

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	200	3(RS) + 7(QC TEST)	ISSUED DATE	15-Jan-21
ITEM CODE :	H0100016	PACK SIZE :	20/BOX		LOT NO	A11505
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	15-Jan-21
		ORD. NO	A096		EXP DATE:	2022-07

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE : CHECK : pH / VISCOSITY / FAC	1:15 PM 19-01-21 3:30 PM 19-01-21 Refer attachment: PR-HR001 QC-HR003	210	210	Nil	Roshni (931) 3:30pm 19/01/2021	/1
LABELLING/GEL TUBE						
TIME START : DATE : TIME COMPLETE : DATE :	10:40 AM 20-01-21 11:15 PM 20-01-21	210	210	Nil	Erd (932) Roshni 1:15 pm 21/01/2021	5/5
GEL FILLING						
TIME START : DATE : TIME COMPLETE : DATE :	10:45 AM 20-01-21 11:40 AM 20-01-21	210	210	Nil	Kyti (890) Roshni 11:40AM 20/01/2021	5/5
SEALING AND CUTTING GEL TUBE						
TIME START : DATE : TIME COMPLETE : DATE :	10:45 AM 20-01-21 1:45 PM 20-01-21	210	210	Nil	Kyti (890) Roshni 1:45 pm 20/01/2021	5/5
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : DATE : TIME COMPLETE : DATE :	9:30 AM 20-01-21 10:00 AM 20-01-21	203	203	Nil	Kyti (890) Roshni 10:00 am 20/1/2021	5/5
BOX PACKING & FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	1:50 PM 20-01-21 5:00 PM 20-01-21	203	203	Nil	Kyti (890) Roshni 4:55 PM 20/01/2021	FCTR
CARTON PACKING						
TIME START : DATE : TIME COMPLETE : DATE :	5:00 pm 21-01-21 5:10 pm 21-01-21	10	10	Nil (847)	Jinca 21/01/2021	NA

QUANTITY PRODUCED
210 PCS
QUANTITY FOR QC/RETAIN SAMPLE
3 PCS
SHIPMENT QUANTITY PCS / CTNS :
200 PCS
FINAL SHIPMENT DATE
22-01-2021
COMPLETE/PARTIAL :
COMPLETE

210 PCS
3 PCS
200 PCS
22-01-2021
COMPLETE PARTIAL



Checked by (PR),
Signature : *M. Muniraj*
Name : M. Muniraj

Approved by (QA),
Signature : *M. Leguanan*
Name : M. Leguanan

21/01/2021

- 22/01/2021 - 200 pcs - Tee Pham

LABEL APPROVAL

HYDROCYN | *gel*
aqua

15g

Soothing & Bacteriostatic effects
For External Use Only

Active Ingredients:
Sodium Hypochlorite (0.05%)

REF:HW40F900
⊗ △ ✨

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, Penang Science Park,
14100 Penang, Malaysia.



Manufactured by:
Vigilenz Medical Devices Sdn. Bhd.
308 b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, MY.
www.vigilenzmd.com

LOT : A11505
EXP : 2022-07

HGBL001-R2

Distributed by:

REF:HW40F900 ⊗ △ ✨

HYDROCYN | *wound*
aqua | *gel*

Soothing & Bacteriostatic effects
For External Use Only

15g

VIGILENZ®
Medical Devices

✓ Roshni
20/1/2021

LBH001



HYDROCYN
aqua

✓ Roshni
20/1/2021



NA

Hydrocyn aqua® *gel*

REF HW40F900

LOT A11505

Qty 20 pcs / box

Weight 15 g / pc

Nanfani
20/1/2021

Roshni
20/01/2021

⊗ △ ✨

VIGILENZ®
MALAYSIA

VIGILENZ®

HYDROCYN AQUA GEL - RECORDS OF PREPARATION

Doc. No.	PR-HR001
Rev.	02

Date : 19/01/2021

Batch No : GB19012101

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QC IN-PROCESS INSPECTION RECORD - HYDROCYN AQUA® GEL

Doc No.	QC-IP004
Rev.	00

Reference / Lot No.	HW401900 / A11505
Order Qty.	200

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)
61B19010101	G11	9.63	comply	9,229	✓	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

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 : RoshniName : DOSTHNEDate : 20/01/2024

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QC IN-PROCESS INSPECTION RECORD – HYDROCYN AQUA® GEL

Doc No.	QC-IP004
Rev.	00

C. Filling Process

Sampling / Frequency	Weight of Sample (16 g ± 1 g)						Leak Test	Test disposition (PASS / FAIL)
	1	2	3	4	5	Average		
5/5	15.68	15.72	15.68	15.92	15.82	15.76	✓	PASS
1/5	15.66	15.52	15.55	15.92	15.97	15.73	✓	PASS
2/5	16.16	16.01	15.86	15.91	15.92	15.97	✓	PASS
3/5	16.06	16.09	16.00	15.82	15.66	16.04	✓	PASS
4/5	15.99	15.83	15.86	15.97	16.03	15.94	✓	PASS
5/5	15.82	15.86	15.98	15.91	16.11	15.94	✓	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 (5 mm ± 1 mm)	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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FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

Doc. No.	QC-FC006
Rev.	03

REF : HW40F900QTY PRODUCED (pcs) : 203LOT NO : A11505RETAIN 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	8	0	1	8	0	PASS
2	Availability of Hologram and Secure Sticker.	S3,0.15	8	0	1	8	0	PASS
3	Free from contamination, deformed or damaged on packaging.	S3,0.15	8	0	1	8	0	PASS
4	Proper sealing and no leakage.	S3,0.15	8	0	1	8	0	PASS
5	Correct quantity in secondary box packaging.	S3,0.15	8	0	1	8	0	PASS

