

CONTROL REPORT

Customer JOHNSON Diversey LTD	Management Quality Manual n° MMMQ0000 (contractual)
Product : Clearklens Bi-Spore RTU VH26S Specification reference : NA Analyst : LGR	Control report n° : CERT 9817 Purchase order n° : 4700806488 Date of reception : 09/2009

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

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

Clarikens Bi-spore RTU

Lot ENT 04445 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.

J. Burgos

Isotron France S.A.S,

S. LE GONIDEC
Quality Assistant

C. SIMONIN
Quality Officer

Certificate # 14314401/1

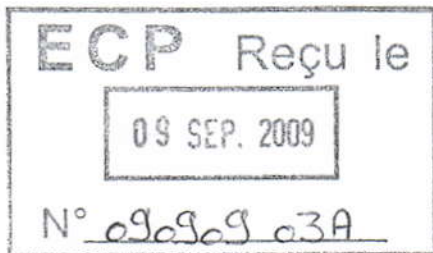
CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE



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 dosimetry # 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

Cleublers Bispore RTU

Lot ENT 0445 09 250

Date fab: 09/2009

Date pec: 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.

[Signature]

Isotron France S.A.S.,

S. LE GONIDEC
Quality Assistant

C. SIMONIN
Quality Officer

[Signature]
Certificate # 14501401/1

[Signature]

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 European Pharmacopée 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

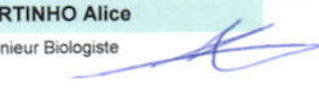
CONTROLS

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

CONCLUSION

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

No product has been positive during the test.

Redact by : **BERTHOME Audrey**  Approved by : **MARTINHO Alice** 
Technicien Biologiste 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)

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