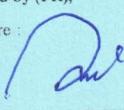
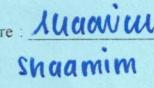


SHOP PACKET - HYDROCYN AQUA GEL SPRAY (BOV)

REFERENCE	VW42E800	ODR. QTY	200	RS 2 + 1 (QC TEST)	ISSUED DATE	06/09/2022
ITEM CODE	H0100047	PACK SIZE	50/BOX	LOT NO.	I20606	
ITEM DESCRIPTION	Aniocyn Hydrogel (BOV) 50g, (Bactiguard)	CUSTOMER	Bactiguard AB	MFG. DATE	06/09/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 06/09/2022	ODR. NO	I033	EXP. DATE	2024-03	
		VERIFIED BY	NAME : MUHD ARIFUDDIN DATE : 06/09/2022		INT. ORDER	IO/BAC/005083/02

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 4.30 PM DATE : 06-09-22 TIME COMPLETE : 4.38 PM DATE : 06-09-22	203	203	NIL	yati (115#)	DEVA 06/09/22	NIL
GASSING AND CRIMPING						
TIME START : 02.10 PM DATE : 09-09-22 TIME COMPLETE : 02.50 PM DATE : 09-09-22	203	203	NIL	yati (115#)	Devq 09/09/22	NIL
GEL FILLING						
TIME START : 02.10 PM DATE : 09-09-22 TIME COMPLETE : 02.50 PM DATE : 09-09-22	203	201	2	yati (115#)	Devq 09/09/22	- 2 pcs low volume replace to new.
INSERT AND TEST ACTUATOR						
TIME START : 02.10 pm DATE : 09-09-22 TIME COMPLETE : 03.00 PM DATE : 09-09-22	203	203	NIL	Irma (1209)	Devq 09/09/22	NIL
CAPPING						
TIME START : 02.10 pm DATE : 09-09-22 TIME COMPLETE : 03.00 PM DATE : 09-09-22	203	203	NIL	Irma (1209)	DEVA 09/09/22	NIL
LABELLING						
TIME START : 4.50 PM DATE : 09-09-22 TIME COMPLETE : 5.05 PM DATE : 09-09-22	203	203	NIL	Yari ARNA	Devq 09/09/22	NIL
PRINT LOT NUMBER & EXPIRY DATE						
TIME START : 4.50 PM DATE : 09-09-22 TIME COMPLETE : 5.05 DATE : 09-09-22	203	203	NIL	Yati ARNA	Devq 09/09/22	NIL
FINAL CONTROL						
TIME START : 4.50 PM DATE : 09-09-22 TIME COMPLETE : 5.05 PM DATE : 09-09-22	203	203	NIL	Yati ARNA	Devq 09/09/22	NIL
CARTON PACK						
TIME START : 10.00 AM DATE : 10-09-22 TIME COMPLETE : 10.10 AM DATE : 10-09-22	4 CTN	4 CTN	NIL	Herdi (1053) Fashi (1054)	KIRAH 10/09/2022	Munif 10/09/22

QUANTITY PRODUCED :	203
QUANTITY FOR QC / RETAIN SAMPLE :	RS 2+1
SHIPMENT QUANTITY PCS / CTNS :	200 4 CTN
COMPLETE/PARTIAL :	COMPLETE PARTIAL

Checked by (PR), Signature : 	Approved by (QA), Signature : 	Released by (QC), Signature : 
Name : muhs arifip Date : 12/09/2022	Name : Rohamza Othman Date : 24/09/2022	Name : Shuaamim Designation : Srn QA Exe Date : 14/09/2022
Remarks:	Stamp : 	

GEL - RECORDS OF PREPARATION

Document Type:
FORM

Doc Id:
PR-HR001-05

Issue Date:
04/07/20

Page:
1(1)

Date : 06/09/22

VIGILENZ®

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

Reference / Lot No.	VW42E800 / 120606	Doc. No	QC-IP006
Order Qty.	200	Rev.	00

Reference / Lot No.	VW42E800 / 120606
Order Qty.	200

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.: 01C78 Calibration due date: 09/09/2023	Instrument No.: 480004 Calibration due date: 10/10/2024	Instrument No.: 811-96 Calibration due date: 22/08/2023		
G1B0609007	617	9.43	200	9981	✓	pass
G1B0609006	616	9.30	200	9713	✓	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)
	Calibration due date: 10/02/2023					
1	2	3	4	5		
5/5	0.9	0.8	0.9	0.8	0.8	pass
1/5	0.9	0.8	0.8	0.8	0.9	pass
2/5	0.8	0.8	0.9	0.8	0.9	pass
3/5	0.8	0.8	0.9	0.9	0.9	pass
4/5	0.8	0.8	0.9	0.9	0.8	pass
5/5	0.9	0.8	0.8	0.8	0.8	pass

