jours 14 days |
| Validation de la méthode *Method validation* | 09/OI/VAL.STE/016a | | |

## RESULTATS / RESULTS

| Conditions / Milieux de culture *Conditions / Media of culture* | Examen de la croissance microbienne du milieu *Examination of the microbian growth in the media* | | | |
|---|---|---|---|---|
| | Après 7 jours *After 7 days* | | Après 14 jours *After 14 days* | |
| Bactéries aérobies, levures et moisissures / Bouillon Trypcase Soja Aerobic and fungal / Tryptone soy solution | 1 | Limpide/Limpid | 1 | Limpide/Limpid |
| | 0 | Trouble/Cloudy | 0 | Trouble/Cloudy |
| Bactéries anaérobies et aérobies / Bouillon Thioglycolate Anaerobic and aerobic / Thioglycolate Resazurine solution) | 1 | Limpide/Limpid | 1 | Limpide/Limpid |
| | 0 | Trouble/Cloudy | 0 | Trouble/Cloudy |

## CONTRÔLES /CONTROLS

| | | |
|---|---|---|
| Contrôle plan de travail avant / après (UFC) *Work plan control before / after (CFU)* | 0 | 0 |
| Air sous flux laminaire statique / dynamique (UFC) *Laminar flow air control, static / dynamic (CFU)* | 0 | 0 |

| | | |
|---|---|---|
| Contrôle de gants gauche / droit (UFC) : *Glove control product left / right (CFU)* | 0 | 0 |
| Contrôle témoins de manipulation : *Control handling indicators* | Conforme | |

## CONCLUSION

Les échantillons testés ne présentent pas de croissance microbienne après 14 jours d'incubation
*Tested products doesn't shown any microbian development after 14 days of incubation.*

***Aucun*** produit ne s'est révélé positif lors de cet essai.
***No*** *Product was positive during the test.*

Rédigé par : *Written by* Gloria PEISEY
Technicienne Microbiologie
Microbiology Technician

Approuvé par *Approved by* Mathilde DJAALAB
Responsable Laboratoire Microbiologie
Microbiology Laboratory Manager

Date : mercredi 27 septembre 2023



MedicalGroup
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Resultats conformes
le 27/09/2023
AGR2

STERIS

http://www.steris-ast.com

# Certificate of Irradiation

**Date Issued: 10-Jul-2023** **FR02S12751857-1-1**

**This is to certify that Synergy Health Marcoule, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:**

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

**SIMA PHARMA**
**ZI**
**54, avenue de la Plaine**
**13790 ROUSSET**
**FRANCE**

## Order Information

| | |
|---|---|
| Account Number: | 142994 |
| Synergy Health Sales Part Reference: | 1135482 |
| Customer Reference Number: | FBC01062 - 05/07/2023 |
| Product Description: | 320315P - Consommables 5L |
| Validation Reference: | S12119969 |
| Quantity Received: | 12 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | OFC000120 |

## Irradiation Data

| | |
|---|---|
| Date and Time of Irradiation: | 08-JUL-2023 17:12 |
| Calculated Minimum Dose kGy: | 28.9 |
| Calculated Maximum Dose kGy: | 40.0 |

**SIMA PHARMA**
54 Avenue de la Plaine, ZI
13106 ROUSSET Cedex
Tél. 04 42 29 06 43 - Fax 04 42 29 06 75
SAS au capital de 1 000 €
RCS AIX 821 995 511

Reçu 10/07/23
contrôlé OK
CARRIER E.

**Irradiation Release Authorised By Synergy Health Marseille SAS, a STERIS Company**