

Diversey Europe BV

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Tel. +31 (0)30 247 6427

# **CERTIFICATE OF ANALYSIS**

Date: 4/5/12

Product Name	CLEARKLENS DE VH29		
Product Code	6069643		
Batch Number	WO 31947		
Production Date	04/2017		
Expiration Date	04/2014		

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	Mer colourtess
Specific Gravity (20°C)	JDM004	0.880 0.888	0.885

On behalf of Divigrance site	Name :	CHECOE	
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector	

This document being issued electronically does not bear a signature

COA 6009043	Version: 03	Date of issuing: November 28th 2011	

FLE001

## **CERTIFICATE OF IRRADIATION**

Number: B

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P018486

Cust. Ref: Date Rec'd 26/04/12 30/04/12

Date:

Synergy Health plc

Roydsdale Way · Euroway Trading Estate

Bradford · West Yorkshire BD4 6SE · United Kingdom

Telephone: +44 (0)1274 686011 Facsimile: +44 (0)1274 686061 Email:

assistance@synergyhealthplc.con Website: www.synergyhealthplc.com

ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B212040849	JD DE 900ML BOTTLES 25-45kGy	350	B/No.31942 - CUSTOMER B/No.3259
1 To			ROUTINE DOSE 37.5, 38.9, 39.0 kGy
B2FLE0010999 B212040849	SAMPLES	5	
			CUSTOMER BATCH/CODE No.s AS ORDER No.P018486 DATED 25/4/12
	Despatch Text:		
	7PLTS		
	Total	355	Last Page 1 of 1
		All in acco	rdance 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 SYNERGY HEALTH PLC



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

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

**Date Received:** 

08 May 2012

Date Tested:

10 May 2012

**Date Test Completed:** 

10 May 2012

**Purchase Order:** 

18542

### **CERTIFICATE OF ANALYSIS**

Laboratory Reference Number:

0004552/2

**Test Required:** Date Received: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

08/05/2012

Test Article:

Clearklens DE Block 1

Sample Code:

3259

WO31942

Batch Ref: **Qty Received:** 

1 x 900mL

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.25 EU/mL
Spiked Recovery	MM110/01	70 %
Dilution Tested	MM110/04	1/50
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM01

#### Comments

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Eur Leid

Date: 14 May 2012 17:19:14

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

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0004552

Certificate of Analysis - OSMM

Print Number: P0002990

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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

**Date Received:** 

08 May 2012

Date Tested:

15 May 2012

**Date Test Completed:** 

29 May 2012

Purchase Order:

18542

### **CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 

0005046/1

Test Required: Date Received: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

08/05/2012

Test Article:

ClearKlens DE Block 1

Sample Code:

3259

Batch Ref: Qty Received: WO 31942 20 x 900mL + Spare

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM03

#### Comments

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Sun Loud

Date: 07 Jun 2012 19:27:19

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

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0005046

Certificate of Analysis - OSMM

Print Number: P0003379

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