

GREECE
LABEL

SHOP PACKET - HYDROCYN AQUA GEL

REF :	BW42C900	ODR. QTY :	288	RS 3 + 6 (QC TEST)	ISSUED DATE	3-Feb-22
ITEM CODE :	BW010009	PACK SIZE :	12/BOX		LOT NO	B20306
ITEM :	Bactiguard Woundcare, Gel Tube (50g)	CUSTOMER	Bactiguard AB (Lifecym)		MFG. DATE	3-Feb-22
		ORD. NO	B214 BOOT by 5/2/22		EXP DATE:	2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START:	297	297	NIL	1 Camarero (790)	Pashini 6:28pm 07/02/2022	3/2
DATE:						
TIME COMPLETE:						
DATE:						
CHECK : pH / VISCOSITY / FAC Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START:	297	297	NIL	(466 (1109))	Pashini 11:10 pm 07/02/2022	5/5
DATE:						
TIME COMPLETE:						
DATE:						
GEL FILLING						
TIME START:	297	297	NIL	Henningsen 12:40pm	Pashini 2:26pm 08/02/22	3/3
DATE:						
TIME COMPLETE:						
DATE:						
SEALING AND CUTTING GEL TUBE						
TIME START:	297	297	4	FARAH (1051)	Pashini 2:26 pm 08/02/2022	- 4 Tube reject replace with 5 new tube
DATE:						
TIME COMPLETE:						
DATE:						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START:	291	291	NIL	Viki (1094) Dewi (1126)	Pashini 11:40 18/2/22	ND
DATE:						
TIME COMPLETE:						
DATE:						
BOX PACKING & FINAL CONTROL						
TIME START:	291	291	NIL	Chaw (885) Dewi (1126)	Pashini 8:40 pm 22/2/22	Refer FCR
DATE:						
TIME COMPLETE:						
DATE:						
CARTON PACKING						
TIME START:	24 / 4 box / ctn	24 box 4 ctn	NIL	Vistau (1023)	Jinda 23/02/2022	23/02/2022
DATE:						
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED	297 pcs
QUANTITY FOR QC/RETAIN SAMPLE	PS 5 + 4 de
SHIPMENT QUANTITY PCS / CTNS :	297 pcs 24 box / ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR),

Signature : *[Signature]*

Name : *[Signature]*

Date : 24/2/22

Approved by (QC),

Signature : *[Signature]*

Name : *[Signature]*

Date : 24/2/22



LABEL APPROVAL

Οδηγίες χρήσης: Βεβαιωθείτε πρώτα ότι έχει καθαριστεί η πληγή. Εφαρμόστε τη γέλη απευθείας στην πληγή σε κάθε αλλαγή επίδεσμου του τραυματισμού. 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-Κάλιο Πυριτικό και Χλωριούχο Νάτριο.

Bactiguard (South East Asia) Sdn. Bhd.
(formerly known as VIGILENZ Medical Devices Sdn. Bhd.)
308B, Penang Science Park, 14100 Penang, Malaysia.



Bactiguard[®]

ΕΓΧΕΙΡΙΔΙΟ ΣΑ.Ι.Β. ΓΕΝΙΚΗ, ΙΝΦΕΣ ΣΑ.Ι.Β. ΤΙΣΣΕΛΣ, ΒΕΛΓΙΟΜ
MC-011-GR-R0
CE 2292
REF: BW42C900
Διανομή:
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13561 Ayioi Avdyou, Attiki
Τηλ.: +(30) 210 8313616 email: info@lifecyn.com

Bactiguard[®]
WOUND CARE
GEL

50g



Bactiguard[®]



7 333330 201636

LOT : B20306
EXP : 2023-08

Αρ. Γνωστοποίησης ΕΟΦ:
130619/23-12-2021.

