



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARLENs IPA VH01
PRODUCT CODE	7513400
BATCH NUMBER	W026856
PRODUCTION DATE	12/2009
EXPIRY DATE	12/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.865 - 0.885	0.876

Date: 08/01/2010

QA Manager: [Signature]

QA: [Signature] 08-01-10

JD Approval: [Signature]

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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 : 12-Jan-10
Date Tested : 15-Jan-10
Date Completed : 15-Jan-10
Purchase Order No. : PO14952

Test Article : Clearklens IPA Block 1
Sample Code : W026856
Batch Reference : 1336
Laboratory Reference : LR-00921942 **Article Quantity** : 1 x 900mL
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	Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM02

This sample was tested at a 1/40 dilution and spiked with endotoxin to check for interference.
Test carried out according to current Pharmacopoeias.

Suz Wood

Mrs S L Wood, BSc., CBiol, MSB
Laboratory Manager - Pharmaceutical Microbiology

GLP

Compliant
Laboratory

Date 21 Jan 2010

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

Sample Booking Number: CN00145364
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 : 12-Jan-10
Date Tested : 21-Jan-10
Date Completed : 04-Feb-10
Purchase Order No. : PO14952

Test Article : Clearklens IPA Block I
Sample Code :
Batch Reference : W026856
Laboratory Reference : LR-00921941 **Article Quantity** : 20 x 900mL
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

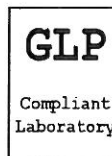
Day Book Ref: 745029
Volume Tested: 20x50mL
Test carried out according to current Pharmacopoeias.

Mrs S L Wood, BSc., CBiol., MSB

Laboratory Manager - Pharmaceutical Microbiology

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

Date 09 Feb 2010



Sample Booking Number: CN\00145364

Certificate of Analysis - OSMM

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FLE001

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Flexible Medical Packaging Ltd
 Unit 8
 White Cross Industrial Estate
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 Lancaster



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 Email: assistance@isotron.com
 Website: www.isotron.com

LA1 4XS

Cust. Ref: P014914
 Date Rec'd 17/12/09
 Date: 7/01/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B209120438	JD IPA BOTTLES 25-45kGy	711	FMP B/No.W026856 - UN1219 B/No.1336 ACTUAL DOSE....36.7 - 38.7....kGy
B2FLE0010999 B209120438	SAMPLES	6	CUSTOMERS BATCH/CODE No.s AS ORDER No.P014914 DATED 16/12/09
Total		717	Last Page 1 of 1

Despatch Text:
14PLTS

All in accordance with current technical agreement

This is to certify that the above items have been irradiated as specified above

Authorising Signature: *J. Gaffey*
 For and on behalf of ISOTRON LIMITED