



CERTIFICATE OF ANALYSIS

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	600253/2
PRODUCTION DATE	01/2009
EXPIRY DATE	01/2011

TEST	METHOD	LIMITS	RESULTS
Appearance	Visual	Clear Colourless Liquid	clear colourless liquid
Density (20°C)	GM 0110 01	0.876 - 0.896	0.886

Date:.....03/02/09.....

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

QA:.....*E. Gwynn*.....

JD Approval:.....*[Signature]*.....

This document has been produced on behalf of JohnsonDiversey by authorised personnel.

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: P013653
 Date Rec'd 29/01/09
 Date: 2/02/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209020036	JD DE 900ML BOTTLES 25-45kGy	169	B/No.W025312 - CUSTOMER B/No.401 ACTUAL <u>39.4 - 41.7</u> ...kGy DOSE
B2FLE0010999 B209020036	SAMPLES	3	
Total		172	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:

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 : 06-Feb-09
Date Tested : 12-Feb-09
Date Completed : 12-Feb-09
Purchase Order No. : 13693

Test Article : ClearKlens DE Block 1
Sample Code : Fluid Batch No: 401
Batch Reference : WO25312
Laboratory Reference : LR-00827672 **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	<0.2500 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	109% Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL
Product Standard Data Sheet	*	MQ002/01	FM01

This sample was tested at a 1/ 50 dilution and spiked with endotoxin to check for interference.
Test carried out according to current Pharmacopoeias.



WR

Date 19 Feb 2009

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

Sample Booking Number: CN\00131763
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 : 06-Feb-09
Date Tested : 13-Feb-09
Date Completed : 27-Feb-09
Purchase Order No. : 13693

Test Article : ClearKlens DE Block 1
Sample Code : Fluid Batch No: 401
Batch Reference : WO25312
Laboratory Reference : LR-00827671 **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: 380023
Volume Tested: 20x50mL
Test carried out according to current Pharmacopoeias.



WJ

Date 02 Mar 09

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

Sample Booking Number: CN00131763
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

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