

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE			
PRODUCT CODE	6069643			
BATCH NUMBER	NO 26667			
PRODUCTION DATE	2009/10			
EXPIRY DATE	2011 /10			

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	liquid
Density (20°C)	GM 0110 01	0.876 - 0.896	0.888

Date:	
QA.Manager: DD O	
QA: EGaugger	*******
JD Approval: Let Att	

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

Page

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FLEGO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd P014623 1/10/09 isotron

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: 6/10/	/ 09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209100068	JD DE 900ML BOTTLES 25-45kGy	706	B/No.W026667 - CUSTOMER B/No.1248 ACTUAL37.439.1kGy DOSE
B2FLE0010999 B209100068	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.P014623 DATED 30/9/D9
	Total	708	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 PO17 5EU England

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

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

CERTIFICATE OF ANALYSIS

Mr J Jackson

Date Received

08-Oct-09

Flexible Medical Packaging Limited

Date Tested : 12-Oct-09

Unit 8, Hightown White Cross Industrial Estate

Date Completed : 12-Oct-09

Lancaster LA1 4XS

Purchase Order No. : PO14650

Test Article

: Clearklens DE Block 1

Sample Code

.

Batch Reference

: WO26667

Laboratory Reference

: LR-00894963

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	<0.2500 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.

GLP

Compliant Laboratory

VVVdn

Date 20 Oct 209

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

Sample Booking Number: Flexible Medical Packaging Limited

CN\00141608

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

08-Oct-09

Date Tested

20-Oct-09

Date Completed

03-Nov-09

Purchase Order No.

PO14650

Test Article

: Clearklens DE Block 1

Sample Code

Batch Reference

: WO26667

Laboratory Reference

: LR-00894964

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: 649026 Volume Tested: 20x 50mL

Test carried out according to current Pharmacopoeias.

 GLP

Compliant Laboratory

Date 06Nb12009

Mrs S.L. Wood, B.Sc. (Hons), C.Biol., MSB., Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00141608

Certificate of Analysis - OSMM

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