

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	900	ISSUED DATE	14-Feb-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX	LOT NO	B21428
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD	MFG. DATE	14-Feb-22
		ORD. NO	B089	EXP. DATE	2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
<b>HYDROCYN AQUA GEL PREPARATION</b>						
TIME START : 1:20pm	910	910	NIL	DEWI (1126)	Poshni 1:28pm 26/02/22	2/3
DATE : 26-02-22						
TIME COMPLETE : 1:28pm						
DATE : 26-02-22						
CHECK : pH / VISCOSITY / FAC Refer attachment: PR-HR001 QC-HR003						
<b>LABELLING GEL TUBE</b>						
TIME START : 8:40 AM	910	910	NIL	Bashirini (1118)	Poshni 1:00pm 01/03/2022	4/5
DATE : 01-03-22						
TIME COMPLETE : 1:00 PM						
DATE : 01-03-22						
<b>GEL FILLING</b>						
TIME START : 12:00pm	910	910	NIL	ANA (1131)	Poshni 2:35pm 01/03/2022	4/5
DATE : 01-03-22						
TIME COMPLETE : 2:35pm						
DATE : 01-03-22						
<b>SEALING AND CUTTING GEL TUBE</b>						
TIME START : 12:00pm	910	908	2	FARAH (1051)	Poshni 2:45pm 01/03/2022	- 2 tube sealing reject replace with new Tube
DATE : 01-03-22						
TIME COMPLETE : 2:35pm						
DATE : 01-03-22						
<b>LOT NUMBER AND EXPIRY DATE PRINTING</b>						
TIME START : 11:00 AM	403	903	NIL	Fabi (1088)	Poshni 1:30pm 02/03/22	4/5
DATE : 02-03-22						
TIME COMPLETE : 1:30 PM						
DATE : 02-03-22						
<b>BOX PACKING &amp; FINAL CONTROL</b>						
TIME START : 6:00 PM	900+3	903	NIL	Ambiga (1129)	Poshni 3:00pm 02/03/2022	Refer PCR
DATE : 02-03-22						
TIME COMPLETE : 3:00 PM						
DATE : 02-03-22						
<b>CARTON PACKING</b>						
TIME START : 5:00pm	45 Box 4ctn	45 box 4ctn	NIL	Heidi (1053)	Nurin 2/3/2022	Refer PCR
DATE : 02-03-22						
TIME COMPLETE : 5:10pm						
DATE : 02-03-22						

QUANTITY PRODUCED : 910 pcs

QUANTITY FOR QC/RETAIN SAMPLE : 3751 / 103

SHIPMENT QUANTITY PCS : 900 pcs

FINAL SHIPMENT DATE : 45 box / 4ctn

COMPLETE/PARTIAL : COMPLETE

Checked by (PR), Signature : [Signature]

Approved by (QC), Signature : [Signature]

Name : KARTUSY CHAM

Name : [Signature]

Date : 3/3/22

Date : 4/3/2022





# HYDROCYN | gel

## 15g

### aquea

Soothing & Bacteriostatic effects

For External Use Only



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**

VIGILENT Medical Devices Sdn. Bhd.  
 108-11, Jalan Perindustrian Bakti, Mukim 18  
 43000 Kajang, Selangor Darul Ehsan, Malaysia  
 www.vigilentmed.com / www.bactiguard.com

181-0001-0048

MSM-DC790K-05-0307

[illegible]

# Hydrocyn aqua<sup>®</sup> gel

[REF]	HW40F900	
[LOT] <td>B21428</td> <td></td>	B21428	
Qty	20 pcs / box	
Weight	15g / pc	



**VIGILENZ<sup>®</sup>**  
MALAYSIA



<b>VIGILENZ<sup>®</sup></b>	<b>HYDROCYN aqua<sup>®</sup> GEL - RECORDS OF PREPARATION</b>	
	Doc. No.	PR-HR001
	Rev.	04


VIGILENZ <sup>®</sup>	HYDROCYN aqua <sup>®</sup> GEL - RECORDS OF PREPARATION
	Doc. No. PR-HR001
	Rev. 04

VIGILENZ <sup>®</sup>	HYDROCYN aqua <sup>®</sup> GEL - RECORDS OF PREPARATION
	Doc. No. PR-HR001
	Rev. 04

Date : 26/2/2022

	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.	HW401900 / B21428
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)
GB2602207	67	9.73	comply	9105	✓	pass
GB2602208	68	9.73	comply	9105	✓	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		 Bactiguard	
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	17.22 g	16.86 g	16.85 g	16.98 g	16.97 g	16.97 g	✓	pass
1/5	17.08 g	17.09 g	17.36 g	17.03 g	17.16 g	17.14 g	✓	pass
2/5	17.29 g	17.39 g	17.09 g	17.18 g	17.32 g	17.35 g	✓	pass
3/5	16.56 g	16.70 g	16.76 g	16.85 g	16.92 g	16.76 g	✓	pass
4/5	17.00 g	17.02 g	16.59 g	16.99 g	17.02 g	16.92 g	✓	pass
5/5	17.07 g	17.17 g	16.52 g	16.82 g	16.79 g	16.87 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)
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. Raj  
 Name : P. RAJINI  
 Date : 02/03/2022

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

REF : HW40F900 : Q100+3  
 LOT NO : B21438 : 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 :	Approved By :
Name : <u>POSHNI</u>	Name : <u>A. A. D. T. N. S.</u>
Date : <u>01/03/2022</u>	Date : <u>3/3/2022</u>



RAW MATERIAL LOADING FORM (RMLF)

Doc No. PR-RM001  
Rev. 06

DATE : 16/02/2022  
REF : HW40F900  
LOT NO. : B21428

SHOP PACKET QTY (pcs) : 900  
CUSTOMER : VMD (MALAYSIA)  
LO NO. : IOVMD/110222/01

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(5 layers), Open End, Gloss Finishing	H022210902	pcs	910	910	1 Canjaya
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gm	800	800	1 Canjaya
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Canjaya
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	1 Canjaya
5	N/A	STOCK SOLUTION	N/A	GB3603207 GB2603208	ltr	20	20	1 Canjaya

(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	1 Canjaya
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	1 Canjaya
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23220101	1821	1 Canjaya
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	1 Canjaya
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	1 Canjaya
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1 Canjaya
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 LR150/MLR150 (BC FLUTE)	H114211101	4	1 Canjaya
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)		417	
2		#N/A			

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

VERIFIED BY (PR) :  
Signature :  
Name :  
Date :



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

Description	Hydrocyn aqua Wound Gel Tube (15g)	Reference No.	HW405400	Date of Inspection	02/03/2022
		Lot No.	B21428	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 )
✓	✓	✓	✓	✓	✓	9.34	comply
							pass

✓ = Pass, X = Fail

Remarks: NA

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Pooj  
 Name : ROSHNI  
 Date : 02/03/2022

Approved By : me  
 Name : MARTINI  
 Date : 3/3/2022

