

SHOP PACKET - GEL TUBE

REF	: HW4CB900	ODR. QTY	: 60	RS: 3 + QC: 6	ISSUED DATE	: 12/09/2022
ITEM CODE	: H0100036	PACK SIZE	: 6/Box	LOT NO	: I21205	<i>Afia</i>
ITEM :	: Hydrocyn Aqua Wound Gel Tube, 100g	CUSTOMER	: VMD	MFG. DATE	: 12/09/2022	<i>Jah</i>
		ORD. NO	: I072	EXP DATE	: 2024-03	

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION				IRMA		
TIME START : DATE : TIME COMPLETE : DATE : CHECK : pH / VISCOSITY / FAC	3.50 12-09-22 3.58 12-09-22 Refer attachment: PR-HR001 QC-HR003	69	69	NIL	Hana 12/09/2022	2/2
LABELLING GEL TUBE				Yati 1157	Hana 13/09/2022	5/5
TIME START : DATE : TIME COMPLETE : DATE :	10:55 am 13-09-22 11:36 am 13-09-22	69	69	NIL	Hana 13/09/2022	5/5
GEL FILLING				Yati (1157)	Hana 13/09/2022	5/5
TIME START : DATE : TIME COMPLETE : DATE :	5.08 AM 13-09-22 5:35 PM 13-09-22	69	69	NIL	Yati(1157) Hana 13/09/2022	5/5
SEALING AND CUTTING GEL TUBE						
TIME START : DATE : TIME COMPLETE : DATE :	5.08 PM 13-09-22 5:35 PM 13-09-22	69	69	NIL	Yati(1157) Hana 13/09/2022	5/5
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : DATE : TIME COMPLETE : DATE :	11:14 am 14-09-22 11:30 am 14-09-22	63	63	NIL	Liana 14/09/2022	5/5
BOX PACKING INSERT IFU & FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	9:40 am 20-09-22 9:55 am 20-09-22	63	63	NIL	Puring (1235) Hana 20/09/2022	Refer: FCTR
CARTON PACKING						
TIME START : DATE : TIME COMPLETE : DATE :	2.40 P.M 20-09-22 2.55 P.M 20-09-22	10 BOX 2CTN	10 BOX 2CTN	NIL	Robin (1088) HIRATH 20/09/2022	<i>sunf</i> 20/09/22

QUANTITY PRODUCED

69

QUANTITY FOR QC / RETAIN SAMPLE

3+6

SHIPMENT QUANTITY PCS / CTNS

60 / 10 BOX
0 CTN

FINAL SHIPMENT DATE

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COMPLETE/ PARTIAL

COMPLETE PARTIAL

Checked by (PR), Signature : <i>Jah</i> Name : Muths AAF 22/09/2022	Released by (QC), Signature : <i>Muanim</i> Name : Shaamim 22/09/2022	Approved by (QA), Signature : <i>Firman</i> Name : Robaniza Firman Designation : Quality Manager Date: 22/09/2022
Remarks:		


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



LABEL APPROVAL

HYDROCYN

aqua

Soothing & Bacterio
For External Use

HYDROCYN

wound
gel



Soothing & Bacteriostatic effects
For External Use Only

CE 2292 100g

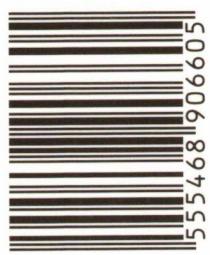


VIGILENZ®

INGREDIENTS
Purified Water, Sodium
(0.05%), Lithium Methyl
Silicate and Sodium Chloride

Direction for use:
Ensure wound is clean
onto the affected area.
For single use only.

VIGILENZ Medical Devices Sdn. Bhd.
308 b, Jalan Perindustrian Bukit Minyak 18
Penang Science Park, 14100 Penang, Malaysia.
www.vigilenzmd.com / www.bactiguard.com



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LBB-020

Bactiguard

✓ 10/01/2022
11/01/2022

Manufactured by:
VIGILENZ Medical Devices Sdn. Bhd.
[a subsidiary of Bactiguard]
308 b, Jalan Perindustrian Bukit Minyak, 18,
Penang Science Park, 14100 Penang, Malaysia.
www.vigilenzmd.com / www.bactiguard.com

MDA-GC9700420-45397
HGBL-004-R1

REF: 121205
LOT: 2024-03
REF: HW4CB900

⊗ △ ☀ ☀

HW4CB900
121205
6 pcs / box
Weight ✓ 100 g / pc
VIGILENZ®
MALAYSIA

HW4CB900
121205
6 pcs / box
Weight ✓ 100 g / pc
VIGILENZ®
MALAYSIA

Boyle
13/01/2022

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CHILDS RECORDS OF PREPARATION

Document Type FORM

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Doc Id:	PR-IHR001-05	Issue Date:	04/07/2022	Page:
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Title GHL - RECORDS OF PREPARATION		Bacitguard	Page: 1(1)
Document Type: FORM	Doc Id: PR-HR001-05	Issue Date: 04/07/2022	

Date

wsc/bq/c1

Title: QC IN-PROCESS INSPECTION RECORD – GEL TUBE		 Bactiguard	Issue Date: 07/07/2022	Page: 1(3)
Document type: FORM	Doc Id: QC-IP004-02			

Reference / Lot No.	Hw4CB900 / 120205 T21205
Order Qty.	60

A. Before Filling

B. Tube Labelling

Sampling / Frequency	Printed label is clear and legible	Reference no. corresponds to Shop Packet and approved artwork	Correct positioning of labelling	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	Pass
1/5	✓	✓	✓	Pass
2/5	✓	✓	✓	Pass
3/5	✓	✓	✓	Pass
4/5	✓	✓	✓	Pass
5/5	✓	✓	✓	Pass

QC IN-PROCESS INSPECTION RECORD – GEL TUBE

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QC-IP004-02

	Bactiguard
Issue Date: 07/07/2022	Page: 2(3)

C. Filling Process

Sampling / Frequency	Weight of Sample					Leak Test	Test disposition (PASS / FAIL)
	1	2	3	4	5	Average	
1/5	103.51	103.21	103.35	104.66	103.54	103.65	Pass
1/5	103.45	103.12	103.80	103.89	103.99	102.92	Pass
2/5	103.69	103.52	103.95	103.14	103.81	103.42	Pass
3/5	103.57	103.72	103.33	103.37	103.09	103.39	Pass
4/5	103.12	103.98	103.45	103.01	103.18	103.14	Pass
5/5	103.76	102.97	103.10	102.89	103.09	103.14	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	Specification: (15g : 4-6mm) (30g/ 50g/ 100g : 6-8mm)	Leak Test	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	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 : Noel Fahana
Name : Noel Fahana
Date : 20/09/2022

Reviewed By : martin
Name : martin
Date : 20/09/2022

FINAL CONTROL TEST REPORT : GEL TUBE

Document Type: FORM	Doc Id: QC-FC006-04	Issue Date: 07/07/2022	Page: 1(1)
REF HW4L3900	QTY PRODUCED (pcs) 121205	RETAIN SAMPLE QTY (pcs) 3	

No	Inspection Criteria	Sampling Details	Sample Size	AQL			Results	Status (PASS/FAIL)
				Accept	Reject	Accept		
1	Legible and correct printing of label.	S3,0,15	69	0	1	69	0	Pass
2	Availability of Hologram and Secure Sticker.	S3,0,15	69	0	1	69	0	Pass
3	Availability of IFU inside the inner box	S3,0,15	69	0	1	69	0	Pass
4	Free from contamination, deformed or damaged on packaging.	S3,0,15	69	0	1	69	0	Pass
5	Proper sealing and no leakage.	S3,0,15	69	0	1	69	0	Pass
6	Correct quantity in secondary box packaging.	S3,0,15	69	0	1	69	0	Pass

Remarks : **N/A**

Inspected by : **Nur Farhana**
 Name : **Nur Farhana**
 Date : **20/09/2022**

Reviewed by : **Leopoldo Martin**
 Name : **Leopoldo Martin**
 Date : **20/09/2022**

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

DATE :	12/09/2022
REF :	HW4CB900
LOT NO. :	121205

SHOP PACKET QTY (pes) : 60
 CUSTOMER : VMD (MALAYSIA)
 I.O NO. : 10\VM\060922\01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		RECEIVED BY
							ISSUED	CONSUMPTION	
1	P0100727	100g Tubes with D40 White Color Screw-on Cap	Diameter 40 x 135 mm, White Colour Tube + neck, 5mm Tube Orifice with Aluminium Foil Seal, Open End	H11G210701	pcs	69	69	69	<i>✓</i>
2	P0100804	White Nozzle Cap (FOR 30, 50 & 100g GEL TUBE)		H12G210701	pcs	138	138	138	<i>✓</i>
3	C0100026	RHEOLOGICAL ADDITIVE (SUBBENT MP)		H080210801	gm	800	800	800	<i>✓</i>
4	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	200	<i>✓</i>
5	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	20	<i>✓</i>
6	N/A	STOCK SOLUTION	N/A	GB12092202	ltr	20	20	20	<i>✓</i>

(3) OVER WRAPPING AND CARTON PACK

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
							NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100770	LBH-020-R0 Tube Label 00g - 110mm x 125mm; Gloss Clear PE; Permanent; 1 Colors; Roll	LH02210701/1	70	<i>✓</i>	1	P0100661	Gel Carton - (L)388mm X (W)293mm X (H)305mm LR150/MLR150 (BC FLUTE)	H114210401	<i>✓</i>	2	JACK
2	P0100848	"Secure-Secure" Round Sticker for Gel Tube (20mm);Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22220101	139	<i>✓</i>	2	P0100767	POF Shrink Film CF; Size: 12mic x 12" x 1667m; - 1 rolls/carton, 5 Layer with perforation	P092210801		3	<i>✓</i>
3	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L02022301	70	<i>✓</i>			#N/A				
4	P0100806	LDPE ZIPPER BAG; Size: 0.05mm x 2" (opening) x 3" (L) - USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	70	<i>✓</i>							
5	P0100789	HGBL-004-R1-Hydrocy Gel 100g (inner box) (ENGLISH) - 300gsm 1 Side Art Card; 166 x 77 x 39mm; 4 colors	PHEN2220101	70	<i>✓</i>	1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	N/A	<i>✓</i>	2	<i>✓</i>
6	P0100790	V09-BX024-00 - Hydrocy Gel 100g (outer box) - 300gsm 1 Side Art Card; 237 x 84 x 168mm	PH02210701	6	<i>✓</i>							
7	P0100208	BLANK LABEL (Shraps Pad/ Gauze/ Gel) SIZE: 8.5mm X 65mm	L190210502	6	<i>✓</i>							

(2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
							NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100770	LBH-020-R0 Tube Label 00g - 110mm x 125mm; Gloss Clear PE; Permanent; 1 Colors; Roll	LH02210701/1	70	<i>✓</i>	1	P0100661	Gel Carton - (L)388mm X (W)293mm X (H)305mm LR150/MLR150 (BC FLUTE)	H114210401	<i>✓</i>	2	JACK
2	P0100848	"Secure-Secure" Round Sticker for Gel Tube (20mm);Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22220101	139	<i>✓</i>	2	P0100767	POF Shrink Film CF; Size: 12mic x 12" x 1667m; - 1 rolls/carton, 5 Layer with perforation	P092210801		3	<i>✓</i>
3	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L02022301	70	<i>✓</i>			#N/A				
4	P0100806	LDPE ZIPPER BAG; Size: 0.05mm x 2" (opening) x 3" (L) - USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	70	<i>✓</i>							
5	P0100789	HGBL-004-R1-Hydrocy Gel 100g (inner box) (ENGLISH) - 300gsm 1 Side Art Card; 166 x 77 x 39mm; 4 colors	PHEN2220101	70	<i>✓</i>	1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	N/A	<i>✓</i>	2	<i>✓</i>
6	P0100790	V09-BX024-00 - Hydrocy Gel 100g (outer box) - 300gsm 1 Side Art Card; 237 x 84 x 168mm	PH02210701	6	<i>✓</i>							
7	P0100208	BLANK LABEL (Shraps Pad/ Gauze/ Gel) SIZE: 8.5mm X 65mm	L190210502	6	<i>✓</i>							

ISSUED BY (MM): *LOVIN*
 Signature: *LOVIN*
 Name: *LOVIN*
 Date: 12/09/2022

VERIFIED BY (PR):
 Signature: *Marys APW*
 Name: *Marys APW*
 Date: 22/09/2022

Title:
PRODUCT RELEASE TEST REPORT – GEL TUBE

Document type:
FORM

Doc Id:
QC-PC008-03

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04/07/2022

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		 Bactiguard	
Description	Hydrocyn Aug gel (10g)	Reference No.	Hu4C8900

Description	Hydrocyn Aug gel (10g)	Reference No.	Hu4C8900	Date of Inspection	22/09/2022
Lot No.	J21205	Sample Size	1 pcs x 10g		

Release Criteria:

Packing Integrity		Visual Inspection		Chemical Testing		Test Disposition
Correct and legible printing of label	Proper sealing	Free from contamination/ deformed/ damaged	No leakage	Free from contamination / particles / foreign matters	pH (9.00 – 10.50) FAC (100 – 200 ppm)	FAC (100 – 200 ppm)
	Ability to dispense			Instrument no.: 480024	Instrument no.: 480024	PASS / FAIL
				Calibration due date: 10/10/2024	Expiry date: 10-2024	

✓ = Pass, X = Fail

Remarks : N/A

CONCLUSIONS: RELEASE ON-HOLD

Inspected By : Norashana
 Name : Norashana
 Date : 22/09/2022

Approved By : Martin
 Name : Martin
 Date : 22/09/2022



BACTIGUARD (S.E.A) SDN BHD
 Quality Assurance Department
 APPROVED
 Martin
 22/09/2022