

GREECE
LABEL

SHOP PACKET - HYDROCYN AQUA GEL

REF :	BW42C900	ODR. QTY :	288	ISSUED DATE	3-Feb-22
ITEM CODE :	BW010009	PACK SIZE :	12BOX	LOT NO	B20308
ITEM :	Bactiguard Woundcare, Gel Tube (50g)	CUSTOMER	Bactiguard AB (Lifecyn)	MFG. DATE	3-Feb-22
		ORD. NO	B216 8009	EXP DATE:	2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 7:00 PM	297	297	Nil	M. Sanyana (790)	Poshini 7:08pm 07/02/2022	2/5
DATE : 07-02-22						
TIME COMPLETE : 7:08 PM						
DATE : 07-02-22						
CHECK : pH / VISCOSITY / FAC						
Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 2:55 PM	297	297	Nil	Viki (1094)	Poshini 4:00pm 08/02/2022	5/5
DATE : 08-02-22						
TIME COMPLETE : 4:00 PM						
DATE : 08-02-22						
GEL FILLING						
TIME START : 4:50 PM	297	297	Nil	May 1049	Poshini 5:50 pm 08/02/2022	5/5
DATE : 08-02-22						
TIME COMPLETE : 5:50 PM						
DATE : 08-02-22						
SEALING AND CUTTING GEL TUBE						
TIME START : 4:50 PM	297	297	Nil	FAPRAT (1051)	Poshini 5:50pm 09/02/2022	5/5
DATE : 08-02-22						
TIME COMPLETE : 5:50 PM						
DATE : 08-02-22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 8:45	290+1	290+1	Nil	Viki (1094) Khin(647)	Buch 18/02/2022	5/5
DATE : 18-02-22						
TIME COMPLETE : 9:15						
DATE : 18-02-22						
BOX PACKING & FINAL CONTROL						
TIME START : 7:00 PM	291	290	Nil	Manyu (846)	Buch 8:30pm 22-2-22	Refer FCIR
DATE : 01-02-22						
TIME COMPLETE : 8:10						
DATE : 01-02-22						
CARTON PACKING						
TIME START : 4:45 AM	94 box 40tn	94 box 40tn	Nil	Vister (1123)	Jinda 22/02/2022	23/02/2022
DATE : 23-02-22						
TIME COMPLETE : 4:50 AM						
DATE : 23-02-22						


Checked by (PR), Signature : <i>[Signature]</i> Name : NATANASEGAM Date : 24/2/22	Approved by (QC), Signature : <i>[Signature]</i> Name : Date :
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QUANTITY PRODUCED	297 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3+6 pcs
SHIPMENT QUANTITY PCS / CTNS :	288 pcs / 24tn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

LABEL APPROVAL

Οδηγίες χρήσης: Βεβαιωθείτε πρώτα ότι έχει καθαριστεί η πληγή. Εφαρμόστε τη γέλη απευθείας στην πληγή σε κάθε αλλαγή επίδεσμου του τραυματία. Μόνο για εξωτερική χρήση. Μετά το άνοιγμα της συσκευασίας, θα πρέπει να χρησιμοποιείται το σύνολο του περιεχομένου.

Συστατικά: Κεκαθαρισμένο ύδωρ, Υποχλωριώδες νάτριο (0,05%) / Λίθιο-Μαγνήσιο-Νάτριο Πυριτικό και Χλωριούχο Νάτριο.

 Bactiguard (South East Asia) Sdn. Bhd.
(Formerly known as VIGILENZ Medical Devices Sdn. Bhd.)
308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia.



Bactiguard[®]

EC REP: FORELS SA, RD. GENERAL, WWHIS 33, 1300 BRUSSELS, BELGIUM

CE 2292



REF: BW42C900

Αναστέλλει: LIFE CYN AE

Bactiguard[®]



7 333330 201636

LOT: B20308

EXP: 2023-08

Αρ. Γνωστοποίησης EΟφ:

130619/23-12-2021.

REF: BW42C900



CE 2292

WOUND CARE

Καταπραυντική & Βακτηριοστατική δράση

Γέλη 50g

 Bactiguard (South East Asia) Sdn. Bhd.
(Formerly known as VIGILENZ Medical Devices Sdn. Bhd.)
308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia.

Αναστέλλει: LIFE CYN AE
Καταπραυντική & Αν. Πονοκέφαλου
13561 Άγιος Ανδρόνικος, Αττική
Τηλ.: +30(0) 210 8313616 email: info@lifecyn.com

EC REP: FORELS SA, RD. GENERAL, WWHIS 33, 1300 BRUSSELS, BELGIUM

Bactiguard Wound Care Gel

REF

BW42C900

LOT

B20308

Qty

12 pcs / box

Weight

50 g / pc

Bactiguard[®]




18.2.2023

car/co/fo

	Equipment ID	
	QC-56	HSM-01
Purified Water (L)	3.0 ± 3.1	20.0 ± 20.1
Lithium Magnesium Sodium Silicate (g)	120 ± 1	800 ± 1
Sodium Hypochlorite (ml)	30.0 ± 0.05	200.0 ± 0.5
PDV Salt (g)	3.0 ± 0.1	20.0 ± 0.1

[illegible]

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 1(3)


Reference / Lot No.	Buy2900 / B20308
Order Qty.	288

A. Before Filling

Batch No.	Container No.	pH (9.00 – 10.50)	FAC (100 – 200 ppm)	Viscosity (8,000 – 10,000 cps)	Gel is clear and free from contamination	Test disposition (PASS / FAIL)
G1807022205	675	9.56	comply	8921	✓	pass
G1807022206	676	9.56	comply	8921	✓	pass

B. Tube Labelling

Sampling / Frequency	Printed label is clear and legible	Reference no. corresponds to Shop Packet and approved artwork	Correct positioning of labelling	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard	
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C. Filling Process

Sampling / Frequency	Weight of Sample						Leak Test	Test disposition (PASS / FAIL)
	Specification: 15g (16.5 – 17.8g) / 30g (31.6 – 33.3g) / 50g (51.9 – 53.4g) / 100g (102.8 – 104.7g)							
	1	2	3	4	5	Average		
7/5	53.12 g	52.60 g	52.81 g	51.93 g	52.85 g	52.66 g	✓	pass
1/5	53.09 g	52.30 g	52.28 g	53.12 g	53.09 g	52.77 g	✓	pass
2/5	53.14 g	53.16 g	53.00 g	52.45 g	52.36 g	52.82 g	✓	pass
3/5	52.57 g	52.41 g	52.70 g	53.01 g	52.48 g	52.63 g	✓	pass
4/5	52.56 g	53.09 g	53.10 g	52.47 g	53.23 g	52.89 g	✓	pass
5/5	52.88 g	52.69 g	52.44 g	52.66 g	52.59 g	52.59 g	✓	pass

D. Sealing and Cutting

Sampling / Frequency	Sealing is intact	No sharp edge and not slanted after sealing and cutting	Lot no. and expiry date on tube is correct as in Shop Packet and legible	Seal Width Specification: (15g : 4-6mm) (30g/ 50g/ 100g : 6-8mm)	Leak Test	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

Title:

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL



Page:

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Issue Date:

15/11/2021

Document type:

FORM

Doc Id:

QC-IP004-01

E. Printing on Primary Packaging

Sampling / Frequency	Print information must be clear / legible and conforms to specifications as stated in approved artwork	Lot no. and expiry date are corresponding to Shop Packet and approved artwork	Correct position of printing	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

F. Primary Packaging

Sampling / Frequency	Product is properly pack in primary packaging	Ref. no., lot no. and expiry date on primary box is correct and legible	Special requirement printing is clear and legible	Presence of secure stickers on both opening sides of the primary box	Presence of hologram sticker on the primary box	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

G. Conclusion

Overall in – process inspection: (PASS / FAIL)

Inspected By :

Wch

Name

Wch Wch

Date

22-02-2022

VIGILENZ®	FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL		Doc. No.	QC-FC006
			Rev.	03

