

SHOP PACKET - EASW

REFERENCE	BW4CG800	ODR. QTY	162	RS 2 +1 (QC TEST)	ISSUED DATE	04/02/2022
ITEM CODE	BW010005	PACK SIZE	54/BOX		LOT NO.	B20414
ITEM DESCRIPTION	Bactiguard Woundcare , Gel Spray (BOV) 100g	CUSTOMER	Bactiguard AB (Lifecyn)		MFG. DATE	04/02/2022
		ODR. NO	B025		EXP. DATE	2023-08
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN		INT. ORDER	10/CYN/060505/01
	DATE : 04/02/2022		DATE : 04/02/2022			
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton	N/A			
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-PI NO. (2nd Packaging) - Carton	N/A			

PROCESS		INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION							
TIME START :	12:05 PM				Makheing		
DATE :	23 14-02-22	165	165	NIL	caog)		2/2
TIME COMPLETE :	12:20 PM				MBA (1118)		
DATE :	23 14-02-22						
UDI PRINTING (Label/Box/Carton)							
TIME START :					N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :							
TIME COMPLETE :							
DATE :							
SOLUTION FILLING & CAPPING							
TIME START :	2:00 PM				FARAH(1051)		
DATE :	24-02-22	165	160	5	DEWI (1126)	Roshni 3:52 PM 24/2/2022	N/A
TIME COMPLETE :	3:52 PM						
DATE :	24-02-22						
SOLUTION FILLING							
TIME START :	09:45 am				Ambiger (1129)		
DATE :	25-02-22	165	165	NIL		Roshni 9:59 am 25/2/22	NA
TIME COMPLETE :	09:59 am						
DATE :	25-02-22						
PRINTING LOT NUMBER							
TIME START :	09:48 am				Ambiger (1129)		
DATE :	25-02-22	165	165	NIL		Roshni 9:59 am 25/2/22	NA
TIME COMPLETE :	09:59 am						
DATE :	25-02-22						
CAP SEALING (Applicable for 100mL)							
TIME START :					NA		
DATE :							
TIME COMPLETE :							
DATE :							
BOX PACKING & PRINTING							
TIME START :					NA		
DATE :							
TIME COMPLETE :							
DATE :							
MANUAL UDI LABELLING							
TIME START :					N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :							
TIME COMPLETE :							
DATE :							
FINAL CONTROL							
TIME START :	09:45 am				Ambiger (1129)		
DATE :	25-02-22	165	165	NIL		Roshni 10:59 am 25/2/22	NA
TIME COMPLETE :	09:59 am						
DATE :	25-02-22						
CARTON PACK							
TIME START :	11:00 am				Vistec		
DATE :	25-02-22	3	3	NIL	(1123)	Nurin 25/2/22	25/02/22
TIME COMPLETE :	11:10 am	ctn	ctn				
DATE :	25-02-22						
UDI LABELLING							
TIME START :					N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :							
TIME COMPLETE :							
DATE :							

QUANTITY PRODUCED	:	165 btl
QUANTITY FOR QC / RETAIN SAMPLE	:	2Rst 16tl
SHIPMENT QUANTITY PCS / CTNS	:	162 btl
FINAL SHIPMENT DATE	:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
COMPLETE/ PARTIAL	:	<div>COMPLETE</div> <div>PARTIAL</div>

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

23/02/22

	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.	BWY01800 / B20414
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:	Instrument No.: Calibration due date:			
G182302205	G15	Instrument No.: Q(- 78 Calibration due date: 12/03/2022 9.74	Instrument No.: 1/30024 Calibration due date: N/A comply	Instrument No.: Q(- 96 Calibration due date: 01/07/2022 9368	✓	pass	
G182302206	G16	9.74	comply	9368	✓	pass	
				NA			

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.:					
	Calibration due date:					
	1	2	3	4	5	

