

**RAPPORT DE CONTRÔLE PHARMACEUTIQUE**

<b>Client</b> JOHNSON DIVERSEY	Référentiel Plan Qualité n° MMMQ0000 (en vigueur)
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<b>Produit dosé :</b> ClearKlens Cleansinald RTU VH9S  <b>Référence CDC :</b> CDC Edition n°2 du 08/11/05  <b>Analyste :</b> DCH	<b>N° rapport d'essai :</b> CERT 9789  <b>N° du bon de commande :</b> 4700796472 <b>Date de réception :</b> 14/08/2009
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**CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES**

<b>Lot de fabrication :</b> ENT 07565 09 226  <b>Date de fabrication :</b> 14/08/2009  <b>Date de péremption :</b> 02/2011  <b>N° LOT ENTEGRIS :</b> 07565	<b>N° certificats ISOTRON :</b> 14424001  <b>Quantité produite :</b> 120 x 5L  <b>FIDT N° :</b> 1047 ind F  <b>Date d'analyse :</b> 14/08/2009
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**Résultats :**

Caractéristiques analysées	Méthode d'analyse	Situation de l'échantillon dans la production				Spécification
		début	milieu 1	milieu 2	fin	
Aspect à 20°C	NA	C	C	C	C	Liquide limpide et incolore
Odeur	NA	C	C	C	C	Odeur très légère
Dosage de la matière active cationique	IDT 0261	0,08%	0,08%	0,08%	0,08%	0,07 à 0,09%
Qualité microbiologique de l'eau WFI	IDT0236	< 1UFC/100mL				< 10 UFC/100mL

C : Conforme NC : Non Conforme

NA : Non Applicable

**Conclusion :**  CONFORME  NON CONFORME

Date : 18/08/09 Analyse et vérifié : D. CHEUNG

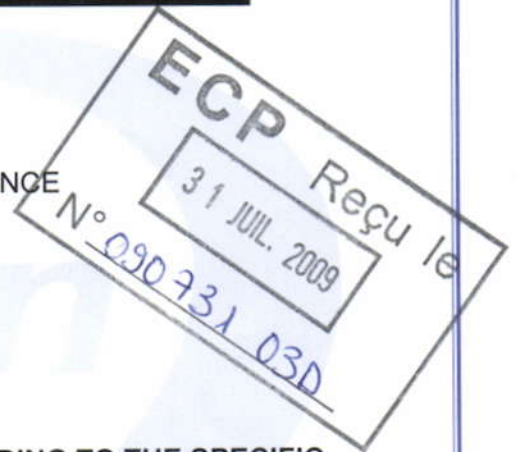
**CERTIFICATE OF TREATMENT BY GAMMA RADIATION**

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 : 5L BOTTLES KITS**

**Customer's reference : ORDER # CF090074 OF 28/01/09**

**Quantity : 1 PALLET**

**Irradiation date : 2009.07.26**

**Irradiation dose : 18.2 kGy to 24.7 kGy**

**Irradiation batch number : 14424001**

*Cleankens Cleansinald RTU*

*Lot ENT 04565 09 226*

*Date fab: 14/08/09*

*Exp: 02/2011*

*J. BURGOS le 20/08/09*

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**

**Certificate # 14424001 / 1**

**T. CAVA**

**Quality Manager**

**Test report Essay of Sterility - Method filtration on membranes**

According to the protocol 2.6.1 described into the sixth European Pharmacopoe Edition

**TEST ARTICLE**

 Name of product : ClearKlens Cleansinald RTU VH6S Order number :  
 Customer reference : 7513719 Internal reference :  
 Batch number : ENT07 565 09 226 Material :  
 Date of receipt : 1 septembre 2009 Date sterilization :  
 Date of test : 4 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/016**
**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 18 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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