

1/3

# SHOP PACKET - HYDROCYN AQUA GEL

HW40F900	RS 3 + 7 (QC TEST)	14-Feb-22
CODE :	900	LOT NO B21431
Hydrocyn Aqua Wound Gel (15g)	20/BOX	MFG. DATE 14-Feb-22
	VMD	EXP DATE: 2023-08
	B092	

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IQC APPROVAL	RESULTS
OCYN AQUA GEL PREPARATION						
START : 7:33 pm	910	910	NIL	FARAH (1051)	Postini	2/5
COMPLETE : 7:41 pm						
START : 9:00 am	910	910	NIL	Era (932)	Wah	5/5
COMPLETE : 10:00 am						
START : 2:15 pm	910	910	NIL	FARAH (1051)	Wah 5:25 pm	5/5
COMPLETE : 5:35 pm					9/3/22	
START : 2:15 pm	910	905	5	SOFIA (1138)	Wah 5:25 pm	5/5
COMPLETE : 5:35 pm					9/3/22	
START : 2:50 pm	903	903	NIL	Era (932)	Wah 3:50 pm	5/5
COMPLETE : 3:50 pm				Lina Pom (1131)	9/3/22	
START : 5:22 pm	180+723	902	NIL	SOFIA (1138)	Wah 9:00 am	Refer FCTS
COMPLETE : 5:45 pm				Siti (1142)	10.03.2022	
START : 12:00 pm	45 box	45 box	4ctn	Fajar (1054)	Nurin	Pickup 885
COMPLETE : 12:10 pm					10/3/2022	
START : 12:10 pm	45 box	4ctn	4ctn			
COMPLETE : 12:10 pm						

Checked by (PR)	Signature : <i>[Signature]</i>	Approved by (QC)	Signature : <i>[Signature]</i>
Name : MUHAMMAD ARKUN	Name : KARTINI	Date : 12/3/22	Date : 12/3/2022



QUANTITY PRODUCED	910
QUANTITY FOR QC/RETAIN SAMPLE	3+7 pcs
QUANTITY FOR SHIPMENT	900
DATE OF SHIPMENT	15 Feb / 4 ctu
SHIPMENT DATE	
SHIPMENT PARTIAL	COMPLETE

**HYDROCYN** | *gel*  
aqua

15g

Soothing & Bacteriostatic effects  
For External Use Only

CE 2292

**INGREDIENTS**  
Purified Water, Sodium Hypochlorite (0.05%), Lithium Magnesium Sodium Silicate and Sodium Chloride.

**Direction for use:**  
Ensure wound is cleaned first. Apply the gel directly onto the affected area during each change of wound dressing. For single use only.

**Bactiguard**

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

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.vigilenznd.com / www.bactiguard.com

MDA- GC9700420-45387

HGBL-001-23

9 555468 912422

**HYDROCYN**  
aqua  
*gel*

WOUND

Soothing & Bacteriostatic effects  
For External Use Only

CE 2292 15g

**Bactiguard** VIGILENZ

MDA : B21431  
G : 2023-08

MDA- GC9700420-45387

321 331 03/23

✓ 200g 01/3/2023

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**Hydrocyn aqua<sup>®</sup> gel**

Y4M/ 2/3/22

REE HW40F900

LOT B21431

Qty 20 pcs / box

Weight 15g / pc


**VIGILENZ<sup>®</sup>**  
MALAYSIA

Y4M/ 2/3/22

2/3/22





Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 1(3)

Reference / Lot No.	HW40F900 / B21431
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)
61807032203	613	9.51	comply	9826	✓	pass
61807032204	614	9.51	comply	9826	✓	pass

#### 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

<b>QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL</b>	<b>Issue Date:</b> 15/11/2021
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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	17.02 g	17.32 g	17.43 g	17.31 g	17.33 g	17.28 g	✓	pass
1/5	17.30 g	17.09 g	17.14 g	16.98 g	17.25 g	17.15 g	✓	pass
2/5	17.02 g	17.11 g	17.22 g	17.34 g	17.02 g	17.14 g	✓	pass
3/5	17.33 g	17.08 g	17.20 g	16.83 g	17.42 g	17.17 g	✓	pass
4/5	16.91 g	17.28 g	17.02 g	17.23 g	17.28 g	17.14 g	✓	pass
5/5	17.21 g	17.37 g	17.39 g	17.40 g	17.13 g	17.03 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 / FAIL)

Inspected By : Lexch  
 Name : Lexch  
 Date : 10-03-2022

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

REF : Hw40F900 QTY PRODUCED (pcs) : 910

LOT NO : B21431 RETAIN SAMPLE QTY (pcs) : 3

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

Remarks : N/A

Inspected By :	<u>Cuch Cuch</u>	Approved By :	<u>[Signature]</u>
Name :	<u>Cuch Cuch</u>	Name :	<u>MARTIN</u>
Date :	<u>10.03.2022</u>	Date :	<u>10/3/2022</u>



# RAW MATERIAL LOADING FORM (RMLF)

16/02/2022
HW40F900
B21431

Doc. No.	PR-RM001
Rev.	06

SHOP PACKET QTY (pcs) :

900

RS 10

CUSTOMER :

VMD (MALAYSIA)

LO NO. :

IO/VMD/110222/01

SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
					REQUIRED	ISSUED	
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	Kayana
C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gsm	800	800	Kayana
C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	Kayana
C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	Kayana
N/A	STOCK SOLUTION	N/A	G1801022203 G1801032204	ltr	20	20	Kayana

## PRODUCT PACKAGING

ITEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
P0100397	LBH-006-R4 - Hydrocyn Tube Label, Size: 65mm x 62mm, Material: Transparent PE	L220211202	911	Kayana
P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	Kayana
P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23220202	1821	Kayana
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	Kayana
P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	Kayana
P0100208	BLANK LABEL (Sharpe Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	Kayana
	#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 LR150M/LR150 (BC FLUTE)	H114211101	4	malu
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			

(MM) :

LOVIN  
16/02/2022

VERIFIED BY (PR) :

Signature :

Name :

Date :

malu  
12/5/22



**VIGILENZ®****PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL**

Doc No. QC-PC008

Rev. 02

Description	Hydrocyn Aqua Wound Gel Tube (15g)	Reference No.	HWC40F900	Date of Inspection	10/03/2022
		Lot No.	B21431	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)	
✓	✓	✓	✓	✓	✓	9.77	PASS / FAIL
						comply	pass

✓ = Pass, X = Fail

Remarks: n/p

CONCLUSIONS: ☒ RELEASE☐ ON-HOLDInspected By : PonyName : ROSINEDate : 10/03/2022Approved By : [Signature]Name : MARTINIDate : 10/03/2022