

# **CERTIFICATE OF ANALYSIS**

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	00 26750
PRODUCTION DATE	10 / 2009
EXPIRY DATE	10/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	Clear Colourless
Density (20°C)	GM 0110 01	0.876 - 0.896	0,885

Date: 19, 10, 2009
QA.Manager:
QA: EGangum
ID Approval: Let Hat

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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FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd P014640 6/10/09

Date:

9/10/09



## **Isotron Limited**

Roydsdale Way · Euroway Trading Estate

1

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: 9/10/	118		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209100159	JD DE 900ML BOTTLES 25-45kGy	712	B/No.W026750 - CUSTOMER B/No.1273  ACTUAL36.137.3kGy  DOSE
B2FLE0010999 B209100159	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.P01464D DATED 5/10/09
	Total	714	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

For and on behalf of ISOTRON LIMITED



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire P017 5EU England

Telephone: +44(0)1329 832511 +44(0)1329 834262 Fax:

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 20-Oct-09

Date Tested 25-Oct-09 :

**Date Completed** 06-Nov-09

Purchase Order No. 14697

**Test Article** 

: Clearklens DE Block 1

Sample Code

: WO26750

**Batch Reference** 

: 1273

Laboratory Reference

: LR-00898629

Article Quantity : 20 Bottles

**Test Required** 

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

Test	- 1	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: 649033 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

Mrs S.J. Wood, BSc., CBiol., MSB

Date 12 Nov 2009

Compliant Laboratory

GLP

K.A.Barker, C.Biol, MSB

Les and the

Business Manager - Microbiology

Sample Booking Number:

CN\00142117

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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** 20-Oct-09

Date Tested 27-Oct-09

**Date Completed** 27-Oct-09

Purchase Order No. 14697

**Test Article** 

: Clearklens DE Block 1

Sample Code

: WO26750

**Batch Reference** 

Laboratory Reference

: LR-00898630

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	<0.2500 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.

Mr K A Barker, CBiol., MSB Business Manager

Date 29 Oct 2009

Compliant Laboratory

GLP

Mrs S.L. Wood, B.Sc. (Hons), C.Biol., MSB.,

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00142117

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