



Diversey Europe BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 05.07.2016

Product Name	CLEARKLENS CLEANSINALD SS VH9S
Product Code	7516431
Batch Number	FMP 16187 40757
Production Date	05/07/2016
Expiration Date	EXP 05/01/2018

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	10.8
Specific Gravity (20°C)	JDM004	0.990	1.010	0.996

On behalf of Diversey site Quality Manager	Name :	<i>Barbara J. H. H. H.</i>
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516431	Version : 04	Date of issuing : November 28 th 2011
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Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

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: 08 Jul 2016
Date Tested: 13 Jul 2016
Date Test Completed: 27 Jul 2016
Purchase Order: 26900

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029867/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 08/07/2016
Test Article: ClearKlens Cleansinald SS
Sample Code: FMP16187 40757
Batch Ref: 7671
Qty Received: 20 x 900mL

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: 27 Jul 2016 15:45:54

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 23-Jun-2016

UK33S11642809-1-1

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:	P026689
Product Description:	C/SINALD SS 900ml Bottle 25-40kGy Validation
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	FMP BATCH: WO40758, 1 Pit TRIPLE VALIDATION
Other Process Details:	Actual min dose: 27.4kGy Actual max dose: 35.3kGy

Irradiation Data

Date and Time of Irradiation:	22-Jun-2016 16:41
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Items irradiated under WO40758 will be used in finished batch code FMP16187 40757

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

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