REF : Bw42c900 QTY PRODUCED (pcs) : 297

LOT NO : B20308 RETAIN SAMPLE QTY (pcs) : 3

No	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and correct printing of label.	S3,0.15	80	0	1	80	0	pass
2	Availability of Hologram and Secure Sticker.	S3,0.15	80	0	1	80	0	pass
3	Free from contamination, deformed or damaged on packaging.	S3,0.15	80	0	1	80	0	pass
4	Proper sealing and no leakage.	S3,0.15	80	0	1	80	0	pass
5	Correct quantity in secondary box packaging.	S3,0.15	80	0	1	80	0	pass

Remarks : N/A

Inspected By : <u>Wch</u>	Approved By : <u>[Signature]</u>
Name : <u>Wch Wch</u>	Name : <u>AARTINI</u>
Date : <u>22.02.2022</u>	Date : <u>23/2/2022</u>

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

04/02/2022	SHOP PACKET QTY (pcs)	288	RS	9
BW42C900	CUSTOMER	BACTIGUARD AB (LIFECYN)		
B20308	LOT NO.	10/CYN/06050501		

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100726	50g Tubes with D30 White Color Screw-on Cap	Diameter 30 x 120 mm, White Colour Tube + neck, 5mm Tube Orifice with Aluminium Foil Seal, Open End	H05G210901	pcs	297	297	1 Ganjaua
	P0100804	White Nozzle Cap	0	H102A1001		594	594	1 Ganjaua
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	grm	800	800	1 Ganjaua
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Ganjaua
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	grm	20	20	1 Ganjaua
5	N/A	STOCK SOLUTION	N/A	G1807022005 G1807022006	ltr	20	20	1 Ganjaua

(2) PRODUCT PACKAGING


NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100895	LBWC-011-GR-R0 (50G - Gel Tube- GREECE), VIGILENZO131; 100MM X 90MM; IN ROLL, TRANSPARENT PE; 4C + WHITE	LG04220201	298	1 Ganjaua
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22210801	595	1 Ganjaua
3	P0100806	LDPE ZIPPER BAG; Size: 0.05mm x 2" (opening) x 3" (L) USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P0100806	298	1 Ganjaua
4	P0100910	BWC-02L INNER BOX 50g BBWC-004 GR-RD - GREECE	BGR220201	291	1 Ganjaua
5	P0100788	V09-BX022-00 - Hydrocort Gel 50g (outer box) 300gm 1 Side Art Card, 192 x 142.5 x 129mm	PH01210702	25	1 Ganjaua
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210801	25	1 Ganjaua
7		#N/A			


(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LR150/MLR150 (BC FLUTE)	H114210801/2	4	1 Ganjaua
2	P0100767	V0047-0154; POF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m; 1 rolls/carton	P092210801		1 Ganjaua
3		#N/A			

(4) SPECIAL REQUIREMENT

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)		1/1	1 Ganjaua
2		#N/A			

ISSUED BY (MM):
Signature: 
Name: LOVIN
Date: 04/02/2022

VERIFIED BY (PR):
Signature: 
Name: P. L. N. M. E. C. A. M.
Date: 04/02/2022

PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL

Doc No. QC-PC008

QC-PC008

Rev.

02

Release Criteria:

Packing Integrity					Visual Inspection	Chemical Testing		Test Disposition
Correct and legible printing of label	Proper sealing	Ability to dispense	Free from contamination/deformed/damaged	No leakage		pH (9.00 – 10.50)	FAC (100 – 200 ppm)	
✓	✓	✓	✓	✓	✓	9.79	comply	pass

 $\checkmark = \text{Pass}, X = \text{Fail}$

Remarks:

N/A

CONCLUSIONS: ☒ RELEASE

RELEASE

☐ ON-HOLD

ON-HOLD

Inspected By

Page

Name

Роснх

Date _____

23/02/2022

Approved By :

me

Name

 $\mu_{A_2B_2TXI}$

Date _____

23/02/2022

