



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026352
PRODUCTION DATE	08/2009
EXPIRY DATE	08/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	VISUAL	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 – 0.896	0.881

Date: 28/08/09

QA Manager: [Signature]

QA: E. Gargan

JD Approval: [Signature]

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

FLE001

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Flexible Medical Packaging Ltd
Unit 8
White Cross Industrial Estate
Hightown
Lancaster



Isotron Limited

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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

LA1 4XS

Cust. Ref: P014441
Date Rec'd 20/08/09
Date: 25/08/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209080466	JD DE 900ML BOTTLES 25-45kGy	703	B/No.W026352 - CUSTOMER B/No.934 ACTUAL....36.8 - 39.4....kGy DOSE
B2FLE0010999 B209080466	SAMPLES	3	 CUSTOMERS BATCH/CODE No.s AS ORDER No.P014441 DATED 19/8/09
Total		706	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: *J. Gaffey*
For and on behalf of ISOTRON LIMITED



CERTIFICATE OF ANALYSIS

Mr J Jackson
Flexible Medical Packaging Limited
Unit 8, Hightown
White Cross Industrial Estate
Lancaster LA1 4XS

Date Received : 02-Sep-09
Date Tested : 08-Sep-09
Date Completed : 08-Sep-09
Purchase Order No. : PO014492

Test Article : Clearlens DE Block 1
Sample Code : WO No. 26352
Batch Reference : 934
Laboratory Reference : LR-00885370 Article Quantity : 1x900mL
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.

WAB

Date 14 Sep 2009

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

GLP
Compliant
Laboratory

Sample Booking Number: CN00140163
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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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 : 02-Sep-09
Date Tested : 08-Sep-09
Date Completed : 22-Sep-09
Purchase Order No. : PO014492

Test Article : Clearklens DE Block 1

Sample Code : WO No. 26352

Batch Reference : 934

Laboratory Reference : LR-00885369

Article Quantity : 20x900mL

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: 649002

Volume Tested: 20x50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant
Laboratory

NR

Date 28 Sep 2009

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

Sample Booking Number: CN\00140163

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