

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE	
PRODUCT CODE	6069643	
BATCH NUMBER	W024288	
PRODUCTION DATE	07 /2008	
EXPIRY DATE	07/2010	

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

Date: 50/C	7/08
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QA: E Gimey	v.i.
JD Approval:	w.

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

0377121 00

FLE001

Flexible Medical Packaging Ltd

White Cross Industrial Estate Hightown

Lancaster

LA1 4XS

Cust. Ref: P012882-883-884-885

Date Rec'd 17/07/08 22/07/08 Data:



Page

Isotron Limited

Roydsdale Way · Euroway Trading Estate

Bradford · West Yorkshire BD4 6SE · United Kingdom

1

Telephone: +44 (0)1274 686011 Facsimile: +44 (0)1274 686061 assistance@isotron.com

Website: www.isotron.com

Date: 22/07/0	DB		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B208070431	JD DE 900ML BOTTLES 25-45kGy	348	B/No.WO24288 CUSTOMER B/No.29373
		p	ACTUAL37.3 - 38.4kGy DOSE
B. LE0010999 B208070431	SAMPLES	4	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.PO12882 DATED 16/7/08
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	-		
		×	×.
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			.
-	Total	352	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:

Drace

For and on behalf of ISOTRON LIMITED



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire P017 5EU England Telephone: +44(0)1329 832511

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28-Jul-08

PO12922

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

Purchase Order No.

Date Tested 31-Jul-08

Date Completed 31-Jul-08

Test Article

: Clearklens DE

Sample Code

Jatch Reference

: WO24288

Laboratory Reference

: LR-00776127

Article Quantity : 1 x900mL

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	Valid 91%
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 aboratory

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

Sample Booking Number: Flexible Medical Packaging Limited

CN\00124385

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 28-Jul-08

Date Tested 07-Aug-08

Date Completed 21-Aug-08

Purchase Order No. PO12922

Test Article

: Clearklens DE

Sample Code

3atch Reference

: WO24288

Laboratory Reference

: LR-00776126

Article Quantity : 20 x900mL

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: 226020 Volume Tested: 20x50mL

Test carried out according to current Pharmacopoeias.

3 bottles were found to be leaking when received, client contacted about how to proceed with testing, proceed with testing.)

GLP

Compliant Laboratory

K.A.Barker, C.Biol, M.I. Biol.,

Business Manager - Microbiology

Sample Booking Number: Flexible Medical Packaging Limited

CN\00124385

Certificate of Analysis - OSMM

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