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 9690
Specification reference : NA	
Analyst : LGR	**Purchase order n° :** 470079447
	Date of reception : 28/05/2009

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

Customer's batch n° : ENT06665 09 145	**ISOTRON certificate n°** : 14184701
Date of manufacturing : 28/05/2009	**Produced quantity** : 492 x 5L
Expiry date : 05/2010	**FIDT N°** : FIDT 1816 C
ECP's batch n° : 06665	**Date of analysis** : 02/06/09

Results :

Solution	Analyzed characteristics	Method of analysis	State in the production: Beginning	Specification
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	1,015	1,015 - 1,035
Bi-Spore Base Solution RTU	Appearance (20°C)	NA	C	Clear blue liquid
	pH (20°C)	NA	3,9	2,5 - 4,5
	Specific gravity (20°C)	IDT 0301	1,000	0,990 - 1,010
Bi-Spore Activator Solution + Base Solution RTU	Appearance (20°C)	NA	C	Clear yellow liquid
	pH (20°C)	NA	3,9	2,5 - 5,5
	Specific gravity (20°C)	IDT 0301	1,000	1,000 - 1,010
	Dosage of the materiel chlorine dioxide	IDT 0261	243 ppm	230 - 280 ppm
Microbiological quality 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 : 02/06/2009	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
09 JUIN 2009
N° 090609 02A

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	:	5L BOTTLES KITS
Customer's reference	:	ORDER # CF 090074 OF 12/05/09
Quantity	:	3 PALLETS
Irradiation date	:	2009.05.15
Irradiation dose	:	17.4 kGy to 24.2 kGy
Irradiation batch number	:	14184701

Clearklens Bi-Spore RTU VH 28S
lot ENT 06665 09 145
Date of m. 28/05/09
Expiry date 05/2010.
CGARY le 15/07/09

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.,

H. OSMAS
Process Control Officer

C. SIMONIN
Quality Officer

Certificate # 14184701 / 1
Enghish translation of the french original certificate.

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712
13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le
28 MAI 2009
N° 09052805A

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	:	BOTTLES 100 ML AND STOPPERS
Customer's reference	:	ORDER # CF 090308 OF 14/05/09
		Clearklens Bi-Spore RTU VH26S
Quantity	:	1 PALLET
		Lot ENT0666S 09 145
		Date of m. 28/05/09
Irradiation date	:	2009.05.23 Expiry date 05/2010
Irradiation dose	:	29.2 kGy to 35.5 kGy
Irradiation batch number	:	14212001

C.GARY le 15/07/09

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 # 14212001 / 1

MedicalLab

Report n° :	**09/OI/STE/071**
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 RTU VH26S	Order number :	CF090335
Customer reference :	7516196	Internal reference :	-
Batch number :	ENT 06 665 09 145	Material :	-
Date of receipt :	5 juin 2009	Data sterilization :	-
Date of test :	29 juin 2009	Comment(s) :	Fin de production Fin de production
Quantity of used sample :	2		

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 : **90** 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
	1	negative	**1**	negative
Thioglycolate Résazurine solution	**0**	positive	**0**	positive
	1	negative	**1**	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 : **PEGOUD Céline**, Technicien Biologiste

Approved by : **MARTINHO Alice**, Ingénieur Biologiste

Date : lundi 13 juillet 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)

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