



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W026304
PRODUCTION DATE	06 / 2009
EXPIRY DATE	06 / 2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 – 0.896	0.880

Date: 03/07/09

QA Manager: [Signature]

QA: [Signature] 03/07/09

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: 14204
Date Rec'd 24/06/09
Date: 29/06/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209060596	JD DE 900ML BOTTLES 25-45kGy	702	BATCH NO: W026304 - CUST NO: 901 ACTUAL . .37.8 - 39.7 .kGy DOSE
B2FLE0010999 B209060596	SAMPLES	2	
B2FLE001VAL	VALIDATION		SINGLE
Total		704	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:

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 : 09-Jul-09
Date Tested : 15-Jul-09
Date Completed : 15-Jul-09
Purchase Order No. : 14262

Test Article : Clearklens DE Block 1
Sample Code : Works Order No. 26304
Batch Reference : 901

Laboratory Reference : LR-00870990

Article Quantity : 1 Bottle

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	<0.25 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	111% 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.

Shirley Wood

Mr S L Wood, BSc., CBiol., MIBiol

Laboratory Manager - Pharmaceutical Microbiology

Date

22 July 2009

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

GLP

Compliant
Laboratory

Sample Booking Number: CN\00137972

Certificate of Analysis - OSMM

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Flexible Medical Packaging Limited

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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 : 09-Jul-09
Date Tested : 16-Jul-09
Date Completed : 30-Jul-09
Purchase Order No. : 14262

Test Article : Clearklens DE Block 1

Sample Code : Works Order No. 26304

Batch Reference : 901

Laboratory Reference : LR-00870989

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: 574021

Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

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

Date *04 Aug 2009*

GLP

Compliant
Laboratory

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

Sample Booking Number: CN\00137972

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