

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	900	ISSUED DATE	15-Jan-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX	LOT NO	A21514
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	15-Jan-22
		ORD. NO	A110	EXP. DATE	2023-07

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IQC APPROVAL	RESULTS
<b>HYDROCYN AQUA GEL PREPARATION</b>						
TIME START :	910	910	NIL	FARAH (1051)	Wah 5:02pm 19-01-22	2/3
DATE :	19-01-22					
TIME COMPLETE :						
DATE :						
CHECK : pH / VISCOSITY / FAC						
<b>LABELLING GEL TUBE</b>						
TIME START :	910	904	6	TASHA (1089)	Roshni 1:13pm 20/01/22	- 6 label reject replace with new label
DATE :						
TIME COMPLETE :						
DATE :						
<b>GEL FILLING</b>						
TIME START :	910	910	NIL	MIMI (1091)	Roshni 4:00pm 20/01/22	- short close 140 pcs not enough gel
DATE :						
TIME COMPLETE :						
DATE :						
<b>SEALING AND CUTTING GEL TUBE</b>						
TIME START :	910	816	14	FARAH (1051)	Roshni 4:00pm 20/01/22	- 14 pcs tube sealing reject replace with new tube
DATE :						
TIME COMPLETE :						
DATE :						
<b>LOT NUMBER AND EXPIRY DATE PRINTING</b>						
TIME START :	903	893	10	NETRA (1103) SARAH (1102)	Roshni 3:30pm 21/01/22	- 10 box reject replace with new box
DATE :						
TIME COMPLETE :						
DATE :						
<b>BOX PACKING &amp; FINAL CONTROL</b>						
TIME START :	903	903	NIL	NETRA (1103) SARAH (1102)	Roshni 4:30pm 21/01/22	Refer PCR
DATE :						
TIME COMPLETE :						
DATE :						
<b>CARTON PACKING</b>						
TIME START :	45 Box 4ctn	45 Box 4ctn	NIL	FASLI (1054) HEK01 (1053)	Farah 24/01/2022	Din 24/01/2022
DATE :						
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED	910 pcs	Checked by (PR),	Signature : S. Raj	Approved by (QC),	Signature : S. Raj
QUANTITY FOR QC/RETAIN SAMPLE	3 RS + 7 pcs	Name :	Murugan	Name :	ARTINI
SHIPMENT QUANTITY PCS	900 pcs	Date :	24/01/2022	Date :	24/01/2022
FINAL SHIPMENT DATE					
COMPLETE/PARTIAL :	PARTIAL				

LABEL APPROVAL

**HYDROCYN** | *gel*  
**aqua** 15g

Soothing & Bacteriostatic effects  
For External Use Only **CE** 2292

**INGREDIENTS**  
Purified Water, Sodium Hypochlorite (0.5%), Lithium Magnesium Sodium Silicate and Sodium Chloride.

**Direction for use:**  
Ensure wound is cleaned first. Apply the gel directly into 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.vigilenzmd.com / www.bactiguard.com

MDA-CG9700420-45397

**HYDROCYN** | *gel*  
**aqua** 15g

Soothing & Bacteriostatic effects  
For External Use Only **CE** 2292

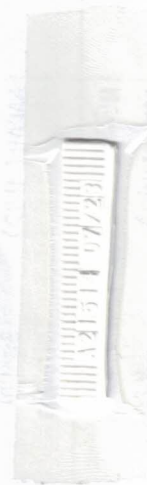
**Bactiguard**  
VIGILENZ

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.vigilenzmd.com / www.bactiguard.com

MDA-GC9700420-45397

✓ KOSHTNI  
2010113022

✓ KOSHTNI  
2010113022



✓ KOSHTNI  
2010113022

**Hydrocyn aqua® gel**

[REF] HW40F900  
[LOT] A21514  
Qty 20 pcs / box  
Weight 15g / pc

Naif Rini  
24/11/22

M. Husein  
24/01/22

**VIGILENZ®**  
MALAYSIA


APD



19/01/2022

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


Reference / Lot No.	<b>HW40F900 / A 21514</b>
Order Qty.	<b>900</b>

**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)
GB19012201	G11	9.96	comply	8862	✓	pass
GB19012202	G12	9.96	comply	8862	✓	pass
		NA				

**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		
5/5	17.66	17.35	17.32	17.40	17.22	17.39 g	pass
1/5	17.31	17.06	17.30	16.97	17.33	17.19 g	pass
2/5	17.24	17.01	17.17	17.10	17.15	17.14 g	pass
3/5	16.99	17.16	17.13	17.12	17.09	17.09 g	pass
4/5	17.26	17.11	17.19	17.21	17.30	17.22 g	pass
5/5	17.29	17.27	17.29	17.08	17.36	17.26 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



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

#### 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 : Peggy  
 Name : PASHALE  
 Date : 21/01/22

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

REF : HW40F900 QTY PRODUCED (pcs) : 903

LOT NO : A21514 RETAIN SAMPLE QTY (pcs) : 903

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 : <span style="border: 1px solid black; padding: 2px 20px;">Rajy</span>	Approved By : <span style="border: 1px solid black; padding: 2px 20px;">[Signature]</span>
Name : <span style="border: 1px solid black; padding: 2px 20px;">Rajy</span>	Name : <span style="border: 1px solid black; padding: 2px 20px;">RAJYENDU</span>
Date : <span style="border: 1px solid black; padding: 2px 20px;">24/01/2022</span>	Date : <span style="border: 1px solid black; padding: 2px 20px;">24/01/2022</span>



RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001  
Rev. 06

DATE :	20/01/2022	SHOP PACKET QTY (pcs) :	900	RS	10
REF :	HW40F900	CUSTOMER :	VMD (MALAYSIA)		
LOT NO. :	A21514	LO NO. :	IOVMD/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(5 layers), Open End, Glass Finishing	H022210902	pcs	910	910	1 Kanjano
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gsm	800	800	1 Kanjano
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Kanjano
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	1 Kanjano
5	N/A	STOCK SOLUTION	N/A	6B19012201 6B19012202	ltr	20	20	1 Kanjano

(2) PRODUCT PACKAGING						(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	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	<i>1 Kanjano</i>	1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LRI150M/LRI150 (BC FLUTE)	H114210801/2	4	<i>m de la...</i>
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	<i>1 Kanjano</i>	2		#N/A			
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	<i>1 Kanjano</i>	3		#N/A			

ISSUED BY (MM) :	VERIFIED BY (PR) :
Signature :	Signature :
Name : LOVIN	Name :
Date : 20/01/2022	Date : 24/1/2023



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

Description	Hydrocyn Aqua Wound gel Tube (15g)	Reference No.	HW405900	Date of Inspection	24/01/2022
		Lot No.	A21514	Sample Size	2PCS 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) 9.25 FAC (100 – 200 ppm) comply	PASS / FAIL pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : ROSHALI  
 Name : MARTINI  
 Date : 24/01/2022

Approved By : [Signature]  
 Name : MARTINI  
 Date : 24/01/2022

