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mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received 23-Sep-08

Date Tested 02-Oct-08

Date Completed 16-Oct-08

Purchase Order No. P013167

Test Article

: ClearKlens BI Spore

Sample Code

: Base

Batch Reference

: W024956

Laboratory Reference

: LR-00791319

Article Quantity: 20 x 100mL

Test Required

: Sterility Method I: Membrane Filtration by Steritest. BP, Ph Eur and USP.

Test		Method	Result	
Sterility Test by Membrane Filtration (Steritest) Method	*	MM107	Pass	
Growth in Tryptone Soya Broth at 22°C after 14 days	*	MM107/01	0/2	
Growth in Fluid Thioglycollate at 32°C after 14 days	*	MM107/02	0/2	2
Product Standard Data Sheet	*	MQ002/01	FM05	

Day Book Ref: 226053 Volume Tested: 2 X 500mL

Test carried out according to current Pharmacopoeias.

See Investigation Report PHM 2008 130

GLP

Compliant Laboratory

Date 22 Oct Los

K.A.Barker, C.Biol, M.I. Biol., Business Manager - Microbiology

Sample Booking Number:

CN\00126543

Certificate of Analysis - OSMM

Page 1 of 2

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Date Received

23-Sep-08

Date Tested

02-Oct-08

Date Completed

16-Oct-08

Purchase Order No.

P013167

Test Article

: ClearKlens BI Spore

Sample Code

: Activator

Batch Reference

: W024956

Laboratory Reference

: LR-00791320

Article Quantity : 20 x 100mL

Test Required

: Sterility Method I: Membrane Filtration by Steritest. BP, Ph Eur and USP.

Test		Method	Result
Sterility Test by Membrane Filtration (Steritest) Method	*	MM107	Pass
Growth in Tryptone Soya Broth at 22°C after 14 days	*	MM107/01	0/2
Growth in Fluid Thioglycollate at 32°C after 14 days	*	MM107/02	0/2
Product Standard Data Sheet	*	MQ002/01	FM04

Day Book Ref: 226053 Volume Tested: 2 X 500mL

Test carried out according to current Pharmacopoeias.

See Investigation Report PHM 2008 130

GLP

Compliant Laboratory

22 Oct 2008

K.A.Barker, C.Biol, M.I. Biol., Business Manager - Microbiology

Sample Booking Number:

CN\00126543

Certificate of Analysis - OSMM

Page 2 of 2

Flexible Medical Packaging Limited

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CERTIFICATE OF IRRADIATION Number: B

0382225 00

FLE001

Date:

Flexible Medical Packaging Ltd

Unit 3

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P013111 Cust. Ref: 5/09/08 Date Rec'd 9/09/08



Page

Email:

Isotron Limited

Roydsdale Way · Euroway Trading Estate

assistance@isotron.com

Bradford · West Yorkshire BD4 6SE · United Kingdom Telephone: +44 (0)1274 686011 Facsimile: +44 (0)1274 686061

Website: www.isotron.com

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010113 B208090168	JD-BOTTLES/CAPS/BAGS 25-40kGy	8	B/No.W024956
			CUSTOMERS BATCH/CODE No.s AS ORDER No.F013111 DATED 4/9/08
7			
	278		
	,	,	
	Total	8	Last Page 1 of 1
			3

All in accordance with current technical agreement

This is to certify that the above items have been irradiated as specified above

Authorising Signature:

Diece

For and on behalf of ISOTRON LIMITED



PRODUCT NAME	CLEARKLENS BI-SPORE ACTIVATOR
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY DATE	09/2010

TEST	METHOD	LIMITS	DEGLE GG
Appearance	1 (a)	01	Clear color less
pH (neat)	G14 (000)	Liquid	(icuid
Density (20°C)	G14 (002) G12 (001)	11.5 – 13.0	11.5
	012 (001)	1.015 - 1.035	1.016

QA.Manager: Jahn Jackson	Date: 25/09/08
QA: ACC	Date: 29/09/08
JD Approval:	Date: 29/01/08
-	a difference and the second of

Date above relates to the date of signing of the document by each responsible person.

