

# CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE		
PRODUCT CODE	6069643		
BATCH NUMBER	W025197		
PRODUCTION DATE	02/2009		
EXPIRY DATE	02/2011		

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

Date: 05/03/09
QA.Manager: DO
QA: EGanazni
QA: EGarajni  DApproval: Le Je

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

0399300 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd 19/02/09

P013746



Page 1

#### **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: 24/02/	(09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209020549	JD DE 900ML BOTTLES 25-45kGy	683	172 X B/No.W025362 - CB/No.FC470 340 X B/No.W025197 - CB/No.FC401 171 X B/No.W025751 - CB/No.FC470
			ACTUAL37.6 - 39.3kGy DOSE
B2FLE0010999 B209020549	SAMPLES	7	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013746 DATED 18/2/09
	Total	690	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



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 5EU England Telephone: +44(0)1329 832511

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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** 

06-Mar-09

**Date Tested** 

11-Mar-09

Date Completed

13-Mar-09

Purchase Order No.

PO13783

**Test Article** 

: Clearklens DE Block 1

Sample Code

**Batch Reference** 

: WO25197

Laboratory Reference

: LR-00836266

Article Quantity: 1 x 900mLs

**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	82% 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 19 Mar lean

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

Sample Booking Number:

CN\00132925

Certificate of Analysis - OSMM

Page 1 of 1

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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** 06-Mar-09

**Date Tested** 10-Mar-09

**Date Completed** 24-Mar-09

Purchase Order No. PO13783

**Test Article** 

: Clearklens DE Block 1

Sample Code

**Batch Reference** 

: WO25197

Laboratory Reference

: LR-00836265

Article Quantity : 23 x 900mLs

**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: 380037 Volume Tested: 20x50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date 27 Mar 2009

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

Sample Booking Number:

CN\00132925

Certificate of Analysis - OSMM

Page 1 of 1

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