

25/1

# SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	949	RS 3+7 (QC TEST)	15-Jan-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX	LOT NO	A21518
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	15-Jan-22
		ORD. NO	A114	EXP. DATE:	2040-01

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
<b>HYDROCYN AQUA GEL PREPARATION</b>						
TIME START :	910	910				
DATE :						
TIME COMPLETE :						
DATE :						
CHECK : pH / VISCOSITY / FAC Refer attachment: PR-HR001 QC-HR003						
<b>LABELLING GEL TUBE</b>						
TIME START :	910	910				
DATE :						
TIME COMPLETE :						
DATE :						
<b>GEL FILLING</b>						
TIME START :	910	910				
DATE :						
TIME COMPLETE :						
DATE :						
<b>SEALING AND CUTTING GEL TUBE</b>						
TIME START :	910	910				
DATE :						
TIME COMPLETE :						
DATE :						
<b>LOT NUMBER AND EXPIRY DATE PRINTING</b>						
TIME START :	903	903				
DATE :						
TIME COMPLETE :						
DATE :						
<b>BOX PACKING &amp; FINAL CONTROL</b>						
TIME START :	903	903				
DATE :						
TIME COMPLETE :						
DATE :						
<b>CARTON PACKING</b>						
TIME START :	45 box 40tn	45 box 40tn				
DATE :						
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED	910 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3 B357 7 pcs
SHIPMENT QUANTITY PCS / CTNS :	900 pcs / 45 box / 40tn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR),	Signature :	Approved by (QC),	Signature :
Name :	Name :	Name :	Name :
Date :	Date :	Date :	Date :

LABEL APPROVAL

**HYDROCYN<sup>®</sup> | 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:**  
The affected area should be cleaned first. Apply the gel directly onto the affected area during each change of wound dressing. For single use only.

**Bactiguard<sup>®</sup>**

VIGILENZ Medical Devices Sdn. Bhd.  
Penang Science Park, 14100 Penang, Malaysia  
www.vigilenz.com / www.bactiguard.com

MDA- GC9700420-45397

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**aqua**  
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MDA- GC9700420-45397

**Hydrocyn aqua<sup>®</sup> gel**

**[REF]** HW40F900 *Not Recd 25/1/22*  
**[LOT]** A21518 *25/1/22*  
**Qty** 20 pcs / box *25/1/22*  
**Weight** 15g / pc *25/1/22*

**VIGILENZ<sup>®</sup>**  
MALAYSIA



VIGILENZ<sup>®</sup>

## HYDROCYN aqua® GEL - RECORDS OF PREPARATION

Doc. No.

PR-HR001


Rev.	04
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Date \_\_\_\_\_

24/01/22

	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

[illegible]

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.	HW405900 / A21518
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)
G1B24012201	G1	9.33	comply	9659	✓	pass
G1B24012202	G2	9.33	comply	9659	✓	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

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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	16.82 g	17.07 g	16.77 g	16.87 g	17.43 g	16.99 g	✓	pass
1/5	17.51 g	17.60 g	17.61 g	17.52 g	17.65 g	17.58 g	✓	pass
2/5	17.71 g	17.60 g	17.48 g	17.66 g	17.55 g	17.06 g	✓	pass
3/5	17.15 g	16.71 g	16.52 g	16.72 g	17.04 g	16.82 g	✓	pass
4/5	16.98 g	16.89 g	17.22 g	17.40 g	17.02 g	17.10 g	✓	pass
5/5	17.10 g	17.08 g	17.07 g	16.86 g	17.22 g	17.08 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 : P. Raji  
 Name : P. RAJAN  
 Date : 26/11/2022

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

REF : HW40F900 QTY PRODUCED (pcs) : 910

LOT NO : A21518 RETAIN SAMPLE QTY (pcs) : 3 pcs

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 : Raj  
 Name : ROHINI  
 Date : 26/01/2022

Approved By : [Signature]  
 Name : A. K. RTINI  
 Date : 27/01/2022



# RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001  
Rev. 06

19/01/2022	SHOP PACKET QTY (pcs) : 900	RS	10
HW40F900	CUSTOMER : VMD (MALAYSIA)		
A21518	LO NO. : IO/VMD/130122/01		

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(2 layers), Open End, Gloss Finishing	H022210902	pcs	910	910	1. <i>Kanjana</i>
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gms	800	800	1. <i>Kanjana</i>
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1. <i>Kanjana</i>
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gms	20	20	1. <i>Kanjana</i>
5	N/A	STOCK SOLUTION	N/A	64824012201 64824012202	ltr	20	20	1. <i>Kanjana</i>

## (2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100397	LBH-006-R4 - Hydrocort Tube Label, Size: 65mm x 62mm, Material: Transparent PE	L202011202	911	1. <i>Kanjana</i>
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	1. <i>Kanjana</i>
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	1. <i>Kanjana</i>
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. <i>Kanjana</i>
5	P0100318	Outer Tube Box for Hydrocort Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	1. <i>Kanjana</i>
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1. <i>Kanjana</i>
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-QJ388mm X (W)293mm X (H)305mm LRI150/M/LRI150 (BC FLUTE)	H114210801/2	4	1. <i>Melish</i>
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			

ISSUED BY (MM) :

Signature : *[Signature]*  
Name : LOVIN  
Date : 19/01/2022

VERIFIED BY (PR) :

Signature : *[Signature]*  
Name : RA-TUISSECEM  
Date : 27/1/22



VIGILENZ <sup>®</sup>	PRODUCT RELEASE TEST REPORT – HYDROCYN aqua <sup>®</sup> GEL		Doc No.	QC-PC008
			Rev.	02

Description	Hydrocyn Aqua, wound Gel (15g)	Reference No.	H4407900	Date of Inspection	27/01/2022
		Lot No.	A21518	Sample Size	2p15 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) 9.10 FAC (100 – 200 ppm) copy	PASS / FAIL pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : P. Raj  
 Name : POSHNE  
 Date : 27/01/2022

Approved By : [Signature]  
 Name : N. A. V. T. N. S.  
 Date : 27/01/2022

