

**SHOP PACKET - HYDROCYN AQUA GEL**

REF :	BW40F900	ODR. QTY :	780	RS 3 + 7 (QC TEST)	ISSUED DATE	3-Feb-22	
ITEM CODE :	BW010003	PACK SIZE :	20/BOX		LOT NO	B20305	
ITEM :	Bactiguard Woundcare, Gel (15g)	CUSTOMER	Bactiguard AB (Lifecyn)		MFG. DATE	3-Feb-22	
		ORD. NO	B213	B006	EXP DATE:	2023-08	
PROCESS		START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROLYN AQUA GEL PREPARATION							
TIME START :	5:28 pm						
DATE :	03-02-22						
TIME COMPLETE :	5:36 pm						
DATE :	03-02-22						
CHECK : pH / VISCOSITY / FAC	Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE							
TIME START :	3:00 pm						
DATE :	04-02-22						
TIME COMPLETE :	5:00 PM						
DATE :	04-02-22						
GEL FILLING							
TIME START :	2:50 pm						
DATE :	07-02-22						
TIME COMPLETE :	5:30 pm						
DATE :	07-02-22						
SEALING AND CUTTING GEL TUBE							
TIME START :	2:50 pm						
DATE :	07-02-22						
TIME COMPLETE :	5:30 pm						
DATE :	07-02-22						
LOT NUMBER AND EXPIRY DATE PRINTING							
TIME START :	4:15 pm						
DATE :	16-02-22						
TIME COMPLETE :	5:40 pm						
DATE :	16-02-22						
BOX PACKING & FINAL CONTROL							
TIME START :	1:00. pm						
DATE :	16-02-22						
TIME COMPLETE :	5:45 pm						
DATE :	16-02-22						
CARTON PACKING							
TIME START :	9:40 am						
DATE :	16-02-22						
TIME COMPLETE :	1:58 pm						
DATE :	16-02-22						

QUANTITY PRODUCED	190 pcs								
QUANTITY FOR QC/RETAIN SAMPLE	3 pcs + 7 pcs								
SHIPMENT QUANTITY PCS	780 pcs								
CTNS :	39 box								
FINAL SHIPMENT DATE									
COMPLETE/PARTIAL :	COMPLETE								PARTIAL

Checked by (PR) \_\_\_\_\_  
Signature : [Signature]  
Name : KATIE GREGG-CARLSON  
Date : 2/21/22

Approved by (QC),  
Signature : *[Signature]*  
Name : *Harini*  
Date : *1/3/2022*

LABEL APPROVAL

**Bactiguard<sup>®</sup>**

WOUND CARE

Καταπραυντική & Βακτηριοστατική δράση

Γέλη 15 g

Όλες οι πληροφορίες σχετικά με το προϊόν αυτό είναι διαθέσιμες στην ιστοσελίδα της εταιρείας. Παρακαλούμε να ελέγξετε την ιστοσελίδα της εταιρείας για να ενημερωθείτε για τυχόν αλλαγές. Μην χρησιμοποιείτε το προϊόν, μετά το άνοιγμα της συσκευασίας, σε περίπτωση που παρατηρήσετε το ελάττωμα της συσκευασίας.

Συσκευασία: Καταπραυντική Γέλη, Περιεχόμενο: 15g (0.52oz) (15g - 0.52oz) (15g - 0.52oz) (15g - 0.52oz)

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.

Διανομέας: LIFECYN AE  
Καθαρνίου 4 & Αγ. Παντελεήμωνος  
13561 Αγία Ανάργουρος, Αττική  
Τηλ.: +30 210 8313616 email: info@lifecyn.com

CE 2292

REF BW40F900

Διανομέας: LIFECYN AE  
Καθαρνίου 4 & Αγ. Παντελεήμωνος  
13561 Αγία Ανάργουρος, Αττική  
Τηλ.: +30 210 8313616 email: info@lifecyn.com

Αρ. Πρωτοκόλλου ΕΟΦ: 130699/23-12-2021

7 133333 201612

REF: B20305

EXP: 2023-08

**Bactiguard<sup>®</sup>**

WOUND CARE

Καταπραυντική & Βακτηριοστατική δράση

Γέλη 15g

**Bactiguard<sup>®</sup>**

WOUND CARE  
GEL

15g



**Bactiguard<sup>®</sup>**

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

REF: BW40F900

CE 2292

**Bactiguard<sup>®</sup>**

WOUND CARE

Καταπραυντική & Βακτηριοστατική δράση

Γέλη 15g

**Bactiguard Wound Care Gel**

**REF** BW40F900 ✓

**LOT** B20305 ✓

**Qty** 20 pcs / box ✓

**Weight** 15 g / pc ✓

**Bactiguard<sup>®</sup>**



130619/23-12-2021

Ref: 4/03/2023




**VIGILENZ<sup>®</sup>**

Doc. No.	PR-HR001
Rev.	04

	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

Date: 03/02/2022

[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.	BW40F900 / B20305
Order Qty.	780

#### 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)
GB3022203	G3	9.73	comply	9323	✓	pass
GB3022204	G4	9.73	comply	9323	✓	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: <b>QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL</b>			
Document type: <b>FORM</b>	Doc Id: <b>QC-IP004-01</b>	Issue Date: <b>15/11/2021</b>	Page: <b>2(3)</b>


### 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	
5/5	17.47	17.34	17.64	17.47	16.93	17.37	✓ pass
1/5	16.88	17.48	17.60	16.78	17.49	17.25	✓ pass
2/5	17.25	17.50	16.92	17.27	17.04	17.19	✓ pass
3/5	17.29	17.42	17.08	17.31	17.12	17.24	✓ pass
4/5	17.66	17.76	17.52	17.17	17.42	17.51	✓ pass
5/5	16.84	17.36	17.01	17.34	17.27	17.16	✓ 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
9/5	✓	✓	✓	✓	✓	pass
7/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass



<b>Title:</b> QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 <b>Bactiguard</b>	
<b>Document type:</b> FORM	<b>Doc Id:</b> QC-IP004-01	<b>Issue Date:</b> 15/11/2021	<b>Page:</b> 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 : uth  
 Name : uth uth  
 Date : 16/02/2022

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

REF : Bw40f900 QTY PRODUCED (pcs) : 790

LOT NO : B20305 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>Wah</u>	Approved By	:	<u>[Signature]</u>
Name	:	<u>Wah Wah</u>	Name	:	<u>MARTINI</u>
Date	:	<u>22-02-2022</u>	Date	:	<u>23/2/2022</u>



RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001  
Rev. 06

DATE : 03/02/2022  
REF : BW40F900  
LOT NO. : B20305

SHOP PACKET QTY (pcs) : 780  
CUSTOMER : BACTIGUARD AB (LIFECYN)  
LO NO. : IO/CYN/060505/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100225	15ml Long Nozzle Tube with white color screw on cap	Diameter 22 x 80mm, White Colour Tube with Long Nozzle's layers, Open End, Glass Finishing	H0280801	pcs	790	790	1 Kajana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gm	800	800	1 Kajana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Kajana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	1 Kajana
5	N/A	STOCK SOLUTION	N/A	B1B3022203 C1B3022204	ltr	20	20	1 Kajana

(3) OVER WRAPPING AND CARTON PACK						RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)		
1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LRI50M/LRI50 (BC FLUTE)	P100210801	4		1 Kajana
2		#N/A				
3		#N/A				

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

(2) PRODUCT PACKAGING					RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
1	P0100797	LBWC-009-R0 BACTIGUARD WOUND CARE 15G GEL	LB06210701	791	1 Kajana
2	P0100894	LBWC-009-GR-R0 (15G - Gel Tube - GREECE) VIGILENZ0129, 62MM X 65MM, IN ROLL, TRANSPARENT PE, 4C + WHITE	LG01220201	791	1 Kajana
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23210702	1581	1 Kajana
4	P0100908	BBWC-002-GR-R0, INNER BOX 15g. (GREECE)	BG1020201	791	1 Kajana
5	P0100318	Outer Tube Box for Hydrocort Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	39	1 Kajana
6		#N/A			
7		#N/A			

ISSUED BY (MM) :  
Signature :  
Name : LOVIN  
Date : 03/02/2022

VERIFIED BY (PR) :  
Signature :  
Name :  
Date : 24/2/22



# VIGILENZ®

## PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL

Doc No. QC-PC008

Rev. 02

Description	Bactiguard woundcare, Gel (15g)	Reference No.		Date of Inspection
		Lot No.		Sample Size
		Bw40f900		23/02/2022
		B20205		2 PCS x 15g

### 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)	
✓	✓	✓	✓	✓	Free from contamination / particles / foreign matters	9.72	PASS / FAIL
						copy	pass

✓ = Pass, X = Fail

Remarks: n/p

CONCLUSIONS: ☒ RELEASE☐ ON-HOLD

Inspected By : Peggy  
Name : ROSHNI  
Date : 23/02/2022

Approved By : [Signature]  
Name : MARTINI  
Date : 23/2/2022

