

CERTIFICATE OF ANALYSIS

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PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W025089
PRODUCTION DATE	11/2008
EXPIRY DATE	11/2010

TEST	METHOD	LIMITS	RESULTS
Appearance		Clear Colourless Liquid	clear colourless
Density (20°C)	GM 0110 01	0.876 - 0.896	0.885

Date: 1911 OS

QA.Manager: Jahn July

QA.: JD Approval:

This document has been produced on behalf of Johnson Diversey by authorised personnel.

Issue no. 4
Issued by W. Ashton
Issue date 07.04.2006

CERTIFICATE OF IRRADIATION Number: B

0389737 00

FLE001

Flexible Medical Packaging Ltd

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

P013404 Cust. Ref: 13/11/08 Date Rec'd 18/11/08 Date:



Page

Isotron Limited

Roydsdale Way · Euroway Trading Estate

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

Email: Website:	assistance@isotron.com
	P. S. P. P. S. W. C. S.

Date: 16/11/	'U8		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B208110429	JD DE 900ML BOTTLES 25-45kGy	706	B/No.W025089 CUSTOMER B/No.F/C 146
			ACTUAL36.0 – 38.3kGy DOSE
B2FLE0010999 B208110429	SAMPLES	10	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013404 DATED 13/11/08
	Total	716	Last Page 1 of 1

All in accordance with current technical agreement

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

Authorising Signature: C D. OCC.

For and on behalf of ISOTRON LIMITED



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CERTIFICATE OF ANALYSIS

Mr J Jackson

Date Received

21-Nov-08

Flexible Medical Packaging Limited

Date Tested : 08-Dec-08

Unit 8, Hightown

Date Completed : 08-Dec-08

Lancaster LA1 4XS

White Cross Industrial Estate

Purchase Order No. :

PO13435

Test Article

: Clearklens DE Block 1

Sample Code

: Works Order No. 25089

Batch Reference

: 146

Laboratory Reference

: LR-00809062

Article Quantity: 4 Bottles

Test Required

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. BP, Ph Eur and USP.

Test		Method	Result
Bacterial Endotoxin by LAL, Kinetic QCL Test	*	MM110	<0.2500 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	66% Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL

This sample was tested at a 1/50 dilution and spiked with endotoxin to check for interference.

Test carried out according to current Pharmacopoeias.

Product Standard Data Sheet: FM01

GLP

Compliant Laboratory

K.A.Barker, C.Biol, M.I. Biol.,

Business Manager - Microbiology

Sample Booking Number: Flexible Medical Packaging Limited

CN\00129067

Certificate of Analysis - OSMM

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Date 16 Dec Word



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CERTIFICATE OF ANALYSIS

21-Nov-08 **Date Received** Mr J Jackson **Date Tested** 26-Nov-08 Flexible Medical Packaging Limited : Unit 8, Hightown **Date Completed** 10-Dec-08 White Cross Industrial Estate Purchase Order No. PO13435 Lancaster LA1 4XS

Test Article

: Clearklens DE Block 1

Sample Code

: Works Order No. 25089

Batch Reference

: 146

Laboratory Reference

: LR-00809061

Article Quantity : 20 Bottles

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	0/1
Growth in Fluid Thioglycollate at 32°C after 14 days	*	MM107/02	0/1
Product Standard Data Sheet	*	MQ002/01	FM03

Day Book Ref: 306032 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

16 Re, 2008

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

Sample Booking Number:

CN\00129067

Certificate of Analysis - OSMM

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