

## CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE		
PRODUCT CODE	6069643		
BATCH NUMBER	W026350		
PRODUCTION DATE	08/2009		
EXPIRY DATE	08/2011		

TEST	METHOD	LIMITS	RESULTS
Appearance	Hicard	Clear Colourless	Clear Colourless
	V15091	Liquid	Liquid
Density (20°C)	GM 0110 01	0.876 - 0.896	0.884

Date: 26/08/09
QA.Manager:
QA: E Garajny
D Approval: VELAL

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

0417776 00

FLEO01

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: P014389
Date Rec'd 13/08/09
Date: 20/08/09



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. 257 CG7			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209080347	JD DE 900ML BOTTLES 25-45kGy	705	B/No.W026350 - CUSTOMER B/No.933 ACTUAL36.1 - 37.9kGy DOSE
[ LE0010999 B209080347	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.P014389 DATED 12/8/09
	Total	707	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: J. Go

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

Flexible Medical Packaging Limited

Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

**Date Received** 

27-Aug-09

**Date Tested** 

02-Sep-09

**Date Completed** 

02-Sep-09

Purchase Order No.

P014475

**Test Article** 

: Clearklens DE Block 1

Sample Code

: Works Order No. 26350

**Batch Reference** 

: 933

Laboratory Reference

: LR-00884096

Article Quantity: 1 Bottles

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.

Mr K.A. Barker C.Biol., M.I. Biol. Business Manager

Date 11 Sep 2009

Compliant Laboratory

GLP

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

Sample Booking Number:

CN\00139998

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 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

Flexible Medical Packaging Limited
Unit 8, Hightown
White Cross Industrial Estate
Lancaster LA1 4XS

Date Received : 27-Aug-09

Date Tested : 03-Sep-09

Date Completed : 17-Sep-09

Purchase Order No. : P014475

Test Article : Clearklens DE Block 1
Sample Code : Works Order No. 26350

Batch Reference : 933

Laboratory Reference : LR-00884095 Article Quantity : 20 Bottles

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: 574 045 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

Mrs S L Wood, BSc., CBiol., MIBiol

Taboratory Manager - Flar conceptical Microbiology

Date 24 Sep 2007

Compliant Laboratory

GLP

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

Sample Booking Number: Flexible Medical Packaging Limited

CN\00139998

Certificate of Analysis - OSMM

Page 1 of 1

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