

20/12

# SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	900	ISSUED DATE	14.1.2022
ITEM CODE :	HO100016	PACK SIZE :	20/BOX	LOT NO	B21421
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD	MFG. DATE	14.1.2022
		ORD. NO	B082	EXP DATE:	2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
<b>HYDROCYN AQUA GEL PREPARATION</b>						
TIME START:	910	910	Nil	Melanny (709)	even	2/2
DATE:						
TIME COMPLETE:						
DATE:						
CHECK: pH / VISCOSITY / FAC Refer attachment: PR-HR001 QC-HR003						
<b>LABELLING GEL TUBE</b>						
TIME START:	910	910	Nil	Vicki (1094)	Pashini 2:00pm 19/2/22	5/5
DATE:						
TIME COMPLETE:						
DATE:						
<b>GEL FILLING</b>						
TIME START:	910	910	Nil	Dani (1106)	Pashini 2:15pm 21/2/22	5/5
DATE:						
TIME COMPLETE:						
DATE:						
<b>SEALING AND CUTTING GEL TUBE</b>						
TIME START:	910	910	Nil	Eva (932)	Pashini 2:15pm 21/2/22	5/5
DATE:						
TIME COMPLETE:						
DATE:						
<b>LOT NUMBER AND EXPIRY DATE PRINTING</b>						
TIME START:	903	903	Nil	Khin (647) Basini (1117)	Pashini 2:10pm 21/02/2022	5/5
DATE:						
TIME COMPLETE:						
DATE:						
<b>BOX PACKING &amp; FINAL CONTROL</b>						
TIME START:	900 +3	903	Nil	Shanviah C9611	Pashini 2:10pm 21/2/22	20/20 PCR
DATE:						
TIME COMPLETE:						
DATE:						
<b>CARTON PACKING</b>						
TIME START:	45 box 4ctn	45 box 4ctn	Nil	Wister (1123)	Jinda 23/02/2022	23/02/2022
DATE:						
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED	910 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3 RST 7 pcs
SHIPMENT QUANTITY PCS / CTNS :	900 pcs 45 box / 4ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR):	Signature: [Signature]
Name: RANIRISSELMAN	Date: 24/2/22

Approved by (QC):	Signature: [Signature]
Name: Rohman Othman	Date: 24/2/2022



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

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

**HYDROCYN<sup>®</sup>**  
aqua 15g

Soothing & Bacteriostatic effects  
For External Use Only CE 2292

WOUND  
gel



**HYDROCYN<sup>®</sup>**  
aqua 15g

9 555468 912422

LOT : B21421-08 : 2023-08

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.vigilenz.com / www.bactiguard.com

MDA-GC9700420-45397

HGBL-001-R3

HW40F900

21/3/22

**Hydrocyn aqua<sup>®</sup> gel**

[REF] HW40F900

[LOT] B21421

Qty 20 pcs / box

Weight 15g / pc

**VIGILENZ<sup>®</sup>**  
MALAYSIA

21/3/22

21/3/22


21/3/22

21/3/22







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.	H0040F900 / B21421
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)
G19022205	G15	9.67	comply	9214	✓	pass
G19022206	G16	9.67	comply	9214	✓	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

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	16.84 g	16.78 g	16.84 g	16.60 g	17.00 g	16.82 g	✓	pass
1/5	17.36 g	17.13 g	17.32 g	16.95 g	17.27 g	17.21 g	✓	pass
2/5	17.25 g	17.51 g	17.24 g	17.13 g	17.19 g	17.26 g	✓	pass
3/5	17.17 g	17.25 g	17.16 g	17.27 g	17.09 g	17.18 g	✓	pass
4/5	17.28 g	17.26 g	17.27 g	17.28 g	17.36 g	17.29 g	✓	pass
5/5	17.29 g	17.10 g	17.18 g	17.16 g	17.31 g	17.21 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			
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 : Poly  
 Name : ROSINI  
 Date : 22/3/23

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

REF : HW401900 QTY PRODUCED (pcs) : 903

LOT NO : B21421 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		90	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/P

Inspected By :	Approved By :
Name :	Name :
Date :	Date :

Pagay  
PERMUT  
22/2/22

M. MARTIN  
23/2/2022



RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001  
Rev. 06

DATE : 16/02/2022

REF : HW40F900

LOT NO. : B21421

SHOP PACKET QTY (pcs) : 900

CUSTOMER : VMD (MALAYSIA)

LO NO. : IO/VMD/110222/01

RS

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NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100225	1.5ml 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. Ganjuna
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gsm	800	800	1. Ganjuna
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1. Ganjuna
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	1. Ganjuna
5	N/A	STOCK SOLUTION	N/A	GA19032205 GA19032206	ltr	20	20	1. Ganjuna

(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. Ganjuna
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	1. Ganjuna
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. Ganjuna
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. Ganjuna
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	1. Ganjuna
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1. Ganjuna
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/N/LR150 (BC FLUTE)	H114211101	4	1. Ganjuna
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 :  
Name : LOVIN  
Date : 16/02/2022

VERIFIED BY (PR) :  
Signature :  
Name :  
Date : 26/2/22



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.	Hw405900	Date of Inspection	22/2/2022
		Lot No.	B31421	Sample Size	2pcs 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	
✓	✓	✓	✓	✓	Free from contamination / particles / foreign matters	pH (9.00 – 10.50)	FAC (100 – 200 ppm)
						9.29	comply
							PASS

✓ = Pass, X = Fail

Remarks: NA

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Poly  
 Name : POSHNI  
 Date : 22/2/2022

Approved By : M. Martin  
 Name : MARTIN  
 Date : 23/2/2022

