





<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 09-Oct-2018

UK33S12178073-1-1

This is to certify that AST Daventry Synergy Health PLC, 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

Flexible Medical Packaging Ltd
Unit 8, White Cross Ind Estate
Hightown
Lancaster
Lancashire LA1 4XS
UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1104747
Customer Reference Number:	P031851
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	714
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18270 45967, INC 5 SAMPLES, 13 PLTS

Irradiation Data

Date and Time of Irradiation:	08-Oct-2018 23:38
Reference Dose Range kGy:	36.7 - 37.7
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	42.7

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 17 Oct 2018
Date Tested: 19 Oct 2018
Date Test Completed: 19 Oct 2018
Purchase Order: 31899

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0045305/4
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 17/10/2018
Test Article: Clearklens IPA
Sample Code: FMP18270 45967
Batch Ref: 9687
Qty Received: 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	55 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.3 2.6.14, USP 41 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM02-01

Approval is provided by Electronic Signature. Their name and position is shown below.



Date: 22 Oct 2018 10:25:29

Vicky Wilson
Laboratory Manager – Microbiology



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
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Date Received: 17 Oct 2018
Date Tested: 26 Oct 2018
Date Test Completed: 09 Nov 2018
Purchase Order: PO31899

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0045305/3
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 17/10/2018
Test Article: Clearklens IPA
Sample Code: FMP18270 45967
Batch Ref: 9687
Qty Received: 20 x 900mL Bottles (+3 Spare)

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM03-01

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name and position is shown below.

CBiol. MRSB

Date: 14 Nov 2018 12:30:08

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology