

Contact address:

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

CERTIFICATE OF ANALYSIS

Date: 7/4/10

Product Name	CLEARKLENS DE VH29
Product Code	606964
Batch Number	WD 27561
Production Date	03/2010
Expiry Date	03/2012

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	clear habid	
Specific Gravity (20°C)	JDM004	0.880 - 0.888	(2.587	

V

Signature / name
On behalf of Manufacturing Location







CERTIFICATE OF IRRADIATION

isotron

Number: B

0441374 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4X5

Cust. Ref: F' Date Rec'd 1

P015226 18/03/10

18/03/10

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: 23/03/			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B210030427	JD DE 900ML BOTTLES 25-45kGy	378	B/No.W027561 - CUSTOMER B/No.1598 ACTUAL DOSE36.0 - 37.4kGy
B2FLE0010999 B210030427	SAMPLES	5	CUSTOMERS BATCH/CODE No.s AS ORDER No.P015226 DATED 17/3/04
	Despatch Text: 7PLTS		
	Total	383	Last Flago 4 of 4
	10181	000	Last Fage 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. (gffey

For and on behalf of ISOTRON LIMITED

CERTIFICATE OF IRRADIATION Number: B

Page

FLEOO1

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref:

P015249



Isotron Limited

Roydsdale Way · Euroway Trading Estate

0442018 00

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 Rec'd 25/03/ Date: 29/03/			
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B210030542	JD DE 900ML BOTTLES 25-45kGy	320	B/No.WO27561 - CUSTOMER B/No.1598 ACTUAL DOSE35.9 - 38.2kGy
B2FLE0010999 B210030542	Despatch Text: 6PLTS	1	CUSTOMERS BATCH/CODE No.s AS ORDER No.PO15249 DATED 24/3/10
	Total	321	Last Page 1 of 1
		All in acco	ordance with current agreement

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

29-Mar-10

Date Tested

06-Apr-10

Date Completed

06-Apr-10

Purchase Order No.

PO15254

Test Article

: ClearKlens JD DE Block 1

Sample Code

: Work Order No. 27561

Batch Reference

: 1598

Laboratory Reference

: LR-00945488

Article Quantity : 1Bottle+3 Spare

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 98%
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM01

Test carried out according to current Pharmacopoeias.

14: II A Parke, CBiol., MSB

Business Manager

Date 13 Agar 2010

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00148496

Certificate of Analysis - OSMM

Page 1 of 1

GLP

Compliant

Laboratory

Flexible Medical Packaging Limited

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CERTIFICATE OF ANALYSIS

Flexible Medical Packaging Limited

Unit 8, Hightown

Mr J Jackson

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received 29-Mar-10

Date Tested 07-Apr-10

Date Completed 21-Apr-10

Purchase Order No. PO15254

Test Article

: ClearKlens JD DE Block 1

Sample Code

: Work Order No. 27561

Batch Reference

: 1598

Laboratory Reference

: LR-00945487

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: 800020 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

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

Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number:

CN\00148496

Certificate of Analysis - OSMM

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