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# HYDROCYN aqua® GEL - RECORDS OF PREPARATION

Date: 23/02/2023

	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]



VIGILENZ®	QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua®		Doc. No	QC-IP006
	GEL SPRAY (BOV)		Rev.	00

Reference / Lot No.	B04C9800/ B20413
Order Qty.	162

**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)
		Instrument No.: Calibration due date:	Instrument No.: Calibration due date:				
G1B2302203	G13	9.38 Instrument No.: Q1-78 Calibration due date:	140024 Instrument No.: Calibration due date: N/A	9092	✓	pass	
G1B2302204	G14	9.38 Instrument No.: Calibration due date:	comply Instrument No.: Calibration due date: N/A	9092	✓	pass	

**B. Gassing Process**

Sampling / Frequency	Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)					Test Disposition (PASS / FAIL)
	Instrument No.: Q1- 130					
	Calibration due date: 16/02/2023					
	1	2	3	4	5	
5/5	0.9 mpa	0.9 mpa	0.9 mpa	0.8 mpa	0.9 mpa	pass

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### C. Crimping Process

Sampling / Frequency	Crimp width and depth (mm) – 50g / 100g										Test Disposition (PASS / FAIL)
	Depth Specifications: ≥ 5.1 mm					Width Specifications: ≥ 27.1 mm					
	Instrument No.: QC-128 Calibration due date: N/A					Instrument No.: QC-129 Calibration due date: N/A					
	1	2	3	4	5	1	2	3	4	5	
5/5	5.2 mm	5.2 mm	5.3 mm	5.3 mm	5.3 mm	27.7 mm	27.8 mm	27.7 mm	27.9 mm	27.9 mm	pass
1/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.7 mm	27.7 mm	27.5 mm	27.9 mm	27.9 mm	pass
2/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.8 mm	27.8 mm	27.5 mm	27.8 mm	27.8 mm	pass
3/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.9 mm	27.6 mm	27.7 mm	27.8 mm	27.7 mm	pass
4/5	5.3 mm	5.3 mm	5.2 mm	5.2 mm	5.2 mm	27.9 mm	27.6 mm	27.8 mm	27.1 mm	27.7 mm	pass
5/5	5.1 mm	5.3 mm	5.2 mm	5.3 mm	5.2 mm	27.8 mm	27.6 mm	27.4 mm	27.7 mm	27.7 mm	pass

### D. Filling Process

Weight Specifications: 50g : 76.0g – 83.0g  
100g: 139.0 – 154.0g

Sampling / Frequency	Weight of Sample (g)					Test Disposition (PASS / FAIL)
	Instrument No.: <u>QC-WB-01</u> Calibration due date: <u>05/05/2022</u>					
	1	2	3	4	5	
5/5	141.8 g	142.7 g	140.0 g	145.5 g	140.2 g	pass
1/5	141.9 g	141.8 g	143.0 g	148.9 g	143.5 g	pass
2/5	146.3 g	144.6 g	144.5 g	141.8 g	144.5 g	pass
3/5	142.5 g	147.3 g	145.8 g	146.0 g	140.4 g	pass
4/5	140.6 g	144.7 g	145.0 g	140.8 g	143.4 g	pass
5/5	141.8 g	145.0 g	144.5 g	139.9 g	141.0 g	pass

E. Capping Process

### E. Capping Process

VIGILENZ®	QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)		Doc. No	QC-IP006
			Rev.	00

Sampling / Frequency	Actuators are properly fixed onto the canister	Functionality of actuator	Caps are properly fit onto the canister	Test Disposition (PASS / FAIL)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

#### F. Labelling & Printing Process

Sampling / Frequency	Print Information must be Clear / Legible and Conforms to Specifications as Stated in Approved Artwork	Ref No., Lot No. & Expiry Date Corresponds to Shop Packet and Approved Artwork	Correct Label Position	Correct Printing Position	Test Disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	pass

#### G. Attachment (Label)



# BactiGuard®

Για την ενυδάτωση και τον καθαρισμό σε οξεία και χρόνια όπως και σε χρόνια όπως και όπως σε έλκη σταδίου I-IV, διαβητικά έλκη, χειρουργικά εγκαυμάτα (1ου - 2ου βαθμού) κατάκλισης.

Καθίστε το τραύμα πριν την εμφάνιση της υβρένης, ξεκρίστε συνεχώς την υβρένη στο ψέμα, διατηρώντας απόσταση 10-15 εκ.από τον οπίσθιο του τραυματία για ομοιορροή εμφάνισή. Καλύπτετε με κατάλληλη γάζα τραυματία. Χρησιμοποιείτε την υβρένη μεταξύ των δακτύλων των ποδιών για να διατηρήσετε τη βέλτιστη γραμμή στο τραύμα. Ο δούρατος της γάζας με υβρένη θα βοηθήσει στην αφαίρεση της. Η υβρένη μπορεί να χρησιμοποιηθεί ως παράγοντας απομακρυντικός εάν είναι απαραίτητο. Συμβουλευτείτε γιατρό εάν απαιτείται.

CE 2292

**BW4CG800**

**REF** **LOT** **Q**

**220413**  
**2023-08**

**Καταπραϋντική & Βακτηριοστατική δράση**

# WOUND CARE

## Εκνέφωμα Γέλως

**100 g**

**Διοτιμότης LIFECYN AE**  
Κατσάντση 4 & Αν. Παρτελετήριου  
13561 Νέοι Ανάγυροι, Αττική  
Τηλ.: +30 (0) 20 8313616  
email: info@lifecyn.com

Αρ. Πρωτοκολλήσεως ΕΟΦ: 130623/123-12-2021.


Backguard (South East Asia) Sdn. Bhd.  
(formerly known as VIGILENZ Medical Devices Sdn. Bhd.)  
14000, Petaling Science Park,  
14000 Petaling, Malaysia. com

Overall in-process inspection: ~~PASS~~ / ~~FAIL~~

Inspected by :

Name \_\_\_\_\_

Date \_\_\_\_\_

Title: FINAL CONTROL TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)		 Bactiguard	
Document type: FORM	Doc Id: QC-FC009-01	Issue Date: 15/11/2021	Page: 1(1)

REF : Bw409800 : QTY PRODUCED (pcs) : 165

LOT NO : B20413 : RETAIN SAMPLE QTY (pcs) : 2

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.	Free from contamination, deformed or damage on packaging.	S3, 0.15	80	0	1	80	0	pass

Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)		Test Disposition (PASS / FAIL)
Instrument No: QC-130	Calibration due date: 16/2/2023	
Sample 1	Sample 2	
0.8 mpa	0.8 mpa	
pass		

REMARKS: N/D

Inspected By : <u>Raj</u>	Approved By : <u>K. Suresh</u>
Name : <u>RASHMI</u>	Name : <u>MARTINI</u>
Date : <u>25/01/2022</u>	Date : <u>26/2/2022</u>



DATE : 09/02/2022

SHOP PACKET QTY (pcs) : 162

RS 3


REF : BW4CG800




CUSTOMER : BACTIGUARD AB (LIFECYN)

LOT NO. : B20413

LO NO. : IO/CYN/060505/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100723	Aluminium can (Size 4.5x 150mm)	BOV - 100ml; Capacity: 150ml	A020200401	pcs	165	165	1 Cayana
2	P0100344	Plastic Actuator (EVER BRIGHT)	0.46mm (Orifice)	H08350601	pcs	165	165	1 Cayana
3	P0100347	Plastic Cap (White Color)	Diameter: 3.5mm	HW29210701	pcs	165	165	1 Cayana
4	C0100026	RHEOLOGICAL ADDITIVE (SUPPENT MP)	-	H080210801	gms	800	800	1 Cayana
5	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Cayana
6	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gms	20	20	1 Cayana
7		STOCK SOLUTION			ltr	20	20	1 Cayana

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100898	LBWC-014-GR-R0 (100G - BOV - GREECE), VIGILENZ0134; 135MM X 115MM; IN ROLL, GLOSS WHITE BOPP, 4C + EYEMARK	LG02220201	166	
2		#N/A			
3		#N/A			
4		#N/A			
5		#N/A			
6		#N/A			
7		#N/A			

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H164220101	2	
2	P0100692	Aerosol Gel Nesting set-Long 5pcs & Short 8pcs - 456(L)x110MM , B/Q-T150/T150 BF	H079200402	2	
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)		NA	
2		#N/A			

ISSUED BY (MM) :

Signature : 

Name : MMVN

Date : 09/02/2022


VERIFIED BY (PR) :

Signature : 

Name : P. Praveen

Date : 26/2/2022



Title: <b>PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)</b>		 <b>Bactiguard</b>	
Document type: <b>FORM</b>	Doc Id: <b>QC-PC011-01</b>	Issue Date: <b>15/11/2021</b>	Page: <b>1(1)</b>

Description	Bactiguard woundcare, Gel spray (BOV) 100g	Reference No.	BW469800	Date of Inspection	25/01/2022
		Lot No.	B20413	Sample Size	1btl x 100g

Packing Integrity (Visual Inspection)			Chemical Testing		Test Disposition
Correct and Legible Printing of Label	Free from Contamination / Deformed / Damaged	Proper Crimping and Capping	Ability to Dispense	pH (9.00 – 10.50) Instrument No.: 8078 Calibration due date: 12/03/2022	
✓	✓	✓	✓	FAC (100 – 200 ppm) Instrument No.: 480034 Calibration due date: N/D	PASS / FAIL  pass

✓ = Pass X = Fail

REMARKS: N/A

CONCLUSION:

<input checked="" type="checkbox"/>	RELEASE
<input type="checkbox"/>	ON-HOLD

Inspected By : Poly  
 Name : Poly  
 Date : 25/01/2022

Approved By : [Signature]  
 Name : MARTINI  
 Date : 25/01/2022

