



Diversey Europe BV

Maarssebroeksedijk 2
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The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 14.12.12

Product Name	CLEARLENSE CLEANSINALD SC VH9
Product Code	7516429
Batch Number	FMP 12347 33204
Production Date	12/2012
Expiration Date	12/2014

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Slightly Yellow Liquid		clear slightly yellow liquid
pH (100% 20°C)	JDM001	12.0	13.0	12.8
Specific Gravity (20°C)	JDM004	1.040	1.060	1.045

On behalf of Diversey site Quality Manager	Name :	Makus
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516429	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 05-Dec-2012

UK32S11002005-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

ISO 11137:2006 Sterilisation of Health Care Products
 ISO 9001:2008 Quality Management System
 ISO 13485:2003 Quality System - Medical Devices

Flexible Medical Packaging Ltd
 Unit 8, White Cross Ind Estate
 Hightown
 Lancaster
 Lancashire LA1 4XS
 UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Customer Reference Number:	P019535
Product Description:	C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy
Validation Reference:	4.0616
Quantity Received:	33
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	11 X B/No.W033201, 11 X B/No.W033316, 11 X B/No.W033200 - 6 PLTS
Shop Order Number:	S11002005-1-1
Synergy Health Sales Part Reference:	1002719

Irradiation Data

Date and Time of Irradiation:	04-Dec-2012 18:15
Reference Dose Range kGy:	33.9 - 35.8
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	36.6

Comments:

Irradiation Release Authorised By Synergy Health plc

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



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

Date Received: 21 Dec 2012
Date Tested: 04 Jan 2013
Date Test Completed: 18 Jan 2013
Purchase Order: PO19650

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0008187/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 21/12/2012
Test Article: Clearlens Cleansinald SC
Sample Code: FMP12347 33204
Batch Ref: VLF99CO1 12-093
Qty Received: 20 x 25mL bottles

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Volume Tested	MM107/05	20 x 25 mL
Product Standard Data Sheet	FG047/psd	FM06

Comments

Test carried out according to current Pharmacopoeias.

Approval is provided by Electronic Signature. Their name is shown below.

Date: 22 Jan 2013 08:28:23

Mrs P. Pham-Lengoc, BSc, MSB
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0008187

Certificate of Analysis - OSMM

Print Number: P0008030

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