REF: BW42C900



CE 2292

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ΕΓΧΕΙΡΙΔΙΟ ΣΑ.Ι.Β. ΓΕΝΙΚΗ, ΙΝΦΕΣ ΣΑ.Ι.Β. ΤΙΣΣΕΛΣ, ΒΕΛΓΙΟΜ

WOUND CARE

Καταπραυντική & Βακτηριοστατική δράση

Γέλη

50g

Bactiguard Wound Care Gel

REF

BW42C900

LOT

B20306

Qty

12 pcs / box

Weight

50 g / pc

Bactiguard[®]



REF: BW42C900
LOT: B20306
Qty: 12 pcs / box
Weight: 50 g / pc

<div>  VIGILENZ[®] </div>	HYDROCYN aqua[®] GEL - RECORDS OF PREPARATION		Doc. No.	PR-HR001
			Rev.	04


HYDROCYN aqua® GEL - RECORDS OF PREPARATION

Doc. No.	PR-HR001
Rev.	04

Date : 07/02/2022

	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.	Bw42900/ B20806
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)
G1B07022201	G11	9.13	comply	8339	✓	pass
G1B07022202	G12	9.13	comply	8339	✓	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

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
Document type: FORM	Doc Id: QC-IP0004-01	Issue Date: 15/11/2021	Page: 2(3)

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)					Average		
5/5	52.34 g	52.72 g	52.70 g	52.43 g	52.27 g	52.49 g	✓	pass
1/5	52.48 g	52.52 g	52.61 g	52.28 g	52.92 g	52.56 g	✓	pass
2/5	52.80 g	52.90 g	52.99 g	53.09 g	52.90 g	52.94 g	✓	pass
3/5	53.10 g	52.88 g	52.64 g	52.78 g	52.99 g	52.88 g	✓	pass
4/5	52.66 g	52.67 g	52.70 g	52.71 g	52.54 g	52.66 g	✓	pass
5/5	52.64 g	52.97 g	52.70 g	52.85 g	52.93 g	52.82 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		Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 3(3)

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 : Pag
 Name : POSHNE
 Date : 22/2/22

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

REF : BW42C 900 QTY PRODUCED (pcs) : 297

LOT NO : B20306 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/D

Inspected By :	Approved By :
Name : <u>Poshine</u>	Name : <u>MARTINI</u>
Date : <u>22/02/22</u>	Date : <u>23/2/2022</u>

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

DATE : 04/02/2022
REF : BW42C900
LOT NO. : B20306

SHOP PACKET QTY (pcs) : 288
CUSTOMER : BACTIGUARD AB (LIFECYN)
I.O NO. : IO/CYN/060505/01

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 Canjana
	P0100804	White Nozzle Cap	0	H125211001		594	594	1 Canjana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	grm	800	800	1 Canjana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Canjana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	grm	20	20	1 Canjana
5	N/A	STOCK SOLUTION	N/A	GB 07022201 GB 07022202	ltr	20	20	1 Canjana

(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), VIGILENZ0131; 100MM X 90MM, IN ROLL, TRANSPARENT PE, 4C + WHITE	LG04220201	298	1 Canjana
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (50g, 50g, 100g)	LB22210801	595	1 Canjana
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 Canjana
4	P0100910	BWC-02L INNER BOX 50g LBWC-004-GR-R0 - GREECE	BR220201	292	1 Canjana
5	P0100788	V09-BX022-00 - Hydrocyn Gel 50g (outer box) 300gsm 1 Side Art Card, 192 x 142.5 x 129mm	PH01210702	25	1 Canjana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210801	25	1 Canjana
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 Canjana
2	P0100767	V0047-0154; PDF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m; 1 roll/carton	P092210801		
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)			
2		#N/A			

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

VERIFIED BY (PR) :
Signature :
Name :
Date : 24/2/2022

VIGILENZ[®]	PRODUCT RELEASE TEST REPORT – HYDROCYN aqua[®] GEL		Doc No.	QC-PC008
			Rev.	02

Description	<i>Back-guard woundcare, Gel Tube 50g</i>	Reference No.	<i>BW42900</i>	Date of Inspection	<i>23/03/2022</i>
		Lot No.	<i>B20306</i>	Sample Size	<i>1pc x 50g</i>

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	Free from contamination / particles / foreign matters	pH (9.00 – 10.50)	FAC (100 – 200 ppm)
<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>9.76</i>	<i>comply</i>
							<i>pass</i>

✓ = Pass, X = Fail

Remarks: *N/A*

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : *Raj*
 Name : *POSHNI*
 Date : *23/03/2022*

Approved By : *M. Arini*
 Name : *M. ARINI*
 Date : *23/03/2022*

