

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	ND 26599
PRODUCTION DATE	2009 /09
EXPIRY DATE	20h /09

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	Cleor Colourless Liquid
Density (20°C)	GM 0110 01	0.876 - 0.896	0,887

Date:		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		**********	
QA.Man	ager:		<u>)</u>		*****
QA.:	k. (raya)	in ;		*********	
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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

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FLEGO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P014602

Cust. Ref: 24/09/09 Date Rec'd Date: 2/10/09



Isotron Limited

Roydsdale Way · Euroway Trading Estate

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

Website: www.isotron.com

Date: 2/10.	709		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209090589	JD DE 900ML BOTTLES 25-45kGy	1415	B/No.W026599 - CUSTOMER B/No.1249
			ACTUAL35.737.7kGy DOSE
B2FLE0010999 B209090589	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P014602 DATED 24/9/09
			•
	Total	1417	Last Page 1 of 1

All in accordance with current technical agreement

For and on behalf of ISOTRON LIMITED

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

Authorising Signature: J. (offer



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CERTIFICATE OF ANALYSIS

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received : 08-Oct-09

Date Tested : 22-Oct-09

Date Completed : 05-Nov-09

Purchase Order No. : PO14652

Test Article

: Clearklens DE Block 1

Sample Code

:

Batch Reference

: WO26599

Laboratory Reference

: LR-00895013

Article Quantity: 20 x 900mL

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: 649026 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

Mrs S L Wood Laboratory Manage.

aniol., MSB

..... Microbiology

Date 12 Nos 2009

Compliant Laboratory

GLP

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

Sample Booking Number:

CN\00141620

Certificate of Analysis - OSMM

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Flexible Medical Packaging Limited

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CERTIFICATE OF ANALYSIS

Mr J Jackson

Date Received

08-Oct-09

Flexible Medical Packaging Limited

Date Tested

12-Oct-09

Unit 8, Hightown White Cross Industrial Estate

Date Completed

12-Oct-09

Lancaster LA1 4XS

Purchase Order No.

PO14652

Test Article

: Clearklens DE

Sample Code

Batch Reference

: WO26599

Laboratory Reference

: LR-00895012

Article Quantity: 1 x 900mL

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	Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM01

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

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date 20 Oct 2009

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

Sample Booking Number: Flexible Medical Packaging Limited

CN\00141620

Certificate of Analysis - OSMM

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