

RAPPORT DE CONTRÔLE PHARMACEUTIQUE

Client
JOHNSON DIVERSEY

Référentiel Plan Qualité n° MMMQ0000 (en vigueur)

Produit dosé :

Clearklens First

N° rapport d'essai :

CERT 9795

Référence CDC :

CDC Edition n°1 du 08/11/05

Analyste :

JBU

N° du bon de commande :

4700810714

Date de réception :

20/08/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Lot de fabrication :

ENT 07610 09 232

N° certificats ISOTRON :

14232101

Date de fabrication :

20/08/2009

Quantité produite :

120 x 5L

Date de péremption :

08/2011

FIDT N° :

FIDT 1048 ind C

N° LOT ENTEGRIS :

07610

Date d'analyse :

20/08/2009

Résultats :

Caractéristiques analysées	Méthode d'analyse	Situation de l'échantillon dans la production				Spécification
		début	milieu 1	milieu 2	fin	
Dosage de la matière active cationique	IDT 0261	0,096%	0,095%	0,095%	0,097%	0,094 à 0,102 %
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 : 20/08/09

Analyste : J. BURGOS

Vérifié : D. CHEUNG

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE

CleauPens First

Pot ENT 04610 09 232

Date Sub: 20/08/09

Date pu: 08/2011

J. BURGOS & 25/09/09 

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 dosmapping # 110505 of 30/03/2006

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : 5L BOTTLES KITS

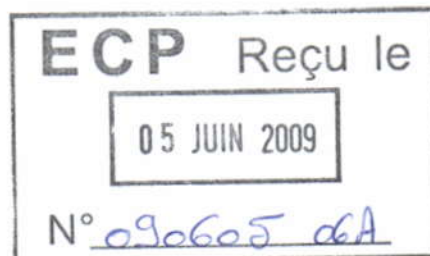
Customer's reference : ORDER # CF090074 OF 27/05/09

Quantity : 2 PALLETS

Irradiation date : 2009.05.31

Irradiation dose : 16.6 kGy to 23.2 kGy

Irradiation batch number : 14232101



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 # 14232101 / 1

C. SIMONIN

Quality Officer



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 :	ClairKlens First	Order number :	CF090541
Customer reference :		Internal reference :	
Batch number :	ENT07 610 09 232	Material :	
Date of receipt :	10 septembre 2009	Date sterilization :	
Date of test :	10 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 fungal	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/021		

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 Technicien Biologiste	Approved by :	MARTINHO Alice Ingénieur Biologiste
Date :	jeudi 24 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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ECP Reçu le

24 SEP. 2009

N° 090924 0YA