

CONTROL REPORT**Customer**

JOHNSON DIVERSEY LTD

Management Quality Manual n° MMMQ0000 (contractual)

Product :

ClearKlens Cleansinald RTU VH9S

Control report n° :

CERT 9705

Specification reference : NA**Analyst :**

ECH

Purchase order n° :

4700794447

Date of receipt :

12/06/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES**Customer's batch n° :** ENT 06790 09 163**ISOTRON certificate n° :** 14137301**Date of manufacturing :** 12/06/2009**Produced quantity :** 120 x 5L**Expiry date :** 12/12/2010**FIDT N° :** 1812 ind D**ECP's batch n° :** 06790**Date of analysis :** 12/06/2009**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
Smell	NA	C	C	C	C	Slightly perfumed
Dosage of the material activates cationique	IDT 0261	0,08%	0,08%	0,08%	0,08%	0,07 à 0,09%
Specific gravity (base) (20°C)	IDT 0301	0,990	0,990	0,990	0,990	0,990 - 1,010
pH (base) (20°C)	NA	10,4				9,0 - 11,7
Microbiological quality of the WFI	IDT 0236	< 1cfu/100mL				< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable**Conclusion :**

CONFORM



NOT CONFORM

Date : 12/06/2009

Analyst : L. GRESSE

Checked : D. CHEUNG

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

ECP Reçu le

25 MAI 2009

N° 090525 A

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

Reactions Cleanings

Lot ENT 06490 09 J63

Date fab: 12/06/09

Date pu: 12/12/10

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

Customer : **ECP ENTEGRIS CLEANING PROCESS**

Product : **5L BOTTLE KIT**

Customer's reference : **ORDER # CF 090074 OF 24/04/09**

J. BURGOS

le 16/06/09

J. Burgos

Quantity : **2 PALLETS**

Irradiation date : **2009.04.29**

Irradiation dose : **19.2 kGy to 25.7 kGy**

Irradiation batch number : **14137301**

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



Certificate # 14137301 / 1

English translation of the french original certificate.

C. SIMONIN

Quality Officer



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

Cleankins Cleansing

Lot ENT 06490 09 J63

Date fab: 12/06/09

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

Date rec: 12/12/10

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : 5L BOTTLES KITS

J. BURGOS R 16/06/09

Customer's reference : ORDER # CF090074 OF 28/05/09

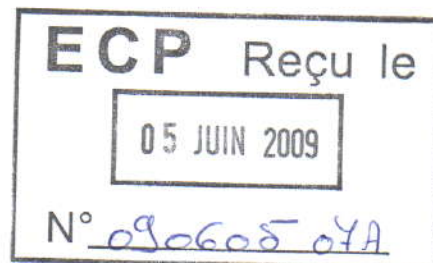
J. Burgos

Quantity : 1 PALLET

Irradiation date : 2009.05.31

Irradiation dose : 17.7 kGy to 24.6 kGy

Irradiation batch number : 14242601



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

A handwritten signature in blue ink, appearing to be 'H. Osmas'.

Certificate # 14242601 / 1

C. SIMONIN

Quality Officer

A handwritten signature in blue ink, appearing to be 'C. Simonin'.

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 Cleansinald RTU VH9S	Order number :	CF090335
Customer reference :	7513719	Internal reference :	-
Batch number :	ENT 06 790 09 163	Material :	-
Date of receipt :	16 juin 2009	Data sterilization :	-
Date of test :	29 juin 2009	Comment(s) :	begin of product 3/4 de production
Quantity of used sample :	2		

PROTOCOL

Tested volume of product :	500	ml		
Neutralizing solution :	DNP 900 ml	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/016		

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 microbial 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)

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