

Contact address:

JohnsonDiversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 9.08,2010

Product Name	CLEARKLENS DE VH29		
Product Code	6069643		
Batch Number	NO 28210		
Production Date	07/2010		
Expiry Date	07 12012.		

This is to certify that the above batch of product has been produced conforming to the manufacturing dossier from JohnsonDiversey in which the formula and processing instructions are defined and has been tested with the following Quality Control specification for the product.

Test	Test Method	Limits	Results
Appearance	Visual	Clear Liquid	Clean Liquial
Specific Gravity (20°C)	JDM004	0.880 - 0.888	0,386

Signature / name Ogo Fixel
On behalf of Manufacturing Location







CERTIFICATE OF IRRADIATION Number: B

0456405 00

FLEGO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P015700

Cust. Ref: Date Rec'd 29/07/10



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 assistance@isotron.com Email:

Website: www.isotron.com

Date: 3/08/	/10		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	ОТУ	ADDITIONAL DETAILS
B2FLE0010121 B210080012	JD DE 900ML BOTTLES 25-45kGy	704	B/No.W028270 - CUSTOMER B/No.1935 ACTUAL DOSE36.2 - 38.2kGy
B2FLE0010999 B210080012	Despatch Text: 13PLTS	5	CUSTOMERS BATCH/CODE No.s AS ORDER No.P015700 DATED 28/7/10
	Total	709	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:

For and on behalf of ISOTRON LIMITED



Wickham Laboratories Limited, Winchester Road, Wickham, Fareham, Hampshire PO17 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 09-Aug-10

Date Tested 17-Aug-10

Date Completed 17-Aug-10

Purchase Order No. 15732

Test Article

: DE Block I

Sample Code

: Works Order: 28270

Batch Reference

: 1935

Laboratory Reference

: LR-00978093

Article Quantity : 1 Bottle

Test Required

: LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. 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 59%	
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL	
Product Standard Data Sheet	*	MQ002/01	FM01	

Test carried out according to current Pharmacopoeias.

Compliant Laboratory

GLP

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00153279

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

09-Aug-10

Date Tested

12-Aug-10

Date Completed

26-Aug-10

Purchase Order No.

15732

Test Article

: Clearklens DE Block 1

Sample Code

: Works Order: 28270

Batch Reference

: 1935

Laboratory Reference

: LR-00978092

Article Quantity : 20 Bottles

Test Required

: Sterility Method I: Membrane Filtration by Steritest. 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: 900040 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Mr K A Barker, CBiol., MSB

Business Manager

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00153279

Certificate of Analysis - OSMM

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