

## SHOP PACKET - GEL TUBE

REF	BW42C900	ODR. QTY	48	RS: 3 + QC: 16	ISSUED DATE	08/09/2022
ITEM CODE	BW010009	PACK SIZE	12/Box	Ref. 8/9/22.	LOT NO	I20800
ITEM :	Bactiguard Woundcare, Gel 50g	CUSTOMER	Bactiguard AB	Dave	MFG. DATE	08/09/2022
		ORD. NO	1039		EXP DATE	2024-03

PROCESS	START QTY	OUTPUT	REJECT	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 01.40 pm						
DATE : 15-09-22						
TIME COMPLETE : 01.48 pm						
DATE : 15-09-22						
CHECK : pH / VISCOSITY / FAC	Refer attachment: PR-HR001 OC-HR003					
LABELLING GEL TUBE						
TIME START : 9.30 am						
DATE : 19-09-22						
TIME COMPLETE : 10.30 am						
DATE : 19-09-22						
GEL FILLING						
TIME START : 1.50 pm						
DATE : 19-09-22						
TIME COMPLETE : 2.40 pm						
DATE : 19-09-22						
SEALING AND CUTTING GEL TUBE						
TIME START : 1.50 pm						
DATE : 19-09-22						
TIME COMPLETE : 2.40 pm						
DATE : 19-09-22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 1:00 PM						
DATE : 19-09-22						
TIME COMPLETE : 1:15 PM						
DATE : 19-09-22						
BOX PACKING INSERT IFU & FINAL CONTROL						
TIME START : 3:00 PM						
DATE : 19-09-22						
TIME COMPLETE : 3:38 PM						
DATE : 19-09-22						
CARTON PACKING						
TIME START : 5.15 PM						
DATE : 19-09-22						
TIME COMPLETE : 5.20 PM						
DATE : 19-09-22						

QUANTITY PRODUCED

57

QUANTITY FOR QC / RETAIN SAMPLE

RS 3+6

SHIPMENT QUANTITY PCS / CTNS

48/1CTN

FINAL SHIPMENT DATE

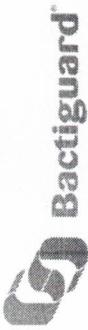
[ ]

COMPLETE/ PARTIAL

COMPLETE PARTIAL

Checked by (PR), Signature :	Released by (QC), Signature :	Approved by (QA), Signature :
Name : MURDO ARIF 02/09/2022	Name : MARTINI 02/09/2022	Name : ROBERT NGUYEN Designation : QMg Mgr Date: 29/09/2022
Remarks:		

BACTIGUARD (S.E.A) SDN BHD  
RELEASED BY CONTROL



## LABEL APPROVAL



SE Hydrogel för sårvård  
NO Hydrogé til sårpleie  
DK Hydrogel til sårpleje  
FIN Hydrogeeli haavanhoitoon

Bactiguard®  
(formerly known as VIGLENZ Medical Devices Sdn. Bhd.)  
308b, Jalan Perindustrian Bukit Mertajam 18,  
Penang Science Park, 14100 Penang, Malaysia.



**Bactiguard®**  
**WOUND CARE**  
**GEL**

**Bactiguard®**

50g

REF BW42C900

120800  
2024-03



**Bactiguard®**  
**WOUND CARE**  
**GEL**

**Bactiguard®**

50g

**Bactiguard Wound Care Gel**

REF	120800
LOT	120800
Qty	12 pcs / box
Weight	50 g / pc

REF	BW42C900
LOT	120800
Qty	12 pcs / box
Weight	50 g / pc

**Bactiguard®**  
DEA  
1919122  
②△\*

✓  
1919122

✓  
191910033



## JEL - RECORDS OF PREPARATION

Document Type:  
**FORM**

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 <b>BacGuard</b> <b>Model - RECORDS OF PREPARATION</b> <b>FORM</b>	Doc Id: <b>PR-HR001-05</b>  Document Type: <b>FORM</b>	Issue Date: <b>04/07/2022</b>  Page: <b>1(1)</b>
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Date : 15/09/22

	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

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Title: QC IN-PROCESS INSPECTION RECORD – GEL TUBE	 Bactiguard		

