

# CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01 7513400		
PRODUCT CODE			
BATCH NUMBER	W025161		
PRODUCTION DATE	11/2008		
EXPIRY DATE	11/2010		

TEST	TEST METHOD LIMITS		RESULTS	
Appearance		Clear Colourless Liquid	Clear codoviless	
Density (20°C)	GM 0110 01	0.865 - 0.885	ררץ.פ	

Date:	21.98.	********	*********	
QA.Manager:	0	$\triangle$		******
QA: ÉGON	iazbir		,	
JD Approyal:	Ter		/	

This document has been produced on behalf of Johnson Diversey by authorised personnel and is valid unsigned.

Issue no. 4 Issued by W. Ashton Issue date 07.04,2006

Lineston, a contract,

## CERTIFICATE OF IRRADIATION Number: B

0391345 00

FLED01

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: Date Rec'd

P013447 27/11/08

5/12/08



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: 5/12/	<sup>'</sup> 08		
ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	ОТУ	. ADDITIONAL DETAILS
B2FLE0010081 B208120083	JD IPA BOTTLES 25-45kGy	527	B/No.W025161
			ACTUAL38.6 - 41.2kGy DOSE
Ы LE0010999 B208120083	SAMPLES	2	
			CUSTOMERS BATCH/CODE No.s AS ORDER No.P013447 DATED 26/11/08
	Total	529	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: 

DITCE

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

**Date Received** :

12-Dec-08

Flexible Medical Packaging Limited Unit 8, Hightown

Date Tested : 17-Dec-08

White Cross Industrial Estate

**Date Completed** 31-Dec-08 Purchase Order No. PO13517

Lancaster LA1 4XS

**Test Article** 

: Clearklens IPA

Sample Code

: Works Order: 25161

**Batch Reference** 

: 255

Laboratory Reference

: LR-00814236

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: 306045 Volume Tested: 20 x 50mL

Test carried out according to current Pharmacopoeias.

GLP

Compliant Laboratory

Date OS Jin was

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

Sample Booking Number:

CN\00129848

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 P017 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** 

12-Dec-08

**Date Tested** 

17-Dec-08

**Date Completed** 

17-Dec-08

Purchase Order No.

PO13517

**Test Article** 

: Clearklens IPA

Sample Code

: Works Order: 25161

**Batch Reference** 

: 255

Laboratory Reference

: LR-00814237

Article Quantity: 3 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	<0.2000 EU/mL
Dilution	*	MM110/01	1/40
Spiked Recoveries	*	MM110/02	102 Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL

This sample was tested at a 1/40 dilution and spiked with endotoxin to check for interference.

Test carried out according to current Pharmacopoeias.

Product Standard Data Sheet: FM02

 $\operatorname{GLP}$ 

Compliant Laboratory

Date 22 Der Zeel

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

Sample Booking Number:

CN\00129848

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