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

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	5.2mm	5.2mm	5.3mm	5.2mm	5.2mm	27.7mm	27.8mm	27.8mm	27.8mm	27.9mm	pass
1/5	5.2mm	5.1mm	5.2mm	5.2mm	5.2mm	27.7mm	27.7mm	27.8mm	27.9mm	27.8mm	pass
2/5	5.2mm	5.2mm	5.2mm	5.2mm	5.2mm	27.7mm	27.7mm	27.8mm	27.7mm	27.8mm	pass
3/5	5.2mm	5.2mm	5.3mm	5.2mm	5.2mm	27.9mm	27.7mm	27.7mm	27.9mm	27.7mm	pass
4/5	5.2mm	5.2mm	5.2mm	5.2mm	5.2mm	27.9mm	27.9mm	27.6mm	27.6mm	27.7mm	pass
5/5	5.3mm	5.2mm	5.2mm	5.2mm	5.2mm	27.9mm	27.9mm	27.6mm	27.5mm	27.9mm	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.: WB-01					
	Calibration due date: 05/05/2022					
	1	2	3	4	5	
5/5	146.1 g	145.5 g	146.8 g	146.1 g	142.7 g	pass
1/5	148.6 g	147.7 g	152.9 g	151.4 g	149.0 g	pass
2/5	150.0 g	151.1 g	150.4 g	148.8 g	149.1 g	pass
3/5	150.8 g	147.8 g	151.2 g	153.5 g	148.1 g	pass
4/5	149.9 g	149.3 g	151.1 g	153.2 g	151.0 g	pass
5/5	145.0 g	152.0 g	148.3 g	151.1 g	148.3 g	pass
E. Canning 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
3/5	✓	✓	✓	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)

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 : B044800 : QTY PRODUCED (pcs) : 165

LOT NO : B20414 : RETAIN SAMPLE QTY (pcs) : 0

No.	Inspection Criteria	Sampling Details	Sample size	AQL		Results		Status (Pass / Fail)
				Accept	Reject	Accept	Reject	
1.	Legible and correct printing of label.	<u>S₂, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>pass</u>
2.	Free from contamination, deformed or damage on packaging.	<u>S₂, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>pass</u>

Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)		Test Disposition (PASS / FAIL)
Instrument No: <u>QC-130</u>	Calibration due date: <u>16/11/2023</u>	
Sample 1	Sample 2	
<u>0.8 mpa</u>	<u>0.9 mpa</u>	<u>pass</u>

REMARKS: N/A

Inspected By : <u>Peng</u>	Approved By : <u>HAZTINI</u>
Name : <u>Peng Hui</u>	Name : <u>HAZTINI</u>
Date : <u>25/11/2022</u>	Date : <u>25/11/2022</u>

DATE :

09/02/2022

REF :

BW4CG800

LOT NO. :

B20414

SHOP PACKET QTY (pcs)

162


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	P0100723	Aluminium can (Size:45x150mm)	BOV: 100ml; Capacity: 150ml	A020200401	pcs	165	165	1 Canjauq
2	P0100344	Plastic Actuator (EVER BRIGHT)	0.46mm (Orifice)	H08350601	pcs	165	165	1 Canjauq
3	P0100347	Plastic Cap (White Color)	Diameter: 35mm	HW29210701	pcs	165	165	1 Canjauq
4	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gm	800	800	1 Canjauq
5	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Canjauq
6	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	1 Canjauq
7		STOCK SOLUTION			ltr	20	20	1 Canjauq

(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			

Title: **PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)**

Document type: **FORM**

Doc Id: **QC-PC011-01**

Issue Date: **15/11/2021**

Page: **1(1)**

Bactiguard

Description: **Bactiguard woundcare, Gel spray (BOV) 100g**

Reference No.: **BWH49800**

Lot No.: **B20414**

Date of Inspection: **25/2/2022**

Sample Size: **1611 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.: QC-78 Calibration due date: 12/03/2022	
✓	✓	✓	✓	9.61	pass

✓ = Pass X = Fail

REMARKS: **N/D**

CONCLUSION: ☒ RELEASE ☐ ON-HOLD

Inspected By: **Pinky**

Name: **Poovne**

Date: **25/02/2022**

Approved By: **[Signature]**

Name: **ANITA**

Date: **25/2/2022**