Reference / Lot No.	BW449900 / 100800
Order Qty.	48

#### 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)
61315090001	611	9.80	200	9136	/	pass
61315091102	613	9.80	200	9136	/	pass

## B. Tube Labelling

## IN-PROCESS INSPECTION RECORD – GEL TUBE

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### C. Filling Process

Sampling / Frequency	Weight of Sample					Test disposition (PASS / FAIL)	
	1	2	3	4	5		
5/5	51.96	52.43	52.00	52.01	51.92	52.09	pass
1/5	52.03	52.26	51.98	51.96	52.76	52.19	pass
3/5	51.95	52.25	52.43	52.08	52.19	52.17	pass
3/5	52.05	52.07	52.23	52.09	52.11	52.01	pass
4/5	52.01	52.16	52.46	52.04	52.17	52.17	pass
5/5	52.57	51.95	52.15	52.55	52.26	52.39	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)
1/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

Title: QC IN-PROCESS INSPECTION RECORD – GEL TUBE

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#### 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 IFU in the primary box	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 : Chaitu  
Name : DECA  
Date : 19/09/2022

Reviewed By : “E. Pass”  
Name : Naraini  
Date : 19/09/2022

## FINAL CONTROL TEST REPORT : GEL TUBE

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QC-FC006-04

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07/07/2022

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REF

BW42900

LOT NO

L20850

QTY PRODUCED (pcs)

48

RETAIN SAMPLE QTY (pcs)

2

No	Inspection Criteria	Sampling Details	Sample Size	AQL	Accept	Reject	Accept	Reject	Results	Status (PASS/FAIL)
1	Legible and correct printing of label.	S3,0.15	80	0	0	1	80	0	0	Pass
2	Availability of Hologram and Secure Sticker.	S3,0.15	80	0	0	1	80	0	0	Pass
3	Availability of IFU inside the inner box	S3,0.15	80	0	0	1	80	0	0	Pass
4	Free from contamination, deformed or damaged on packaging.	S3,0.15	80	0	0	1	80	0	0	Pass
5	Proper sealing and no leakage.	S3,0.15	80	0	0	1	80	0	0	Pass
6	Correct quantity in secondary box packaging.	S3,0.15	80	0	0	1	80	0	0	Pass

Remarks :

N/A

Inspected by : Dev  
 Name : DEVA  
 Date : 19/09/2022

Reviewed by : W.Martin  
 Name : Martin  
 Date : 19/09/2022

## RAW MATERIAL LOADING FORM (RMLF)

Rev.

DATE :	09/09/2022
REF :	BW42C900
LOT NO. :	120800

SHOP PACKET QTY (pes)	
CUSTOMER :	
LO NO. :	10/BAC005083/01
	48

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)		RECEIVED BY
								CONSUMPTION	CONSUMPTION	
1	P0100726	-	50g Tubes with D30 White Color Screw-on Cap	H05G220101	pes	57	57	57	57	M.Bastiau
2	P0100804	-	White Nozzle Cap (FOR 30, 50 & 100g GEL TUBE)	H12G211001	pes	114	114	114	114	M.Bastiau
3	C0100026	-	RHEOLOGICAL ADDITIVE (SUPBENT MP)	H080220301	gram	800	800	800	800	M.Bastiau
4	C0100048	-	Sodium Hypochlorite, 10% Available Chlorine	CO23220201	ml	200	200	200	200	M.Bastiau
5	C0100024	-	Pure Dry Vacuum Salt (2.5kg)	C021211101	gram	20	20	20	20	M.Bastiau
6	N/A	STOCK SOLUTION	N/A	G1815091201 G18150912201	ltr	20	20	20	20	M.Bastiau