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PRODUCT NAME	CLEARKLENS BI-SPORE BASE
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY DATE	09/2010

Pale Blue Liquid	RESULTS
Polo Divo Timit	
Tight and and ridgid	Pale Gue liquid
1.5 - 3.5	7.7
1.5 3.3	1.031
	1.020 - 1.060

QA.Manager: Jak Justin	Date: 25 /09 /08
QA: QIO	Dota: 79/09/0%
JD Approval: Leellt	Date: 29/01/08
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PRODUCT NAME	CLEARKLENS BI-SPORE WORKING SOLUTION
PRODUCT CODE	7514852
BATCH NUMBER	WO24956
DATE OF MANUFACTURE	09/2008
EXPIRY	24 hours from generation of solution

TEST	METHOD	LIMITS	RESULTS
Appearance	1 (a)	Clear Yellow Liquid	
pH (neat)	G14 (002)	2.5 – 5.5	3.0
Density (20°C)	G12 (001)	1.000 - 1.010	1.002
Chlorine Dioxide Content		230 – 280ppm	244 ppm

QA.Manager: Jahn Juelley	. Date: 25/09/08
	. Date: 29/09/08
JD Approval: LCLA	

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PRODUCT NAME	CLEARKLENS BI-SPORE ACTIVATOR
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY DATE	09/2010

TEST	METHOD	LIMITS	RESULTS
Appearance	1 (a)		
pH (neat)	G14 (002)	11.5 – 13.0	11.5
Density (20°C)	G12 (001)	1.015 – 1.035	1.016

QA Manager: July flushy	Date: 25/09/08
QA: ROCK	Date: 29/09/08
JD Approval: LOEALT	Date: 29/09/08

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PRODUCT NAME	CLEARKLENS BI-SPORE BASE
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09 /2008
EXPIRY DATE	09/2010

TEST	METHOD	LIMITS	DECLIE INC
Appearance	1 (a)		RESULTS
pH (neat)		Pale Blue Liquid	Itale blue liquic
	G14 (002)	1.5 - 3.5	2.7
Density (20°C)	G12 (001)	1.020 - 1.060	1-031

QA.Manager: Jaku Jackson	Date: 25/09/08
QA:	Data 20 /10/018
JD Approval:	Date: 29/07/08
Date above relates to the date of signing o person.	f the document by each responsible

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PRODUCT NAME	CLEARKLENS BI-SPORE WORKING SOLUTION
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY	24 hours from generation of solution

TEST	METHOD	LIMITS	RESULTS
Appearance	1 (a)	Clear Yellow Liquid	•
pH (neat)	G14 (002)	2.5 – 5.5	2.9
Density (20°C)	G12 (001)	1.000 - 1.010	1.002
Chlorine Dioxide Content		230 – 280ppm	241ppm

QA.Manager for furn	
QA: RAGO	Date: 29/09/08
JD Approval: Well t	Date: 29/09/08
	ng of the document by each responsible

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PRODUCT NAME	CLEARKLENS BI-SPORE ACTIVATOR
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY DATE	09/2010

TEST	METHOD	LIMITS	DEGET MG
Appearance			RESULTS
	1 (a)	Clear Colourless Liquid	Clear Colourless Uquid
pH (neat)	G14 (002)	11.5 – 13.0	11.5
Density (20°C)	G12 (001)	1.015 – 1.035	1.016

QA.Manager: John Justing	Date: 25/09/08
QA: PLOU O	Date: 29/09/08
JD Approval: LEATH	Date: 27/09/6
A 1	

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PRODUCT NAME	CLEARKLENS BI-SPORE BASE
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY DATE	09/2010

TEST	METHOD	LIMITS	RESULTS
Appearance	1 (a)	Pale Blue Liquid	Rustini
pH (neat)	G14 (002)	1.5 – 3.5	2.7
Density (20°C)	G12 (001)	1.020 - 1.060	1.031

QA.Manager: John fuokon	Date: 25/09/08
QA: AUS	Date: 29/10/108
JD Approval: LEMAT	Date: 29/09/08
Data about the	

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PRODUCT NAME	CLEARKLENS BI-SPORE WORKING SOLUTION
PRODUCT CODE	7514852
BATCH NUMBER	W024956
DATE OF MANUFACTURE	09/2008
EXPIRY	24 hours from generation of solution

TEST	METHOD	LIMITS	RESULTS
Appearance	1 (a)	Clear Yellow Liquid	
. pH (neat)	G14 (002)	2.5 – 5.5	2.9
Density (20°C)	G12 (001)	1.000 - 1.010	1.002
Chlorine Dioxide Content		230 - 280ppm	241 ppm

QA.Manager: for sustay	
QA 2066	Date: 29/09/08
JD Approval:	Date: 27/09/08
.	l l

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