

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ISSUED DATE	14-Feb-22
ITEM CODE :	H0100016	LOT NO	B21423
ITEM :	Hydrocyn Aqua Wound Gel (15g)	MFG. DATE	14-Feb-22
		EXP DATE:	2023-08

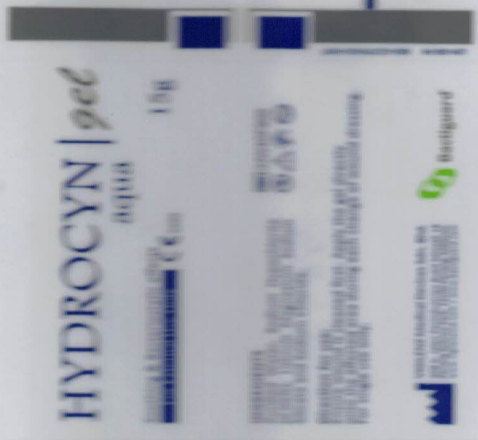
PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
<b>HYDROCYN AQUA GEL PREPARATION</b>						
TIME START :	910 +60	910 +60	NIL	MIRA	Wah	2/2
DATE :				(1118)	23/2/22	
TIME COMPLETE :						
DATE :						
CHECK : pH / VISCOSITY / FAC						
<b>LABELLING GEL TUBE</b>						
TIME START :	970	970	Nil	Vilki (1094)	Wah	5/5
DATE :					23/2/22	
TIME COMPLETE :						
DATE :						
<b>GEL FILLING</b>						
TIME START :	970	970	Nil	Daareny	Wah	5/5
DATE :				(1120)	25/2/22	
TIME COMPLETE :						
DATE :						
<b>SEALING AND CUTTING GEL TUBE</b>						
TIME START :	970	961	9	Era (932)	Roshmi	5/5
DATE :					23/2/22	
TIME COMPLETE :						
DATE :						
<b>LOT NUMBER AND EXPIRY DATE PRINTING</b>						
TIME START :	963	963	Nil	Viki (1094)	Roshmi	5/5
DATE :				Susi (1125)	10:30 pm	
TIME COMPLETE :					26/02/22	
DATE :						
<b>BOX PACKING &amp; FINAL CONTROL</b>						
TIME START :	963	963	Nil	Vilki (1094)	Roshmi	Peter FCTR
DATE :					10:30 pm	
TIME COMPLETE :					26/2/22	
DATE :						
<b>CARTON PACKING</b>						
TIME START :	48 box	48 box	48 box	Egadi	Janan	26/2/2022
DATE :				(1054)	26/02/2022	
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED	970 PCS
QUANTITY FOR QC/RETAIN SAMPLE	3PCS + 7PCS
SHIPMENT QUANTITY PCS	960 PCS
CTNS :	
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	PARTIAL

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

LABEL APPROVAL



Wah 2-22

Wah 2-22

<p>Wah 2-22</p>	
<p>MD</p>	


<p>Hydrocyn aqua gel</p>	
[REF]	HW40F900
[LOT]	B21423
Qty	20 pcs / box
Weight	15g / pc
<p>VIGILENZ<sup>®</sup> MALAYSIA</p>	



Doc. No.	PR-HR001
Rev.	04

	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		 Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 1(3)


Reference / Lot No.	Hw40F900 / B21423
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)
G1230222 13	G113	9.79	comply	9982	✓	pass
G1230222 14	G114	9.79	comply	9982	✓	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	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 2(3)


### 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	17.50 g	17.55 g	17.77 g	17.70 g	16.60 g	17.42 g	✓	pass
1/5	17.59 g	17.15 g	17.72 g	17.63 g	17.35 g	17.48 g	✓	pass
2/5	16.82 g	16.78 g	16.53 g	16.57 g	16.72 g	16.64 g	✓	pass
3/5	16.52 g	16.50 g	16.63 g	16.61 g	16.62 g	16.57 g	✓	pass
4/5	16.78 g	16.61 g	16.66 g	17.50 g	16.72 g	16.85 g	✓	pass
5/5	16.78 g	16.82 g	16.72 g	16.59 g	16.75 g	16.75 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



Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard	
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)
6/5	✓	✓	✓	✓	✓	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 : Peggy  
 Name : Post-HL  
 Date : 26/10/2021

VIGILENZ®

## FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

Doc. No.	QC-FC006
Rev.	03

REF

HW40F900

:

QTY PRODUCED (pcs)

910

:

LOT NO

B21423

:

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

Paj

Name

ROSHNI

Date

26/02/2023

Approved By

Raj

Name

RASHINI

Date

28/4/22



# RAW MATERIAL LOADING FORM (RMLF)

Doc. No.	PR-RM001
	Rev.

SHOP PACKET QTY (pcs)	900	RS	10
CUSTOMER	VMD (MALAYSIA)		
LO NO.	10VMD/11022201		

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 + 60	910 + 60	1. Ganjaya
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gsm	800	800	1. Ganjaya
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1. Ganjaya
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	1. Ganjaya
5	N/A	STOCK SOLUTION	N/A	G023022013 G023022014		20	20	1. Ganjaya

(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	wady
2		#N/A	Mk	1	medk
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)				Nk		—	
2			#N/A							

(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	L220211202	971	1. Ganjaya					
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	971	1. Ganjaya					
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23220101	1824	1. Ganjaya					
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	971	1. Ganjaya					
5	P0100318	Outer Tube Box for Hydrocort Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	48	1. Ganjaya					
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	48	1. Ganjaya					
7		#N/A								

ISSUED BY (MM)	Signature : 	VERIFIED BY (PR)	Signature : 
	Name : LOVIN		Name : LOVIN
	Date : 16/02/2022		Date : 26/02/2022



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

Description	Hydrocyn Aqua Wound Gel (15g)	Reference No.	HW4CFQ20	Date of Inspection	26/2/2022
		Lot No.	B2423	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 )
✓	✓	✓	✓	✓	✓	9.28	comply
							PASS / FAIL
							pass

✓ = Pass, X = Fail

Remarks: n/a

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Ray  
 Name : POONE  
 Date : 26/2/2022

Approved By : [Signature]  
 Name : MARTINI  
 Date : 26/2/2022