Remarks : N/A

Inspected By : Roshni
 Name : ROSHNI
 Date : 10/01/2021

Approved By : A. Devi
 Name : A. Devi
 Date : 10/01/2021

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.	PR-RM001
Rev.	06

REF :	18/01/2021
REF :	HW40F900
LOT NO. :	A11505

SHOP PACKET QTY (pcs)	200	RS	10
CUSTOMER	VMD (MALAYSIA)		
I.O NO.	IO/VMD/091120/01		

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)			RECEIVED BY
						REQUIRED	ISSUED	CONSUMPTION	
1	P0100225	15ml Long Nozzle Tube	Diameter 22 x 80mm, White Colour Tube with Long Nozzle(5 layers), Open End, Gloss Finishing	H022200701 ✓	pcs	210	210	210	
2	P0100226	White Colour Screw on Cap	0	H023200701 ✓	pcs	210	210	210	
3	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080200901 ✓	grm	240	246	240	
4	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023201001 C023200602 18/01/21	ml	60	60	60	
5	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021201001 ✓	grm	6	6	6	
6	N/A	STOCK SOLUTION	N/A	G1B19012101	ltr	-60- 6	-60- 6	6	

(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	JY 18/01/21 L220210101- L22020B702	211	
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020200701 ✓	211	
3	P0100426	Secure Round Sticker For Gel Tube - Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form	L021200702 ✓	421	
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 (2 colors), Rev: 1	H076200701 ✓	211	
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077201201 ✓	10	
6		#N/A			
7		#N/A			

(3) OVER WRAPPING AND CARTON PACK

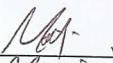
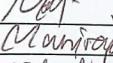
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100371	Corrugated Carton Box (Part No: ZV07VIGILENZC) - Size: 595 x 375 x 365mm, Printing Plate: P12697	P100200901		
2		#N/A			
3		#N/A			

(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)	NA	210	NA
2		#N/A			

ISSUED BY (MM) :

Signature : 
Name : FIRDAUS
Date : 18/01/2021

VERIFIED BY (PR) : 
Signature : 
Name : Manager
Date : 19/01/2021

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PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL

Doc No.	QC-PC008
Rev.	02

Description	Hydrocyn Aqua. Wound Gel (15g)	Reference No.	HW40F900	Date of Inspection	20/01/2021
		Lot No.	A11505	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)	PASS / FAIL
✓	✓	✓	✓	✓	✓	9.56	comply	PASS

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: RELEASE

ON-HOLD

Inspected By : Roshni

Name : ROSHNI

Date : 20/01/2021

Approved By : D

Name : A Dewi

Date : 20/01/2021



**PRODUCT TRANSFER SLIP –
ETO STERILIZATION & HYDROCYN ITEMS**

Doc No. PR-TS003

Rev 00

Date	21/01/2021			Lot No	A11505	
Product Detail	Gel			Customer	VMD	
Reference No.	HW405900					
Order Qty	200	Retain Sample Qty	3	Sterilization	ETO (Yes / No)	
Final Packaging Process						
Process	Input Qty	Output Qty	Rejects	Operator	QC Approval	Remarks
OVERWRAPPING			Nil	Anil (QA7)		NA
	TIME START :	TIME COMPLETE :				
	DATE :	DATE :				
CARTON PACK	10 box	10 box	Nil		Signature	NA
	TIME START : 5:00 pm	TIME COMPLETE : 5:15 pm				
	DATE : 21-01-2021	DATE : 21-01-2021				
OQC Inspection	Inspected by: JUNYA	Date: 21/01/2021	Status:	Release <input checked="" type="checkbox"/>	Onhold <input type="checkbox"/>	
Remarks						

DATE :	20-01-2021
TIME COMPLETE :	10:00 am
DATE :	20-01-2021
BOX PACKING & FINAL CONTROL	
TIME START :	1:30 pm
DATE :	20-01-2021
TIME COMPLETE :	3:00 pm
DATE :	20-01-2021
CARTON PACKING	
TIME START :	5:00 pm
DATE :	21-01-2021
TIME COMPLETE :	5:10 pm
DATE :	21-01-2021

QUANTITY PRODUCED	210 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3 PCS
SHIPMENT QUANTITY PCS / CTNS :	200 PCS
FINAL SHIPMENT DATE	22-01-2021
COMPLETE/PARTIAL :	COMPLETE

210 pcs	
3 PCS	
200 PCS	
22-01-2021	
COMPLETE	PARTIAL



ISSUED DATE	15-Jan-21
LOT NO	A11505
IFG. DATE	15-Jan-21
EXP DATE:	2022-07

IPQC APPROVAL	RESULTS
Roshni 3:30 pm 19/01/2021	1/1
Roshni 1:15 pm 21/01/2021	5/5
Roshni 11:40 am 20/01/2021	5/5
Roshni 1:45 pm 20/01/2021	5/5
Roshni 10:00 am 20/01/2021	5/5
Roshni 4:55 pm 20/01/2021	FCTR
JUNYA 21/01/2021	NA

Checked by (PR)
Signature :
Name : Junya
Date : 21/01/2021

Approved by (QA),
Signature :
Name : M. Lequenan
Date : 22/01/2021