



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W025334
PRODUCTION DATE	12 / 2008
EXPIRY DATE	12 / 2010

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.865 – 0.885	0.880

Date:..... 20/11/09

QA.Manager:..... [Signature]

QA:..... [Signature]

JD Approval:..... [Signature]

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

FLE001

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Flexible Medical Packaging Ltd
 Unit 8
 White Cross Industrial Estate
 Hightown
 Lancaster



Isotron Limited

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 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

LA1 4XS

Cust. Ref: P013537
 Date Rec'd 18/12/08
 Date: 6/01/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B208120653	JD IPA BOTTLES 25-45kGy	176	B/No.W025334 ACTUAL....40.0 - 40.9....kGy DOSE
B2FLE0010999 B208120653	SAMPLES	2	CUSTOMERS BATCH/CODE No,s AS ORDER No.P013537 DATED 17/12/08
Total		178	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: *C. Drace*

For and on behalf of ISOTRON LIMITED



CERTIFICATE OF ANALYSIS

Mr J Jackson
Flexible Medical Packaging Limited
Unit 8, Hightown
White Cross Industrial Estate
Lancaster LA1 4XS

Date Received : 15-Jan-09
Date Tested : 20-Jan-09
Date Completed : 03-Feb-09
Purchase Order No. : 13601

Test Article : Clearklens IPA
Sample Code : Works Order No. 25334
Batch Reference : 428
Laboratory Reference : LR-00821238 **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: 380013
Volume Tested: 1 Litre
Test carried out according to current Pharmacopoeias.



W.A. Barker

Date 6 Feb 2009

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

Sample Booking Number: CN00130882
Flexible Medical Packaging Limited

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 : 15-Jan-09
Date Tested : 29-Jan-09
Date Completed : 29-Jan-09
Purchase Order No. : 13601

Test Article : Clearklens IPA
Sample Code : Works Order No. 25334
Batch Reference : 428
Laboratory Reference : LR-00821239 **Article Quantity** : 4 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	80% 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
Result: PASS

Corrected Certificate of Analysis to LR-00821239, 03 February 2009 - Typographical error for Endotoxin Result and Interpretation added.



WAB

Date 6 Feb 2009

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

Sample Booking Number: CN\00130882
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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