

CERTIFICATE OF ANALYSIS

Date issue: 14/09/2021


Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	<input checked="" type="checkbox"/> 101105062/ <input type="checkbox"/> 101105063/ <input type="checkbox"/> 101105064
Batch Number	FMP21322; 53409
Production date	18/11/2021
Expiration Date	EXP 18/11/2023

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/cm ³	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	53409
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK 22116 - 766
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK22116 - 767

	Date of released On behalf of Diversey's Manufacturing location: 31/01/2022	by : Olga Kirchner Position: QA Admin
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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

R55480102

 11/29/2021 16:08:39 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3011410
P.O.#	401342			Sales Order #	2919103
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/28/2021 05:42:59 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	707	BX	101101081	Diversey Clearklens DE 900ml	FMP21319	53411/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP21319	53411/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	190	BX	101105062	Diversey Clearklens IPA 900ml	FMP21322	53409/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	900	BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.4 KGY	Pass	SWARD	11/29/2021 02:45:57 GMT
		Reason Code Test				SIMON WARD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.8 KGY	Pass	ESILLS	11/29/2021 13:29:13 GMT
		Reason Code Test				EMMA SILLS	

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
 Reason: Work Order Completions

Date: 11/29/2021 16:08:17 GMT

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12/06/2021 12:43:29 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3015390
P.O.#	401400			Sales Order #	2923457
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	12/04/2021 03:54:06 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	950	BX	101105062	Diversey Clearklens IPA 900ml	FMP21322	53409/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	950	BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By-----	
						User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	26.8 KGY	Pass	PSAXTON	12/04/2021 17:00:41 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.6 KGY	Pass	PSAXTON	12/04/2021 17:01:00 GMT
		Reason Code Test				PAUL SAXTON	

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
 Reason: Work Order Completions

Date: 12/06/2021 12:43:12 GMT

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12/13/2021 13:55:37 GMT

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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3018970
P.O.#	401439			Sales Order #	2928053
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	12/11/2021 05:08:13 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	289	BX	101105062	Diversey Clearklens IPA 900ml	FMP21322	53409/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP21322	53409/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	658	BX	101105062	Diversey Clearklens IPA 900ml	FMP21334	53410/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	950	BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.1 KGY	Pass	TKVARDA	12/11/2021 17:36:33 GMT
		Reason Code Test				TOMAS KVARDA	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.8 KGY	Pass	TKVARDA	12/11/2021 17:36:56 GMT
		Reason Code Test				TOMAS KVARDA	

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: STEVEN WHELAN
 Reason: Work Order Completions

Date: 12/13/2021 13:52:32 GMT

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Clear Klens IPA

Sample Description: Sample Code: FMP21322 53409

Lucideon Sample Number: UK22116-766

Lucideon Report Number: UK22116-766/MFEP

Issue Number: 1

Date Logged: 11-Jan-2022

Order Number: PO401662

Date Reported: 31-Jan-2022

Date(s) of Test(s): 15-Jan-2022 to 29-Jan-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

NCR001 31-JAN-22
Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Clear Klens IPA

Sample Description: Sample Code: FMP21322 53409

Lucideon Sample Number: UK22116-767

Lucideon Report Number: UK22116-767/ETEP

Issue Number: 1

Date Logged: 11-Jan-2022

Order Number: PO401662

Date Reported: 31-Jan-2022

Date(s) of Test(s): 28-Jan-2022 to 28-Jan-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

NB Boot 31-Jan-22

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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