

CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE		
PRODUCT CODE	6069643		
BATCH NUMBER	WO 26230		
PRODUCTION DATE	07/2009		
EXPIRY DATE	07/2011		

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	Clear Colourless
Density (20°C)	GM 0110 01	0.876 - 0.896	0.881

Date:17/07/09
Date:171.07.109 QA.Manager:
QA: L. GENLYM 17-07-09
ID Approval: Leafth

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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Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

F014231 Cust. Ref: 2/07/09 Date Rec'd 10/07/00



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: 10/07.	/09		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209070209	JD DE 900ML BOTTLES 25-45kGy	705	B/No.W026230 - CUSTOMER B/No.909
			ACTUAL37.7 - 39.7kGy DOSE
B2FLE0010999 B209070209	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P014231 DATED 29/6/09

Total

All in accordance with current technical agreement

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This is to certify that the above items have been irradiated as specified above

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Authorising Signature:

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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CERTIFICATE OF ANALYSIS

Mr J Jackson Flexible Medical Packaging Limited Unit 8, Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received 17-Jul-09

Date Tested 22-Jul-09

Date Completed 22-Jul-09

Purchase Order No. PP14298

Test Article

: Clearklens DE Block 1

Sample Code

Batch Reference

: WO26230

Laboratory Reference

: LR-00873292

Article Quantity: 1 bottle

Test Required

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. BP, Ph Eur and USP.

Test	1	Method	Result
Bacterial Endotoxin by LAL, Kinetic QCL Test	*	MM110	<0.2500 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	94% 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 Laborator

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

Sample Booking Number:

CN\00138338

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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

17-Jul-09

Date Tested

24-Jul-09

Date Completed

07-Aug-09

Purchase Order No.

PP14298

Test Article

: Clearklens DE Block 1

Sample Code

Batch Reference

: WO26230

Laboratory Reference

: LR-00873291

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: 574027 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

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

Business Manager - Microbiology

Date 17 Any los

Sample Booking Number:

CN\00138338

Certificate of Analysis - OSMM

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