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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** 

16-Sep-08

**Date Tested** 

24-Sep-08

**Date Completed** 

08-Oct-08

Purchase Order No.

PO13149

**Test Article** 

: Clearklens DE

Sample Code

**Batch Reference** 

: WO24955

**Laboratory Reference** 

: LR-00789659

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: 226049 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date 1400-2002

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

Sample Booking Number: Flexible Medical Packaging Limited

CN\00126309

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** 16-Sep-08

**Date Tested** : 01-Oct-08

**Date Completed** 01-Oct-08

Purchase Order No. PO13149

**Test Article** 

: Clearklens DE

Sample Code

**Batch Reference** 

: WO24955

Laboratory Reference

: LR-00789660

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	<0.25 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	82% Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL

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

Test carried out according to current Pharmacopoeias.

Product Standard Data Sheet: FM01

GLP

Compliant Laboratory

foct was

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

Sample Booking Number:

CN\00126309

Certificate of Analysis - OSMM

Page 1 of 1

Flexible Medical Packaging Limited

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## CERTIFICATE OF IRRADIATION Number: B

0382203 00

FLE001

Flexible Medical Packaging Ltd Unit 8

White Cross Industrial Estate Hightown

Lancaster

LA1 4XS

Cust. Ref:

P013111 5/09/08

Date Rec'd Date:

11/09/08



Page

#### 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

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B208090170	JD DE 900ML BOTTLES 25-45kGy	524	B/No.W024955 - CUST B/NO: 29599
			ACTUAL38.1 - 39.3kGy DOSE
B2FLE0010999 B208090170	SAMPLES	4	
11 000			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013111 DATED 4/9/08
^			
	•		
	Total	528	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

PRODUCT NAME	CLEARKLENS DE		
PRODUCT CODE	6069643		
BATCH NUMBER	WO24955		
PRODUCTION DATE	08 12008		
EXPIRY DATE	09/2010		

TEST	METHOD	LIMITS	RESULTS	
Appearance		Clear Colourless Liquid	Clear colourless	
Density (20°C)	GM 0110 01	0.876 - 0.896	D.882	

Date:l	2/09	loT		
QA.Manage			.,	
QA.:£	Gallym			• • • • • •
JD Approva	i: he	e Ath	5	

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

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