VIGILENZ®

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

Doc. No	QC-IP00
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: 01/03/2023	Instrument No.: GC - 129 Calibration due date: 01/03/2023	1	2	3	4	5	
5/5	5.22	5.23	5.13	5.10	5.16	27.41	
1/5	5.22	5.21	5.16	5.26	5.16	27.78	
2/5	5.12	5.21	5.15	5.11	5.16	27.72	
3/5	5.25	5.19	5.20	5.12	5.26	27.80	
4/5	5.21	5.15	5.16	5.18	5.16	27.46	
5/5	5.15	5.21	5.21	5.19	5.19	27.74	
						27.60	
						27.83	
						27.69	
						27.60	
						27.76	
						27.45	
						27.75	
						PASS	
						PASS	
						PASS	
						PASS	
						PASS	
						PASS	
						PASS	
						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)	
	Calibration due date: 16/05/2023						
	1	2	3	4	5		
5/5	83.2	80.0	80.4	81.1	81.3	PASS	
1/5	78.8	77.6	82.0	77.9	81.1	PASS	
2/5	80.2	77.3	77.1	81.8	80.1	PASS	
3/5	80.7	79.7	80.3	80.4	78.7	PASS	
4/5	80.7	78.5	78.3	76.6	81.3	PASS	
5/5	78.0	76.1	79.7	81.9	86.5	PASS	

E. Capping Process

VIGILENZ®

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

Sampling / Frequency	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)

VIGILENZ®

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua®
GEL SPRAY (BOV)

Doc. No	QC-IP006
Rev.	00



F. Conclusion

Overall in-process inspection: PASS / FAIL

Out.

Inspected by : *Deva*

Name : *Deva*

Date : *10/09/2023*

FINAL CONTROL TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)

Document type:
FORM

REF : VV42E800
LOT NO : T20606

Doc Id:
QC-FC009-01

Issue Date:
15/11/2021

Page:
1(1)

QTY PRODUCED (pcs) : 200

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

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: 16/10/2023			
Sample 1		Sample 2					
0.7		0.9					
pass							

REMARKS: N/A

Inspected By : Null
Name : Devor
Date : 10/09/2023

Approved By : Martin
Name : Martin
Date : 12/09/2023

Bactiguard

RAW MATERIAL LOADING FORM (RMLF)

Doc No.
Rev.

DATE :	09/09/2022
REF :	VW42E800
LOT NO. :	I26606

SHOP PACKET QTY (pes) :
 CUSTOMER :
 I.O. NO. :

RS :
 BACTIGUARD AB
 IO/BAC/05083/02

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pes)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100724	Aluminum can, BOV: 50ml	(Size:35x110mm); Capacity: 90ml	A020220501	pcs	203	203	M.Basthiu
2	P0100344	Plastic Actuator (EVER BRIGHT)	0.46mm (Office)	H083220101	pcs	203	203	M.Basthiu
3	P0100815	Plastic Cap (White Color) - Bactigard Woundcare	Diameter: 35mm (EVER BRIGHT)	H029220101	pcs	203	203	M.Basthiu
4	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080220301	gm	800	800	M.Basthiu
5	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023220801	ml	200	200	M.Basthiu
6	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021220401	gm	20	20	M.Basthiu
7		STOCK SOLUTION	N/A	01206092206 01206092207	ltr	20	20	M.Basthiu

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)	RECEIVED BY	(3) OVER WRAPPING AND CARTON PACK		
						ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)
1	P0100889	LBA-005-SE-RF ANILOCYN HYDROGEL (BOV) 50g - Bactigard (SE,NO,FIN) (DOUBLE LAYER)-10.5mm x 85mm; IN ROLL; GLOSS WHITE PP; 5 COLOR, Double Layer peel off label	LA2SE220401	204	M.Basthiu	100ml Hydrocyan Aqua Printed Carton - 440L X 220W X 156H	H165220301	24
2						100ml nesting short 9pes and Long 4pes -	H079200402	24
3						#N/A		
4								

(4) SPECIAL REQUIREMENT

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)	RECEIVED BY	(4) SPECIAL REQUIREMENT		
						ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 3.5mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	N/A					
2								
3								
4								
5								
6								
7								

ISSUED BY (MM) :

Signature :

Name :

Date :

VERIFIED BY (PR) :

Signature :

Name :

Date :

Title: OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD

OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD		Bacitguard	
Document type:	FORM	Issue Date:	09/02/2022
	Doc ID: QC-OI001-04		Page: 1(2)

 Backguard	Issue Date: 05/06/01	Page: 1(2)
Doc ID: GCR001.04		

SHIPMENT	<u>1</u>
TOTAL LOTS	: <u>1</u>
TOTAL CARTONS	: <u>4</u>
SAMPLING DETAILS	: <u>L, AQL 1.5</u>

N/A _____
(Applicable for _____)
YES _____
(Applicable for _____)

RETURN DATE
AVAILABILITY
SAMPLES

Please bring addition sheet if required

Inspected by _____
Name _____ Date _____

A small blue ink mark located in the bottom right corner of the page.

Verified by
Name _____ Date _____

Alj. K-Naimi 13/09/2022

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)

Description	Anhydro Hydrogen (BOV) 50g Bactiguard	Reference No.	W4407800	Date of Inspection	10/09/2021
Lot No.	120606	Sample Size	1 pc x 50g		

Packing Integrity (Visual Inspection)

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.: QL-78	PASS / FAIL
				✓	✓	Calibration due date: 10/10/2024	

✓ = Pass X = Fail

REMARKS: N/A

CONCLUSION: RELEASE
 ON-HOLD

Inspected By : Ray
Name : Peering
Date : 10/09/2021

Approved By :
Name : Martin
Date : 10/09/2022

