



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	WD 27457
PRODUCTION DATE	01 / 2010
EXPIRY DATE	01 / 2012

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.865 - 0.885	0.877

Date:..... 03/02/10.....
 QA.Manager:..... [Signature].....
 QA:..... [Signature].....
 JD Approval:..... [Signature].....

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FLE001

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



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

LA1 4XS

Cust. Ref: P015042
 Date Rec'd 28/01/10
 Date: 2/02/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B210010586	JD IPA BOTTLES 25-45kGy	699	B/No.W027457 - LABELLED WITH UN1219 ACTUAL DOSE...36.8 - 37.5...kGy
B2FLE0010999 B210010586	SAMPLES	6	CUSTOMERS BATCH/CODE No.s AS ORDER No.P015042 DATED 27/1/10
Despatch Text: 13PLTS			
Total		705	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: *J. Laffey*

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 : 04-Feb-10
Date Tested : 09-Feb-10
Date Completed : 09-Feb-10
Purchase Order No. : 15077

Test Article : Clearklens IPA Block 1
Sample Code : WO27457
Batch Reference : 1523
Laboratory Reference : LR-00928588 **Article Quantity** : 1 x 900mL
Test Required : LAL Test - Kinetic QCL. Inhibition/Enhancement Assay. Ph Eur and USP.

Test		Method	Result
Bacterial Endotoxin by LAL, Kinetic QCL Test	*	MM110	<0.2000 EU/mL
Dilution	*	MM110/01	1/40
Spiked Recoveries	*	MM110/02	Valid 91%
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM02

Test carried out according to current Pharmacopoeias.

Mr K A Barker, CBiol., MSB
Business Manager

Date 11 Feb 2010



Mrs S.L. Wood, B.Sc. (Hons), C.Biol., MSB.,
Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number: CN\00146267
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 : 04-Feb-10
Date Tested : 11-Feb-10
Date Completed : 25-Feb-10
Purchase Order No. : 15077

Test Article : Clearklens IPA Block 1
Sample Code :
Batch Reference : WO27457
Laboratory Reference : LR-00928587 **Article Quantity** : 20 x 900mL
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: 745040
Volume Tested: 20 x 50mL
Test carried out according to current Pharmacopoeias.



Suz Wood

Date 02 March 2010

Mrs S.L. Wood, B.Sc. (Hons), C.Biol., MSB.,
Laboratory Manager - Pharmaceutical Microbiology

Sample Booking Number: CN\00146267

Certificate of Analysis - OSMM

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