



CONTROL REPORT

Customer

JOHNSON DIVERSEY LTD

Management Quality Manual n° MMMQ0000 (contractual)

Product :

Clearklens TEGO 2000 RTU VH25S

Control report n° :

CERT 9811

Specification reference : NA

Analyst : LGR

Purchase order n° :

4700821976

Date of receipt :

09/2009

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT 07730 09 245

ISOTRON certificate n° : 14501401

Date of manufacturing : 09/2009

Produced quantity : 171 x 5L

Expiry date : 09/2010

FIDT N° : FIDT 1813 C

ECP's batch n° : 07730

Date of analysis : 03/09/2009

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Appearance 20°C	NA	C	Clear liquid
Specific gravity (20°C)	IDT0301	0,999	0,980 - 1,000
pH (20°C)	NA	7,72	7,3 - 8,2
Microbiological contagion of the EDI	IDT0236	< 1 cfu/100mL	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion : ☒ CONFORM

☐ NOT CONFORM

Date : 03/09/2009

Analyst : L. GRESSE

Checked : D. CHEUNG

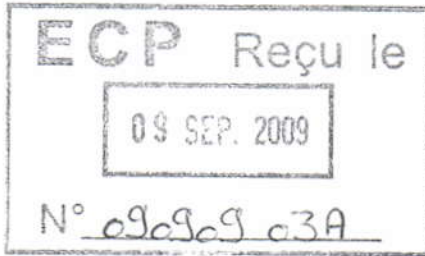
CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE



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 dose mapping # 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

Cleanbens DEGO 2000 RTU

Pot ENT 04430 09 245

Date fab: 09/2009

Date rec: 09/2010

J. BURGOS & 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.

Isotron France S.A.S.,

S. LE GONIDEC
Quality Assistant

C. SIMONIN
Quality Officer

Certificate # 1450140111

Test report Essay of Sterility - Method filtration on membranes

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

TEST ARTICLE

Name of product :	ClearKlens TEGO	Order number :	CF090541
Customer reference :	7516091	Internal reference :	
Batch number :	ENT07 730 09 245	Material :	
Date of receipt :	10 septembre 2009	Data 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 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/022		

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 JJA