

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.	B20412	
ITEM DESCRIPTION	Bactiguard Woundcare , Gel Spray (BOV) 100g	CUSTOMER	Bactiguard AB (Lifecyn)	MFG. DATE	04/02/2022	
		ODR. NO	B023	EXP. DATE	2023-08	
PREPARED BY	NAME : NUR SHAHIRA DATE : 04/02/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 04/02/2022	INT. ORDER	10/CYN/060505/01	
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 : 11:06 am DATE : 23/02/22 TIME COMPLETE : 11:16 am DATE : 23/02/22	165	165	N11	ma khing 1909	19/02/22	2/2
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : 10:45 am DATE : 24-02-22 TIME COMPLETE : 11:17 am DATE : 24-02-22	165	161	4	FARAH (1051) DEWI (1126)	Rashmi 11:17 am 24/02/22	N/A
LABELLING						
TIME START : 8:45 am DATE : 25-02-22 TIME COMPLETE : 8:57 am DATE : 25-02-22	165	163	2	FARAH (1051) Ambiga (1129)	Rashmi 8:57 am 25/2/22	N/A
PRINTING LOT NUMBER						
TIME START : 8:45 am DATE : 25-02-22 TIME COMPLETE : 8:57 am DATE : 25-02-22	165	165	NIL	FARAH (1051) Ambiga (1129)	Rashmi 8:57 am 25/02/22	NA
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :			NA			
BOX PACKING & PRINTING						
TIME START : DATE : TIME COMPLETE : DATE :			NA			
MANUAL UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : 8:45 am DATE : 25-02-22 TIME COMPLETE : 8:57 am DATE : 25-02-22	165	165	NIL	FARAH (1051) Ambiga (1129)	Rashmi 9:30 am 25/2/22	NA
CARTON PACK						
TIME START : 11:00 am DATE : 25-02-22 TIME COMPLETE : 11:10 am DATE : 25-02-22	3 ctn	3 ctn	Nil	Rashmi (1088)	Nurin 25/2/22	lynn 25/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED :	165 btl
QUANTITY FOR QC / RETAIN SAMPLE :	2 RSH btl
SHIPMENT QUANTITY PCS / CTNS :	162 btl
FINAL SHIPMENT DATE :	
COMPLETE / PARTIAL :	COMPLETE

Checked by (PR), Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : 26/2/2022	Approved by (QA), Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : 1/3/2022	Released by (QC), Signature : <i>[Signature]</i> Name : A. A. Q. T. H. I. Designation : IPQC SUP Date : 26/2/2022 Stamp : <i>[Stamp]</i>
Remarks:		



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

Reference / Lot No.	BWYCG800 / B20412
Order Qty.	162

A. Before Filling

Batch No.	Container No.	pH (9.00 – 10.50) Instrument No.: Q1-78 Calibration due date: 12/03/2022	FAC (100 – 200 ppm) Instrument No.: 240024 Calibration due date: N/A	Viscosity (8,000 – 10,000 cps) Instrument No.: Q1-96 Calibration due date: 01/07/2023	Gel is Clear and Free from Contamination	Test Disposition (PASS / FAIL)
B1B2302201	G11	9.76	comply	9921	✓	pass
B1B2302202	G12	9.76	comply	9921	✓	pass
		N A				

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	0.8 mpa	0.8 mpa	0.9 mpa	0.9 mpa	0.8 mpa	pass
1/5	0.7 mpa	0.7 mpa	0.8 mpa	0.7 mpa	0.7 mpa	pass
2/5	0.8 mpa	0.8 mpa	0.9 mpa	0.8 mpa	0.9 mpa	pass
3/5	0.9 mpa	0.8 mpa	0.8 mpa	0.8 mpa	0.9 mpa	pass
4/5	0.8 mpa	0.8 mpa	0.8 mpa	0.8 mpa	0.8 mpa	pass
5/5	0.8 mpa	0.9 mpa	0.8 mpa	0.9 mpa	0.8 mpa	pass

