

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE		
PRODUCT CODE	6069643		
BATCH NUMBER	W026351		
PRODUCTION DATE	08/2009		
EXPIRY DATE	08/2011		

TEST	METHOD	LIMITS	RESULTS
Appearance	VISUAL	Clear Colourless	clear colourless
	010001	Liquid	112010
Density (20°C)	GM 0110 01	0.876 - 0.896	0.381

Date: 25.05.09
QA.Manager:
QA: E Garajan:
JD Approval:

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

0418105 00

FLEOO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

P014417 Cust. Ref: Date Rec'd

17/08/09 27 /00 /00



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

Date: 24/08/	/09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209080400	JD DE 900ML BOTTLES 25-45kGy	704	B/No.W026351 - CUSTOMER B/No.934 ACTUALkGy DOSE
B2FLED010999 B209080400	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.14417 DATED 17/8/09
	Total	706	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: 5. (After

For and on behalf of ISOTRON LIMITED



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

-ax: +44(0)1329 834262

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 : 02-Sep-09

Date Tested : 08-Sep-09

Date Completed : 08-Sep-09

Purchase Order No. : PO14491

Test Article

: Clearklens DE Block 1

Sample Code

: WO No. 26351

Batch Reference

: 934

Laboratory Reference

: LR-00885372

Article Quantity: 1x900mL

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

MR

Date 14 Sep 2009

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

Sample Booking Number:

CN\00140164

Certificate of Analysis - OSMM

Page 1 of 1

Flexible Medical Packaging Limited

This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited







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

+44(0)1329 834262

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

02-Sep-09

Date Tested

10-Sep-09

Date Completed

24-Sep-09

Purchase Order No.

PO14491

Test Article

: Clearklens DE Block 1

Sample Code

: WO No. 26351

Batch Reference

: 934

Laboratory Reference

: LR-00885371

Article Quantity : 20x900mL

:

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: 649002 Volume Tested: 10 x 50mL

Test carried out according to current Pharmacopoeias.

 ${f GLP}$

Compliant Laboratory

Date 30 Sep long

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

Sample Booking Number:

CN\00140164

Certificate of Analysis - OSMM

Page 1 of 1

Flexible Medical Packaging Limited

This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited