

**CERTIFICATE OF ANALYSIS**

PRODUCT NAME	CLEARKLENS DE
PRODUCT CODE	6069643
BATCH NUMBER	W025190
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:..... 20101109 .....

QA.Manager:.....  .....

QA:..... E. Gaurun .....

JD Approval:.....  .....

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

FLE001

Page 1

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: P013574  
 Date Rec'd 8/01/09  
 Date: 12/01/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010121 B209010171	JD DE 900ML BOTTLES 25-45kGy	524	B/No.W025190 - CUSTOMER B/No.259  ACTUAL....37.5 - 39.4....kGy DOSE
B2FLE0010999 B209010171	SAMPLES	2	CUSTOMERS BATCH/CODE No.s AS ORDER No.P013574 DATED 7/1/09
Total		526	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. Drake*

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** : 21-Jan-09  
**Date Tested** : 27-Jan-09  
**Date Completed** : 10-Feb-09  
**Purchase Order No.** : P013618

**Test Article** : Clearklens DE Block 1  
**Sample Code** : Works Order No. 25190  
**Batch Reference** : Fluid Batch No. 259 W025190/2011/01  
**Laboratory Reference** : LR-00823374 **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: 380016  
Volume Tested: 20x50mL  
Test carried out according to current Pharmacopoeias.



*WKB*

Date 13 Feb 2009

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



**CERTIFICATE OF ANALYSIS**

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

**Date Received** : 21-Jan-09  
**Date Tested** : 29-Jan-09  
**Date Completed** : 29-Jan-09  
**Purchase Order No.** : P013618

**Test Article** : Clearklens DE Block 1  
**Sample Code** : Works Order No. 25190  
**Batch Reference** : Fluid Batch No. 259  
**Laboratory Reference** : LR-00823375 **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	<0.2500 EU/mL
Dilution	*	MM110/01	1/50
Spiked Recoveries	*	MM110/02	113% Valid
Endotoxin Spike Level	*	MM110/09	0.5 EU/mL

This sample was tested at a 1/50 dilution and spiked with endotoxin to check for interference.  
Test carried out according to current Pharmacopoeias.  
Product Standard Data Sheet: FM01

*W.A.B.*

Date 3 Feb 2009



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

**Sample Booking Number:** CN\00131148  
Flexible Medical Packaging Limited

Certificate of Analysis - OSMM

Page 1 of 1

*This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited*