



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 24.05.2016

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP 16145 40361
Production Date	24/05/2016
Expiration Date	EXP 24/11/2017

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	9.0	11.4	10.9
Specific Gravity (20°C)	JDM004	0.990	1.010	0.999

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

This document being issued electronically does not bear a signature

COA 100848254	Version : 02	Date of issuing : April 7 th 2016
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Wickham Laboratories

Contract Analytical Services

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mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 27 May 2016
Date Tested: 07 Jun 2016
Date Test Completed: 21 Jun 2016
Purchase Order: PO26691

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029180/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 27/05/2016
Test Article: ClearKlens Cleansinald SS
Sample Code: FMP16145 40361
Batch Ref: 7523
Qty Received: 20 x 900mL 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 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	See external comments
Product Standard Data Sheet	FG047/psd	FM06

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

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

Date: 22 Jun 2016 16:31:59

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 25-Apr-2016

UK32S11609111-1-1

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

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 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

Account Number:	100432
Synergy Health Sales Part Reference:	1002720
Customer Reference Number:	P026412
Product Description:	C/SINALD SS 900ml BOTTLE 25-40kGy
Validation Reference:	4.1909
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	FMP BATCH NO: WO40357 THURS 21ST APR 2016 1 PLT LOT 3

Irradiation Data

Date and Time of Irradiation:	22-Apr-2016 18:47
Reference Dose Range kGy:	34.9 - 35.8
Calculated Minimum Dose kGy:	30.5
Calculated Maximum Dose kGy:	38.4

Items irradiated under WO40357 will be used in finished batch code FMP16145 40361

C. Mascoe 25/5/16

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
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