ENTEGRIS CLEANING PROCESS
E C P
An Entegris Company

CONTROL REPORT

Customer	Management Quality Manual n° MMMQ0000 (contractual)
JOHNSON Diversey LTD	

Product : Clearklens Bi-Spore RTU VH26S	**Control report n° :** CERT 9817
Specification reference : NA	
Analyst : LGR	**Purchase order n° :** 4700806488
	Date of reception : 09/2009

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

Customer's batch n° : ENT07745 09 250	**ISOTRON certificate n°** : 14314401
Date of manufacturing : 09/2009	**Produced quantity** : 120 x 5L
Expiry date : 09/2010	**FIDT N°** : FIDT 1816 E
ECP's batch n° : 07745	**Date of analysis** : 07/09/2009

Results :

Solution	Analyzed characteristics	Method of analysis	State in the production	Specification
			Beginning	
Bi-Spore Activator Solution	Appearance (20°C)	NA	C	Clear colourless liquid
	pH (20°C)	NA	11,5	11,5 - 13,5
	Specific gravity (20°C)	IDT 0301	1,035	1,015 - 1,035
Bi-Spore Base Solution RTU	Appearance (20°C)	NA	C	Clear blue liquid
	pH (20°C)	NA	2,68	2,5 - 4,5
	Specific gravity (20°C)	IDT 0301	0,998	0,990 - 1,010
Bi-Spore Activator Solution + Base Solution RTU	Appearance (20°C)	NA	C	Clear yellow liquid
	pH (20°C)	NA	2,84	2,5 - 5,5
	Specific gravity (20°C)	IDT 0301	1,000	1,000 - 1,010
	Dosage of the materiel chlorine dioxide	IDT 0261	277ppm	230 - 280 ppm
Microbiological contagion of the WFI		IDT 0236	< 1 cfu/100mL	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion : [X] CONFORM [ ] NOT CONFORM

Date : 07/09/2009	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 23 JUIL. 2009 N° 09.07.23.08.A

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

- the specification of treatment # ESSAI 1 DOSE
- the requirements of the European Pharmacopea

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

Customer	:	**ECP ENTEGRIS CLEANING PROCESS**
Product	:	BI-SPORE BOTTLES 100 ml + STOPPERS
Customer's reference	:	Order # CF090369 of 16/06/09
Quantity	:	2 pallets
Irradiation date	:	2009.06.24
Irradiation dose	:	26.2 kGy to 34.0 kGy
Irradiation batch number	:	14314401

Cleanfens Bi-spore RTU
Lot ENT 07745 09 250
Date fab : 09/2009
Date per : 09/2010
J. BURGOS le 25/09/09

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. LE GONIDEC
Quality Assistant

C. SIMONIN
Quality Officer

Certificate # 14314401 / 1

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

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

ECP Reçu le
09 SEP. 2009
N° 090909 a3A

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 PROCESS**
Product	:	BIDONS 5l + BOUCHONS
Customer's reference	:	Order # CF090074 of 26/08/09
Quantity	:	5 pallets
Irradiation date	:	2009.08.27
Irradiation dose	:	18.9 kGy to 26.1 kGy
Irradiation batch number	:	14501401

Cleaukers Baispore RTU
Lot ENT 0745 09 250
Date fab: 09/2009
Date per: 09/2010
J. BURGOS Le 25/09/09

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. LE GONIDEC
Quality Assistant

C. SIMONIN
Quality Officer

Certificate # 14501401 / 1

MedicalLab

Report n° :	**09/OI/STE/152**
Sponsor :	*ECP* 395, rue Louis Lépine 34000 MONTPELLIER

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 :	ClearKlens Bi-Spore	Order number :	CF090541
Customer reference :	7516196	Internal reference :	-
Batch number :	ENT07 745 09 250	Material :	-
Date of receipt :	11 septembre 2009	Data sterilization :	-
Date of test :	11 septembre 2009	Comment(s) :	-
Quantity of used sample :	10		

PROTOCOL

Tested volume of product : **500** ml

Neutralizing solution : **DNP + Thio** Rinsing volume : **3 x 100 ml**

Number of media tested : **2** Immersion volume of membranes : **100** ml

Conditions	Media	Incubation temperature	Time of incubation
Aerobic and fugal	Tryptone soy solution	22,5 ± 2,5°C	14 days
Anaerobic and aerobic	Thioglycolate Résazurine solution	32,5 ± 2,5°C	14 days

Method validation : **09/OI/VAL.STE/017**

RESULTS

Conditions	Assessment of the media turbidimetry			
	After **7** days		After ***14*** days	
Tryptone soy solution	**0**	positive	**0**	positive
	5	negative	**5**	negative
Thioglycolate Résazurine solution	**0**	positive	**0**	positive
	5	negative	**5**	negative

CONTROLS

Work plan control (before and after) :	0	0
Air control :	0	

Glove control :	Conforme
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 : **BERTHOME Audrey** Technicien Biologiste

Approved by : **MARTINHO Alice** Ingénieur Biologiste

Date : vendredi 25 septembre 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

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