(2) PRODUCT PACKAGING										
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)	RECEIVED BY	ITEM DESCRIPTION 1			Q'TY REQUIRED (pes)	RECEIVED BY
						NO.	SYSTEM CODE	ITEM DESCRIPTION 1		
1	P0100949	LBWC-011-NORD-R0 (50G); VIGILENZ0182; BWC NORDIC LABEL GEL TUBE(100 X 90 mm, IN ROLL; TRANSPARENT PE; 5C; EYEMARK	LN01220601	58	M.Bastiau	1	P0100661	Gel Carton - (L)38mm X (W)293mm X (H)305mm LR1.50/MLR1.50 (BC FLUTE)	H114220301	1 Jack
2	P0100848	"Secure-Secure" Round Sticker for Gel Tube (20mm)-Material: Breakable PVC, Printing: 1 colour (black) (30g-50g, 100g)	PN01220601	115	M.Bastiau	2	P0100767	POF Shrink Film CF. Size: 12mic x 12" x 1667m, - 1 rolls/carton, 5 Layer with perforation	P092210801	1 Jack
3	P0100806	LDPE ZIPPER BAG: Size: 0.05mm x 2" (opening) x 3" (L) - USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	58	M.Bastiau	3	_____	#N/A	_____	_____
4	P0100956	BBWC-004-NORD-R0; V09-BX029-40 BWC GEL INNER BOX 50G - (NORDIC)-310GSM 1 SIDE ART CARD, 62 X 31 X 141MM; 4C, GLOSS LAMINATION	BN04220601	58	M.Bastiau	(4) SPECIAL REQUIREMENT				
5	P0100788	V09-BX022-00 - Hydrocyt Gel 50g (outer box) - 300gsm 1 Side Art Card, 192 x 142.5 x 29mm	PH01210702	5	M.Bastiau	NO	SYSTEM CODE	ITEM DESCRIPTION 1	1. Q'TY NO.	Q'TY REQUIRED (pes)
6	P0100208	BLANK LABEL (Sharks Pad' Gauze/Gel) SIZE: 8.5mm X 65mm	L1190211201	5	M.Bastiau	1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	N/A	N/A
7	P0100951	IFU NORDIC BWC, VIGILENZ0184, With one fold finishing-110 X 110 mm, IN PCS, 60gsm SIMILI PAPER, 1C	PN02220601	5	M.Bastiau	2	_____	#N/A	_____	_____

ISSUED BY (MM):

Signature :   
Name : FARAH  
Date : 09/09/2022

VERIFIED BY (PR):

Signature :   
Name : FARAH  
Date : 22/09/2022

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

W/A

(Applicable for Gamma only)

AVAILABILITY OF RETAIN : YES / NO  
(Applicable for Gamma only)

RETURN DATE

SHIPMENT	<input checked="" type="checkbox"/>	TOTAL LOTS
	<input type="checkbox"/>	TOTAL CARTONS
	<input type="checkbox"/>	SAMPLING DETAILS

\*Please print addition sheet if required

Inspected by  
Name \_\_\_\_\_ Date \_\_\_\_\_

Name \_\_\_\_\_ Date \_\_\_\_\_

K-Nalini  
21/09/2022

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Title: PRODUCT RELEASE TEST REPORT - GEL TUBE

Document type:  
FORM

Doc Id:	QC-PC008-03	Issue Date: 04/07/2022

Description	Bactiguard second stage gel tube 50g	Reference No.	Bw42C900	Date of Inspection	20/9/22
Lot No.	120800	Sample Size	1 pc x 50g		

*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) FAC	(100 – 200 ppm)
						Instrument no.: 8C-78	Instrument no.: 420024

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) FAC	(100 – 200 ppm)	Test Disposition
/	/	/	/	/	/	Instrument no.: 8C-78	Instrument no.: 420024	PASS / FAIL
/	/	/	/	/	/	Calibration due date: 10/10/2022	Expiry date: 10-2024	

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) FAC	(100 – 200 ppm)	Test Disposition
/	/	/	/	/	/	Instrument no.: 8C-78	Instrument no.: 420024	PASS / FAIL
/	/	/	/	/	/	Calibration due date: 10/10/2022	Expiry date: 10-2024	

/ = Pass, X = Fail

Remarks : **N/A**

CONCLUSIONS:  RELEASE  ON-HOLD

Inspected By : *Devu*  
Name : *Deva*  
Date : *20/9/2022*



Approved By : *B. Arora*  
Name : *B. Arora*  
Date : *20/9/2022*