



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 25.04.2017

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	100848254
Batch Number	FMP 17115 42462
Production Date	25/04/2017
Expiration Date	Exp. 25/10/2018

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	0.996

On behalf of Diversey site Quality Manager	Name :	Olgo. Kirschner, A. Kirschner
	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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 22-Mar-2017

UK33S11833820-1-1

This is to certify that AST Daventry 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:	1105380
Customer Reference Number:	P028550
Product Description:	C/SINALD SS 900ml Bottle DV4673 25-40kGy
Validation Reference:	4673
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO42463, INC 2 SAMPLES, 1 PLT

Irradiation Data

Date and Time of Irradiation:	22-Mar-2017 16:10
Reference Dose Range kGy:	31.4 - 32.0
Calculated Minimum Dose kGy:	28.8
Calculated Maximum Dose kGy:	35.0

Items irradiated under WO42463, are to be used in finished product batch FMP17115 42462

28/04/17

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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

Contract Analytical Services

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

Date Received: 28 Apr 2017
Date Tested: 10 May 2017
Date Test Completed: 24 May 2017
Purchase Order: PO28835

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0035294/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 28/04/2017
Test Article: ClearKlens Cleansinald SS
Sample Code: 8386
Batch Ref: FMP17115 42462
Qty Received: 20 Bottles (900mL Each)

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

Replacement samples received 05.05.17. Quantity 2 x Bottles, have been allocated to Lab Ref: 0035294/1A.
See Investigation Report PHM 2017 104.

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.

Corrected Certificate of Analysis to LR0035294/1 authorised 02/06/2017 due to fluid batch number missing.

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

 CMOORE MRSB

Date: 05 Jun 2017 15:40:16

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology