

PROCESS				START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION									
TIME START:	3:07 pm								
DATE:	16-02-22								
TIME COMPLETE:	3:15 pm								
DATE:	16-02-22								
CHECK: pH / VISCOSITY / FAC	Refer attachment: PR-HR001 QC-HR003								
LABELLING GEL TUBE									
TIME START:	10:00 am								
DATE:	16-02-22								
TIME COMPLETE:	4:00 pm								
DATE:	16-02-22								
GEL FILLING									
TIME START:	11:15 am								
DATE:	17-02-22								
TIME COMPLETE:	4:50 pm								
DATE:	17-02-22								
SEALING AND CUTTING GEL TUBE									
TIME START:	11:15 am								
DATE:	17-02-22								
TIME COMPLETE:	4:50 pm								
DATE:	17-02-22								
LOT NUMBER AND EXPIRY DATE PRINTING									
TIME START:	10:40 am								
DATE:	21-02-22								
TIME COMPLETE:	11:30 am								
DATE:	21-02-22								
BOX PACKING & FINAL CONTROL									
TIME START:	5:00								
DATE:	19-02-22								
TIME COMPLETE:	3:55 pm								
DATE:	21-02-22								
CARTON PACKING									
TIME START:	9:30 am								
DATE:	23-02-22								
TIME COMPLETE:	9:40 am								
DATE:	23-02-22								

QUANTITY PRODUCED	910 pcs
QUANTITY FOR QC/RETAIN SAMPLE	25377 pcs
SHIPMENT QUANTITY PCS	900 pcs
/ CTNS :	45 box / ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR): _____

Signature : [Signature]

Name : Pranav Sharma

Date : 24/2/20

Approved by (QC),

Signature _____

Name _____

Date _____

Approved by (QC),

Signature _____

Name _____

Date _____

Approved by (QC),

Signature _____

Name _____

Date _____

LABEL APPROVAL

HYDROCYN[®] | aqua

15g

Soothing & Bacteriostatic effects

For External Use Only

CE 2292

INGREDIENTS

Water, Sodium Hypochlorite (0.05%), Methylparaben, Sodium Silicate and Sodium Chloride.

Direction for use:

Ensure wound is cleaned first. Apply the gel directly to the wound area during each change of wound dressing. For single use only.

Bactiguard

MDA-GC9700420-45397



9 555468 912422

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

LOT: B21419
EXP: 2023-08

HW40F900

HYDROCYN[®] | aqua

Soothing & Bacteriostatic effects

CE 2292

15g

Bactiguard VIGILENZ[®]

HGBL-001-R3
MDA-GC9700420-45397

Hydrocyn aqua[®] gel

[REF] HW40F900

[LOT] B21419

Qty 20 pcs / box

Weight 15g / pc

VIGILENZ[®]
MALAYSIA

Not in
21/2/22

21/2/22

21/2/22

21/2/22

error/20/91

	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]

Title:

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL

Document type:
FORM

Doc Id:

QC-IP004-01

Issue Date:

15/11/2021

Page:

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Reference / Lot No.

Hwy0Fg00 / B21414

Order Qty.

900

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)
B1B16022211	G11	9.82	comply	9917	✓	pass
B1B16022212	G12	9.82	comply	9917	✓	pass
			N/A			

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	✓			
4/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass


Bactiguard	
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C. Filling Process

Sampling / Frequency	Weight of Sample						Leak Test	Test disposition (PASS / FAIL)
	Specification: 15g (16.5 – 17.8g) / 30g (31.6 – 33.3g) / 50g (51.9 – 53.4g) / 100g (102.8 – 104.7g)							
	1	2	3	4	5	Average		
5/5	17.45 g	17.06 g	17.52 g	17.38 g	17.43 g	17.37 g	✓	pass
1/5	17.64 g	17.74 g	17.58 g	16.79 g	17.49 g	17.45 g	✓	pass
2/5	17.76 g	17.17 g	17.07 g	17.46 g	16.79 g	17.25 g	✓	pass
3/5	16.76 g	16.79 g	17.01 g	17.76 g	16.86 g	17.04 g	✓	pass
4/5	16.98 g	16.75 g	16.72 g	17.16 g	17.39 g	17.00 g	✓	pass
5/5	17.21 g	17.36 g	17.28 g	17.25 g	17.28 g	17.27 g	✓	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)
5/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

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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 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 / **FAH**)

Inspected By : Poly
 Name : POSHINE
 Date : 21/02/2020

VIGILENZ®	FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL		Doc. No.	QC-FC006
			Rev.	03

REF : Hw40E900 QTY PRODUCED (pcs) : 903

LOT NO : B21419 RETAIN SAMPLE QTY (pcs) : 3

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	pass
2	Availability of Hologram and Secure Sticker.	S3,0.15	80	0	1	80	0	pass
3	Free from contamination, deformed or damaged on packaging.	S3,0.15	80	0	1	80	0	pass
4	Proper sealing and no leakage.	S3,0.15	80	0	1	80	0	pass
5	Correct quantity in secondary box packaging.	S3,0.15	80	0	1	80	0	pass

Remarks : N/D

Inspected By : Peggy
 Name : ROSENE
 Date : 21/02/2022

Approved By : [Signature]
 Name : AARTINI
 Date : 21/02/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.

PR-RM001

Rev.

06

16/02/2022

16/02/2022

HW40F900

VMD (MALAYSIA)

B21419

IOVMD/110222/01

SHOP PACKET QTY (pcs)

900

CUSTOMER

VMD (MALAYSIA)

LO NO.

IOVMD/110222/01

UOM

RS

10

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100225	15ml Long Nozzle Tube with white color screw on cap	Diameter 22 x 80mm, White Colour Tube with Long Nozzle(5 layers), Open End, Glass Finishing	H022210902	pcs	910	910	1 Canjana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gm	800	800	1 Canjana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Canjana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	1 Canjana
5	N/A	STOCK SOLUTION	N/A	GB16022211 GB16022212	ltr	20	20	1 Canjana

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100397	LBH-006-R4 - Hydrocyn Tube Label, Size: 65mm x 62mm, Material: Transparent PE	L220211202	911	Canjana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	Canjana
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23220101	1821	Canjana

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LR150M/LR150 (BC FLUTE)	H114211101	4	medull
2		#N/A			
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			
2				#N/A							

4	P0100399	BX002, Inner Tube Box for Hydrocort Gel - Size: 30mm(L) x 25mm(W) x 116mm(H), Material 310gsm 1 Side Coated Art Card (4 colors), Rev. 3	H076210801	911	1	Campano
5	P0100318 JF 21/2/22	Outer Tube Box for Hydrocort Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back - H08L-001-R3	H077210801	45	1	Campano
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1	Campano
7		#N/A				

ISSUED BY (MM) :

Signature :

LOVIN

Name :

LOVIN

Date :

16/02/2022

VERIFIED BY (PR) :

Signature :

KARIMASRI CHARM

Name :

KARIMASRI CHARM

Date :

24/2/22

VIGILENZ [®]	PRODUCT RELEASE TEST REPORT – HYDROCYN aqua [®] GEL		Doc No.	QC-PC008
			Rev.	02

Description	Hydrocyn Aqua wound Gel Tube (15g)	Reference No.	HW40F900	Date of Inspection	21 2 22
		Lot No.	B21419	Sample Size	2 pcs x 15g

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)
✓	✓	✓	✓	✓	✓	9.30	comply
							pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : sander
 Name : sander moe
 Date : 21 | 2 | 22

Approved By : [Signature]
 Name : A. K. T. N. I.
 Date : 22 | 2 | 2022

