

Customer DIVERSEY	Management Quality Manual n° MMMQ0000 (contractual)
-----------------------------	---

Product : Clearklens Bi-Spore RTU VH26S	Control report n° : 11244
Specification reference : NA	
Analyst : GGE	Purchase order n° : 4701055855
	Date of reception : 26/07/2011

PHYSICAL AND CHEMICAL PROPERTIES CONTROL

Customer's batch n° : ENT 15226 11 206	ISOTRON certificate(s) n° : 16730201
Date of manufacturing : 26/07/2011	Produced quantity : 480 x 5L
Expiry date : 06/2012	FIDT N° : 1816 ind L
ECP's batch n° : 15226	Date of analysis : 26/07/2011

Results :

Solution	Analyzed characteristics	Method of analysis	State in the production	Specification
			Beginning	
Bi-Spore Activator Solution	Appearance (20°C)	NA	Clear colourless liquid	Clear colourless liquid
	pH (20°C)	NA	11,9	11,5 - 13,5
	Specific gravity (20°C)	IDT 0301	1,020	1,015 - 1,035
Bi-Spore Base Solution RTU	Appearance (20°C)	NA	Clear blue liquid	Clear blue liquid
	pH (20°C)	NA	2,00	2,5 - 4,5
	Specific gravity (20°C)	IDT 0301	1,030	0,990 - 1,010
Bi-Spore Activator Solution + Base Solution RTU	Appearance (20°C)	NA	Clear yellow liquid	Clear yellow liquid
	pH (20°C)	NA	2,94	2,5 - 5,5
	Specific gravity (20°C)	IDT 0301	1,000	1,000 - 1,010
	Dosage of the material chlorine dioxide	IDT 0261	250 ppm	230 - 280 ppm
Microbiological contagion of the WFI		IDT 0236	9 CFU/100mL	< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion :

☒ CONFORM ☐ NOT CONFORM

Date : 01/08/2011	Written by : G. GEORGES	Checked by : D. GHERSY
-------------------	-------------------------	------------------------

IMP 0180 - L

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le

21 JUN 2011

N° 110621 03A

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 : "Kits bidons 5l"

Customer's reference : ORDER # CF110501 OF 15/06/2011

Quantity : 4 PALLETS

Irradiation date : 2011.06.19

Irradiation dose : 17.7 kGy to 23.9 kGy

Irradiation batch number : 16744701

DIVERSEY LTD

clearklean BiSpare RTU

Batch N° ENT15226 M 206

D. GHERSY, 2011.09.16

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. DEFAZIO

Quality / Production Assistant

Certificate # 16744701 / 1

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 # 224514P.
- The requirements of the European Pharmacopoeia
- the results of the dose mapping # 135901 of 28/10/2008

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : BOTTLES 100 ML + STOPPERS

Customer's reference : ORDER # CF110573 OF 06/07/11

Quantity : 1 PALLET

Irradiation date : 2011.07.10

Irradiation dose : 26.9 kGy to 33.1 kGy

Irradiation batch number : 16821301

DIVERSEY LTD
Clear-kleus Bi-Spore RTU
Batch N° EXT 15226 M 206
D. GHERSY, 2011.09.16

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 # 16821301 / 1

C. SIMONIN

Quality Officer



CERTIFICATE OF ANALYSIS

Mr. Bill Ashton
Diversy Limited
Cotes Park Industrial Estate
Somercotes
Alfreton
Derbyshire
DE55 4PA

Date Received: 22 Aug 11
Date Tested: 07 Sep 11
Date Completed: 21 Sep 11
Purchase Order: -

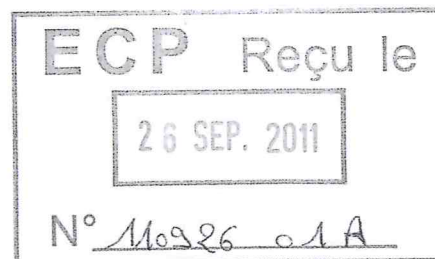
Test Article: ClearKlens Bi-Spore Base
Sample Code: SKU: 7516196
Batch Ref: ENT15226 11 206
Qty Received: 10 x 4.9L Bottles
Laboratory Reference: 0002218/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Product Standard Data Sheet	FG047/psd	FM05
Volume Tested	MM107/05	2 x 500 mL

External Comments

Test carried out according to current Pharmacopoeias.

2 Sample containers (1 x Debut + 1 x 3/4) were selected at random and tested as per Client's email.



Approval is provided by Electronic Signature. Their name is shown below.

Susan Wood

Date: 22 Sep 11 16:32:53

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0002218
Diversy (Alfreton)

Certificate of Analysis - OSMM

Print Number

P0000046

This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited



Wickham Laboratories
contract analytical services

Wickham Laboratories Limited,
Winchester Road, Wickham, Fareham,
Hampshire PO17 5EU England
Telephone: +44(0)1329 832511
Fax: +44(0)1329 834262

mail@wickhamlabs.co.uk
www.wickhamlabs.co.uk

CERTIFICATE OF ANALYSIS

Mr. Bill Ashton
Diversy Limited
Cotes Park Industrial Estate
Somercoates
Alfreton
Derbyshire
DE55 4PA

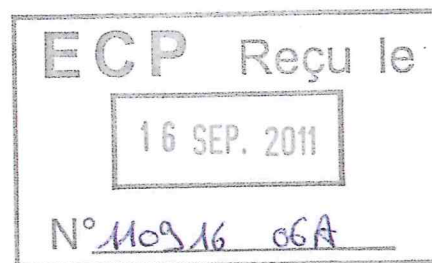
Date Received: 22 Aug 11
Date Tested: 26 Aug 11
Date Completed: 09 Sep 11
Purchase Order: -

Test Article: ClearKlens Bi-Spore Activator
Sample Code: SKU: 7516196
Batch Ref: ENT15226 11 206
Qty Received: 10 x 100 mL
Laboratory Reference: 0002218/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Product Standard Data Sheet	FG047/psd	FM04
Volume Tested	MM107/05	10 x 50 mL

External Comments

Test carried out according to current Pharmacopoeias.



Approval is provided by Electronic Signature. Their name is shown below.

Suz Wood

Date: 12 Sep 11 11:44:06

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0002218
Diversy (Alfreton)

Certificate of Analysis - OSMM

Print Number

P0004981

This report shall not be reproduced except in full, without the written approval of Wickham Laboratories Limited