



Date of issuing : November 28th 2011



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: 19 Jan 2015
Date Tested: 27 Jan 2015
Date Test Completed: 10 Feb 2015
Purchase Order: 23603

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0020703/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 19/01/2015
Test Article: CLEARKLENS DE Block 2
Sample Code: 6139
Batch Ref: FMP 14350 37375
Qty Received: 20 x 900mL Bottles + 1 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
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: 11 Feb 2015 15:27:52

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0020703

Certificate of Analysis - OSMM

Print Number: P0025426

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ISO
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire



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Date Received: 19 Jan 2015
Date Tested: 21 Jan 2015
Date Test Completed: 21 Jan 2015
Purchase Order: 23603

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0020703/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 19/01/2015
Test Article: CLEARKLENS DE Block 2
Sample Code: 6139
Batch Ref: FMP 14350 37375
Qty Received: 1 x 900mL

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	97 %
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: 22 Jan 2015 12:04:53

Mr K.A. Barker
Business Manager - Microbiology

Consignment: 0020703

Certificate of Analysis - OSMM

Print Number: P0025095

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ISO
17025

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Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 12-Jan-2015

UK32S11307708-1-1

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:	P023531
Product Description:	JD DE 900ML BOTTLES 25-45kGy
Validation Reference:	4.1756
Quantity Received:	699
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	695 X B/N FMP14350 37375 + 4 SAMPLES THUR 08.01.2015 13 PLTS LOT 1

Irradiation Data

Date and Time of Irradiation:	11-Jan-2015 00:36
Reference Dose Range kGy:	36.5 - 37.8
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	40.9

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