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C. Crimping Process

Crimp width and depth (mm) – 50g / 100g												Test Disposition (PASS / FAIL)
Sampling / Frequency	Depth Specifications: ≥ 5.1 mm					Width Specifications: ≥ 27.1 mm						
	Instrument No.: QC-128 Calibration due date: NA					Instrument No.: QC-129 Calibration due date: NA						
	1	2	3	4	5	1	2	3	4	5		
5/	5.3	5.3	5.2	5.2	5.2	27.8	27.1	27.9	27.6	27.8	pass	
1/5	5.3	5.2	5.2	5.2	5.2	27.7	27.9	27.8	27.6	27.6	pass	
2/5	5.2	5.2	5.2	5.2	5.2	27.8	27.8	27.5	27.7	27.8	pass	
3/5	5.2	5.3	5.2	5.2	5.2	27.6	27.7	27.6	27.8	27.8	pass	
4/5	5.2	5.2	5.2	5.2	5.2	27.6	27.6	27.7	27.8	27.9	pass	
5/5	5.2	5.2	5.2	5.2	5.2	27.6	27.6	27.7	27.8	27.8	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: 5/05/2022					
	1	2	3	4	5	
5/5	145.6 g	146.2 g	148.3 g	153.6 g	150.4 g	PASS
1/5	146.0 g	146.9 g	147.7 g	145.1 g	146.8 g	PASS
2/5	150.5 g	145.1 g	145.9 g	143.2 g	145.5 g	PASS
3/5	148.2 g	145.2 g	142.9 g	145.2 g	145.6 g	PASS
4/5	142.7 g	142.2 g	141.0 g	144.1 g	148.8 g	PASS
5/5	147.1 g	142.6 g	143.9 g	143.8 g	147.7 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
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)

Inspected by : Wach
Name : Wach Wach
Date : 25.2.22

F. Conclusion

Overall in-process inspection: PASS / FAIL

4 of 4

Title: FINAL CONTROL TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)			
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.	33, 0.15	80	0	1	80	0	pass
2.	Free from contamination, deformed or damage on packaging.	33, 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: QN-150	Calibration due date: 16/1/2025	
Sample 1	Sample 2	
0.8 mpa	0.8 mpa	
		pass

REMARKS: N/A

Inspected By : <u>Raj</u>	Approved By : <u>M. J. J.</u>
Name : <u>ROSINE</u>	Name : <u>MARTINI</u>
Date : <u>25/1/20</u>	Date : <u>26/02/2022</u>

DATE : 09/02/2022

REF : BW4CG800

LOT NO. : B20412

SHOP PACKET QTY (pcs) : 162

CUSTOMER : BACTIGUARD AB (LIFECYN)

LO NO. : IO/CYN/060505/01

RS 3

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	<i>Kanyana</i>
2	P0100344	Plastic Actuator (EVER BRIGHT)	0.46mm (Orifice)	H08350601	pcs	165	165	<i>Kanyana</i>
3	P0100347	Plastic Cap (White Color)	Diameter: 35mm	HW29210701	pcs	165	165	<i>Kanyana</i>
4	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gm	800	800	<i>Kanyana</i>
5	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	<i>Kanyana</i>
6	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	<i>Kanyana</i>
7		STOCK SOLUTION			ltr	20	20	<i>Kanyana</i>

(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	<i>Kaly</i>
2	P0100692	Acrosol Gel Nesting set-Long Spes & Short Spes - 456(L)x110MM, BQ-T150/T150 BF	H079200402	2	<i>maulur</i>
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)	N/A	N/A	N/A
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. **B041C6800**

Lot No. **B20413**

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

Sample Size **16H 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)	FAC (100 – 200 ppm)	
✓	✓	✓	✓	Instrument No.: Q11-78 Calibration due date: 12/03/2022	Instrument No.: 480024 Calibration due date: NA	PASS / FAIL
				9.65	comp	pass

✓ = Pass X = Fail

REMARKS: **N/A**

CONCLUSION:

☒ RELEASE

☐ ON-HOLD

Inspected By : **Pooj**

Name : **POHANE**

Date : **25/02/2022**

Approved By : **[Signature]**

Name : **NA RTM**

Date : **25/2/2022**

