Diversey Europe Operations BV
Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 22.08.2019

Product Name	**CLEARKLENS IPA VH1**
Product Code	7513400
Batch Number	FMP 19185 47637
Production Date	04/07/2019
Expiration Date	EXP 04/07/2021

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	Limits Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	Clear colourless liquid
Specific Gravity (20°C)	DM004	0.872 0.883	0.877

On behalf of Diversey site Quality Manager	Name :	Navaburden Pantyasb
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON
insight creating advantage

Flexible Medical Packaging
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Alison Siddle

Report of Tests on: Clearklens IPA

Sample Description: Sample Code: FMP19185 47637

Lucideon Sample Number: (194680)-36057

Lucideon Report Number: (194680)-36057/MFEP **Issue Number:** 1

Date Logged: 21-Aug-2019 **Order Number:** PO33752

Date Reported: 18-Sep-2019 **Date(s) of Test(s):** 04-Sep-2019 **to** 18-Sep-2019

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

NCBoot 18 Sep-19

Mrs Natalie Boot
Senior Business Support Assistant

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

PHARMACEUTICAL ANALYSIS REPORT

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FAO: Alison Siddle

Report of Tests on: Clearklens IPA

Sample Description: Sample Code: FMP19185 47637

Lucideon Sample Number: (194680)-36058

Lucideon Report Number: (194680)-36058/ETEP **Issue Number:** 1

Date Logged: 21-Aug-2019 **Order Number:** PO33752

Date Reported: 05-Sep-2019 **Date(s) of Test(s):** 03-Sep-2019 to 04-Sep-2019

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 (<0.2 EU/ml)

Tests carried out in accordance with cGMP

End of Test Report

NcBoot 05-Sep-19

Mrs Natalie Boot
Senior Business Support Assistant

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4459A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19185 47637	270	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP19185 47637, 5 x samples	5	Case
Validation Reference Number: 4648			

Processing Run Start Date: 11-Aug-19 02:00 AM

Processing Run End Date: 11-Aug-19 10:52 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**28.2**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**41.2**

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4661A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19165 47637	324	Case

Validation Reference Number: 4648

Processing Run Start Date: 22-Aug-19 02:05 AM

Processing Run End Date: 22-Aug-19 11:07 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**27.7**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**41.4**

Gamma Process Run Approval authorized by STERIS

REVISION 2

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

29-Aug-2019

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4547A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19185 WO47637	324	Case

Validation Reference Number: 4648

Processing Run Start Date: 22-Aug-19 03:39 AM

Processing Run End Date: 22-Aug-19 12:30 PM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**28.0**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**41.5**

Gamma Process Run Approval authorized by STERIS

Revision 2

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

Mark Morse 23-Aug-2019

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4939A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19185 47637	378	Case

Validation Reference Number: 4648

Processing Run Start Date: 05-Sep-19 12:25 PM

Processing Run End Date: 05-Sep-19 10:46 PM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**26.6**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**39.7**

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

13-Sep-2019

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-5048A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19185 47637	67	Case

Validation Reference Number: 4648

Processing Run Start Date: 12-Sep-19 05:31 AM

Processing Run End Date: 12-Sep-19 01:43 PM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**28.7**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**42.1**

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

13 SEP 2019