

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	QTY :	940	RS 3 + 7 (QC TEST)	ISSUED DATE	15-Jan-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX		LOT NO	A21517
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	15-Jan-22
		ORD. NO	A113		EXP DATE:	2023-01

PROCESS		START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IQC APPROVAL	RESULTS
HYDROGEN AQUA GEL PREPARATION							
TIME START :	5:50pm						
DATE :	19-01-22						
TIME COMPLETE :	5:58pm						
DATE :	19-01-22						
CHECK: pH / VISCOSITY / FAC							
Refer attachment: PR-HR001 QC-HR003							
LABELLING GEL TUBE							
TIME START :	2:00 pm						
DATE :	22-01-22						
TIME COMPLETE :	5:45 pm						
DATE :	22-01-22						
GEL FILLING							
TIME START :	11:00 am						
DATE :	24-01-22						
TIME COMPLETE :	4:30 pm						
DATE :	24-01-22						
SEALING AND CUTTING GEL TUBE							
TIME START :	11:00 am						
DATE :	24-01-22						
TIME COMPLETE :	4:30 pm						
DATE :	24-01-22						
LOT NUMBER AND EXPIRY DATE PRINTING							
TIME START :	3:00 pm						
DATE :	24-01-22						
TIME COMPLETE :	4:30 pm						
DATE :	24-01-22						
BOX PACKING & FINAL CONTROL							
TIME START :	4:30 pm						
DATE :	24-01-22						
TIME COMPLETE :	8:55 pm						
DATE :	24-01-22						
CARTON PACKING							
TIME START :	5:15 pm						
DATE :	25-01-22						
TIME COMPLETE :	5:30 pm						
DATE :	25-01-22						

QUANTITY PRODUCED	916 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3 + 7 pcs
SHIPMENT QUANTITY PCS	900 pcs
CTNS :	US box / 4 Ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

<p>Checked by (PR), Signature : <u>Not</u></p>	<p>Approved by (QC), Signature : <u>ASTINI</u></p>
<p>Name : <u>KATUNGE CARAN</u></p>	<p>Name : <u>ROHMANA OTMAN</u></p>
<p>Date : <u>26/1/22</u></p>	<p>Date : <u>27/1/22</u></p>

LABEL APPROVAL

HYDROCYN[®]
aqua
gel

15g

Soothing & Bacteriostatic effects
For External Use Only

CE 2292

INGREDIENTS

Distilled Water, Sodium Hypochlorite (0.05%), Sodium Chloride, Potassium 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.

MDA-GC9700420-45397

Bactiguard[®]

HYDROCYN[®]
aqua
gel

15g

Soothing & Bacteriostatic effects
For External Use Only

CE 2292

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

Bactiguard[®]

HYDROCYN[®]
aqua
gel

15g

Soothing & Bacteriostatic effects
For External Use Only

CE 2292

Hydrocyn[®] aqua gel

[REF]

HW40F900

[LOT]

A21517

Qty

20 pcs / box

Weight

15g / pc

VIGILENZ[®]

MALAYSIA

Page 2 of 2


Doc. No: PR-SP013

HYDROCYN aqua® GEL - RECORDS OF PREPARATION

19.10.2022

	Equipment ID	
	QC-56	HSM-01
Purified Water (L)	3.0 ± 3.1	800 ± 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		 Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 1(3)


Reference / Lot No.	H1640F900 / A21517
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)
G1B19012207	G17	9.06	comply	9954	✓	pass
G1B19012208	G18	9.06	comply	9954	✓	pass
			NA			

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


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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	17.62	17.65	17.16	17.10	17.17	17.34 g	✓	pass
1/5	17.38	17.35	17.27	17.33	16.94	17.25 g	✓	pass
2/5	17.26	17.18	17.17	17.10	17.28	17.19 g	✓	pass
3/5	16.92	17.30	16.90	17.07	17.08	17.05 g	✓	pass
4/5	17.19	17.08	17.14	17.15	17.03	17.12 g	✓	pass
5/5	17.14	17.19	16.62	17.21	17.13	17.06 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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Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 3(3)

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 / ~~FAIL~~)

Inspected By : Wah
 Name : Wah Wah
 Date : 25.01.22

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

REF : HW40F900 : QTY PRODUCED (pcs) : 910

LOT NO : A21517 : 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/A

Inspected By : Wach
 Name : Wach Wach
 Date : 25.01.2022

Approved By : M. J. J. J.
 Name : M. J. J. J.
 Date : 25/01/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

19/01/2022

HW40F900

A21517

SHOP PACKET QTY (pcs) : 900

CUSTOMER : VMD (MALAYSIA)

LO NO. : IOVMD/130122/01

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, Gloss Finishing	H022210902	pcs	910	910	Kanjana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gsm	800	800	Kanjana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	Kanjana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	Kanjana
5	N/A	STOCK SOLUTION	N/A	GB19012207 GB19012208	ltr	20	20	Kanjana

(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	L220211201	911	Kanjana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	Kanjana
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23210801/3	1821	Kanjana
4	P0100399	BX002, Inner Tube Box for Hydrocyn Gel - Size: 30mm(L) x 25mm(W) x 116mm(H), Material 310gsm 1 Side Coated Art Card (4 colors), Rev: 3	H076210801	911	Kanjana
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	Kanjana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	Kanjana
7		#N/A			

(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 LRI50M/LRI150 (BC FLUTE)	HI14210801/2	4	ndulu
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)		not	
2		#N/A			

ISSUED BY (MM) :

Signature :
Name : LOVIN
Date : 19/01/2022

VERIFIED BY (PR) :

Signature :
Name :
Date : 26/11/22

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

Description	Hydrocyn Aqua Wound Gel Tube (15g)	Reference No.	HW405900	Date of Inspection	25/01/2022
		Lot No.	A21517	Sample Size	2 pcs x 15g

Release Criteria:

Correct and legible printing of label	Packing Integrity			Visual Inspection	Chemical Testing		Test Disposition
	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)	PASS / FAIL
						9.10 comply	pass

✓ = Pass, X = Fail

Remarks: N/P

CONCLUSIONS: ☒ RELEASE
☐ ON-HOLD

Inspected By : Poh
Name : DOSHNI
Date : 25/01/2022

Approved By : [Signature]
Name : MARTINI
Date : 25/01/2022

