

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht, The Netherlands Tel. +31 (0)30 247 6427 www.Diversey.com

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CERTIFICATE OF ANALYSIS

Date issue: 28/01/20222

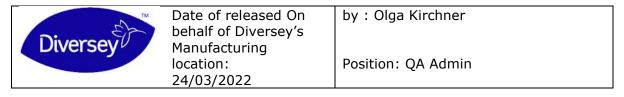
Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	□101105062/⊠101105063/□101105064
Batch Number	FMP22021 53605
Production date	21/01/2022
Expiration Date	EXP 21/01/2024

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

Test	Test Method	Specification	Unit	Results
Appearance	Visual	Colourless Clear Liquid	N/A	Colourless Clear Liquid
Specific Gravity (20°C)	DM 004	0.872 - 0.883	g/cm³	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference number
Sterilization	Gamma Irradiation	25.0 – 45.0 (kGy)	YES	53605
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK22905- 6145
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK22905- 6146



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

End of certificate of analysis

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Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

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01/31/2022 11:52:31 GMT Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3047597 P.O.# 401760 Sales Order # 2961393

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 01/28/2022 03:03:50 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	417 BX	100862174	Diversey Clearklens DE 900 mL	FMP22013	53417/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP22013	53417/STR001910
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	280 BX	101105063	Clearklens IPA 900 mls	FMP22021	53605/STR002201
	Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	700 BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.6 KGY	Pass	SWARD SIMON WARD	01/29/2022 02:39:32 GMT
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.8 KGY	Pass	SWARD SIMON WARD	01/29/2022 02:40:02 GMT

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: EMMA SILLS Date: 01/31/2022 11:52:20 GMT

Reason: Work Order Completions



Certificate of Processing

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02/07/2022 12:04:29 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3052142 P.O.# 401827 Sales Order # 2966636

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 02/05/2022 01:57:06 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number Load Number 101.000 875 ВХ 101105063 Clearklens IPA 900 mls FMP22021 53605/STR002201 Dose Map 302 0112 RF: 13.5A3, AF Min: 0.717 875 BX Total

Quality Test Summary

						Signea By	•
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	DMARRIOTT	02/07/2022 09:28:53 GMT
		Reason Code Test				DAVID MARRIOTT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	DMARRIOTT	02/07/2022 09:29:22 GMT
		Reason Code Test				DAVID MARRIOTT	

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: EMMA SILLS Date: 02/07/2022 12:04:19 GMT

Reason: Work Order Completions



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02/14/2022 11:18:08 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3056731 P.O.# 401901 Sales Order # 2971852

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 02/11/2022 06:00:29 GMT

SO Line #	Qty U	JOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	273 B	3X	101105063	Clearklens IPA 900 mls	FMP22021	53605/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3 B	3X	101105063_SAMPLE	Clearklens IPA 900 mls	FMP22021	53605/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	434 B	3X	101105063	Clearklens IPA 900 mls	FMP22032	53606/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	140 B	3X	101105063	Clearklens IPA 900 mls	54336	TO21/211
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	850 B	3X	Total			

Quality Test Summary

0	p#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
45	50.00	Minimum Dose	25.0 kGy	45.0 kGy	27.6 KGY	Pass	SWARD	02/11/2022 18:06:09 GMT
			Reason Code Test				SIMON WARD	
45	50.00	Maximum Dose	25.0 kGy	45.0 kGy	39.7 KGY	Pass	SWARD	02/11/2022 18:06:31 GMT
			Reason Code Test				SIMON WARD	

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: EMMA SILLS Date: 02/14/2022 11:17:58 GMT

Reason: Work Order Completions

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp22021 53605

Lucideon Sample Number: UK22905-6145

Lucideon Report Number: UK22905-6145/MFEP

Issue Number:

1

Date Logged:

01-Mar-2022

Order Number:

402069

Date Reported:

23-Mar-2022

Date(s) of Test(s):

04-Mar-2022 to 18-Mar-2022

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



Mrs Natalie Boot

Senior Business Support Administrator

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on:

ClearKlens IPA

Sample Description:

Sample Code: Fmp22021 53605

Lucideon Sample Number: UK22905-6146

Lucideon Report Number: UK22905-6146/ETEP

Issue Number:

1

Date Logged:

01-Mar-2022

Order Number:

402069

Date Reported:

Date(s) of Test(s):

10-Mar-2022 to 10-Mar-2022

11-Mar-2022

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass (<0.2000 EU/ml)

Tests carried out in accordance with cGMP

End of Test Report

BOOK 11-MOT-22

Mrs Natalie Boot

Senior Business Support Administrator

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