



COA 6069643	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 20-Jan-2014

UK32S11099191-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 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:	1002733
Customer Reference Number:	P021609
Product Description:	JD DE 900ML BOTTLES 25-45kGy
Validation Reference:	4.0624
Quantity Received:	710
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	LOT 1; 13 PLTS; THUR 16.01.14; 705 x B/NO. FMP14008 35619 + 5 SAMPLES

Irradiation Data

Date and Time of Irradiation:	17-Jan-2014 10:38
Reference Dose Range kGy:	36.4 - 36.9
Calculated Minimum Dose kGy:	25.9
Calculated Maximum Dose kGy:	39.0

Irradiation Release Authorised By Synergy Health plc

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: 27 Jan 2014
Date Tested: 28 Jan 2014
Date Test Completed: 28 Jan 2014
Purchase Order: P021662

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0014526/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 27/01/2014
Test Article: CLEARKLENS DE BLOCK 1
Sample Code: 5162
Batch Ref: FMP14008 35619
Qty Received: 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	91 %
Dilution Tested	MM110/04	1/50
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM01

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 30 Jan 2014 14:43:52

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0014526

Certificate of Analysis - OSMM

Print Number: P0017132

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Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Winchester Road, Wickham, Fareham, Hampshire



Wickham Laboratories

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Date Received: 27 Jan 2014
Date Tested: 30 Jan 2014
Date Test Completed: 13 Feb 2014
Purchase Order: PO21662

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0014526/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 27/01/2014
Test Article: CLEARKLENS DE BLOCK 1
Sample Code: 5162
Batch Ref: FMP14008 35619
Qty Received: 20 x 900mL Bottles

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
Product Standard Data Sheet	FG047/psd	FM03

Comments

Test carried out according to current Pharmacopoeias.

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



Date: 14 Feb 2014 16:45:56

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0014526

Certificate of Analysis - OSMM

Print Number: P0017568

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