

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	FMP21214; 52591
Production date	02/08/2021
Expiration Date	EXP 02/08/2023

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	52591
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK213927-26497
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK513927-26498

	Date of released On behalf of Diversey's Manufacturing location: 06/10/2021	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

 08/23/2021 9:00:43 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2945247
P.O.#	400580			Sales Order #	2841797
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	08/21/2021 00:54:15 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	FMP21214	WO52591/STR002199
			Dose Map	302_0112		
	950	BX	Total	REF: 13.5A3 AF Min = 0.717		

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	26.6 KGY	Pass	PSAXTON	08/22/2021 04:18:52 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.5 KGY	Pass	PSAXTON	08/22/2021 04:19:12 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: 08/23/2021 09:00:34 GMT

R55480102

 08/31/2021 8:21:08 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2950147
P.O.#	400650			Sales Order #	2847872
	25 - 45 kGy	Gamma Irradiation		Irradiation Date/Time:	08/28/2021 10:59:19 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	487	BX	101105062	Diversey Clearklens IPA 900ml	FMP21214	STR002199/52591
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP21214	STR002199/52591
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
103.000	485	BX	101105062	Diversey Clearklens IPA 900ml	FMP21229	STR002199/52592
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
	975	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	JBEARNE	08/29/2021 04:21:07 GMT
		Reason Code Test				JARETH BEARNE	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.8 KGY	Pass	JBEARNE	08/29/2021 04:21:29 GMT
		Reason Code Test				JARETH BEARNE	

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: 08/31/2021 08:16:23 GMT

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

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: Fmp21214 52591

Lucideon Sample Number: UK213927-26498

Lucideon Report Number: UK213927-26498/ETEP **Issue Number:** 1

Date Logged: 15-Sep-2021 **Order Number:** 400844

Date Reported: 24-Sep-2021 **Date(s) of Test(s):** 22-Sep-2021 to 22-Sep-2021

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 (<0.2000EU/ml)

Tests carried out in accordance with cGMP

End of Test Report



24 SEP 21

Mrs Andrea Saunders

Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp21214 52591

Lucideon Sample Number: UK213927-26497

Lucideon Report Number: UK213927-26497/MFEP **Issue Number:** 1

Date Logged: 15-Sep-2021 **Order Number:** 400844

Date Reported: 06-Oct-2021 **Date(s) of Test(s):** 18-Sep-2021 to 02-Oct-2021

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


06 OCT 21

Mrs Andrea Saunders

Business Support Administrator

Page 1 of 1

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