ENTEGRIS CLEANING PROCESS
E C P
An Entegris Company

CONTROL REPORT

Customer	Management Quality Manual n° MMQ0000 (contractual)
JOHNSON Diversey LTD	

Product : ClearKlens Cleansinald RTU VH9S	**Control report n° :** CERT 9616B
Specification reference : NA	
Analyst : LGR	**Purchase order n° :** 4300244459
	Date of receipt : 01/04/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT06163 09 089	**ISOTRON certificate n° :** 13971501
Date of manufacturing : 01/03/2009	**Produced quantity :** 480 x 5L
Expiery date : 03/2010	**FIDT N° :** FIDT 1812 C
ECP's batch n° : 06163	**Date of analysis :** 01/04/09

Résultats :

Analyzed characteristics	Method of analysis	State in the production				Specification
		Beginning	middle 1	middle 2	end	
Appearance 20°C	NA	C	C	C	C	Clear slightly yellow liquid
Specific gravity (20°C)	IDT0301	0,999	0,999	0,999	0,999	0,990 - 1,010
pH (20°C)	NA	11,3	11,3	11,3	11,3	9,0 - 11,7
Microbiological contagion of the EDI	IDT0236	< 1cfu/100mL	NA	NA	NA	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

[X] CONFORM [ ] NOT CONFORM

Date : 25/06/09	Edited: L. GRESSE	Checked: D. CHEUNG

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.
MIN 712
13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le
29 MAI 2009
N° 090529 12A

CERTIFY THAT WE TREATED BY GAMMA RADIATION ACCORDING TO THE SPECIFIC CUSTOMER'S REQUIREMENTS AND TO :

- the specification of treatment # 224503P
- The requirements of the European Pharmacopoeia
- the results of the dosemapping # 110505 of 30/03/2006

THE FOLLOWING PRODUCTS : (according to the customer's indication)

Customer	:	**ECP ENTEGRIS CLEANING PRO**
Product	:	BOTTLES 5L
Customer's reference	:	ORDER # CF090074 OF 05/03/09
Quantity	:	4 PALLETS
Irradiation date	:	2009.03.07
Irradiation dose	:	18.9 kGy to 25.1 kGy
Irradiation batch number	:	13971501

Cleanklens Cleansinal'd RTU
lot ENT 06163 09 089
Date fab: 01/03/09
Date pér : 03/2010
J. BURGOS le 29/06/09

The control of the applied radiation dose is done by Isotron France SAS using Red Perspex dosimeters calibrated by the English National Physical Laboratory.

Isotron France S.A.S.,

S. DEFAZIO
Process Control

C. SIMONIN
Quality Officer

Certificate # 13971501 / 1

English translation of the french original certificate.

Wickham Laboratories Limited,
Winchester Road, Wickham, Fareham,
Hampshire PO17 5EU England
Telephone: +44(0)1329 832511
Fax: +44(0)1329 834262

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

CERTIFICATE OF ANALYSIS

Mr W Grayson

Johnson Diversy UK Limited
Osier Drive
Sherwood Park
Annesley NG15 0DS

Date Received	:	08-Apr-09
Date Tested	:	09-Apr-09
Date Completed	:	23-Apr-09
Purchase Order No.	:	-

Test Article : Clearklens Cleansinald RTU 5L

Sample Code : Expiry 03/2010

Batch Reference : ENT 06163 09 089 - 7513719

Laboratory Reference : LR-00845495 **Article Quantity** : 10

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	FM06

Day Book Ref: 484010
Volume Tested: 10 x 50mL
Test carried out according to current Pharmacopoeias.

ECP Reçu le
29 MAI 2009
N° 090529 01A

GLP
Compliant Laboratory

Mrs S L Wood, BSc., CBiol., MIBiol
Laboratory Manager - Pharmaceutical Microbiology

Date 27 April 2009

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

MedicalLab

Report n° :	[redacted]
Sponsor :	[redacted]

Test report Essay of Sterility - Method filtration on membranes

According to the protocol 2.6.1 described into the sixth Europeen Pharmacopee Edition

TEST ARTICLE

Name of product :	ClearKeep Cleanseal RTU VHS...	Order number :	[redacted]
Customer reference :	7619716	Internal reference :	[redacted]
Batch number :	ENT 08 183 09 089	Material :	[redacted]
Date of receipt :	6 avril 2009	Data sterilization :	[redacted]
Date of test :	2 juin 2009	Comment(s) :	[redacted]
Quantity of used sample :	2		

PROTOCOL

Tested volume of product : 500 ml

Neutralizing solution : DNP + Thiosulfate — Rinsing volume : 3 x 100 ml

Number of media tested : 2 — Immersion volume of membranes : 90 ml

Conditions	Media	Incubation temperature	Time of incubation
Aerobic and fugal	Tryptone soy solution	20 ± 5°C	14 days
Anaerobic and aerobic	Thioglycolate Résazurine solution	30 ± 5°C	14 days

Fertility validation : 09/OI/VAL_FER/003

RESULTS

Conditions	Assessment of the media turbidimetry			
	After 7 days		After 14 days	
Tryptone soy solution	0	positive	0	positive
	1	negative	1	negative
Thioglycolate Résazurine solution	0	positive	0	positive
	1	negative	1	negative

CONTROLS

Work plan control (before and after) :	0	0	Glove control :	Conforme
Air control :	0		Media sterility control :	Conforme

CONCLUSION

The tested product doesn't shown any microbian development after 14 days of incubation.

No *product has been positive during the test.*

Redact by : PEGOUD Céline — Technicien Biologiste

Approved by : MARTINHO Alice — Ingénieur Biologiste

Date : vendredi 26 juin 2009

Results and conclusion apply only on the test article tested. Any extrapolation of these data to other samples is the responsibility of the Sponsor.

MedicalLab
Microbiological and physico-chemical analysis - process validation
EN ISO 13485 (2003)

5, chemin du Catupolan - 69120 Vaulx-en-Velin - France
Tel. : 33 (0)4 72 81 22 62 - Fax : 33 (0)4 72 81 22 72
E-mail : info@medicallab.fr - www.medicallab.fr