

SHOP PACKET - HYDROCYN AQUA GEL


REF :	HW40F900	ISSUED DATE	15-Jan-22
ITEM CODE :	H0100016	LOT NO	A21521
ITEM :	Hydrocyn Aqua Wound Gel (15g)	MFG. DATE	15-Jan-22
		EXP. DATE:	2040-01-2023-07

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START :	910	910	Nil	Tanjung (7001)	Poshmi 7:28pm 24/1/22	7/5
DATE :						
TIME COMPLETE :						
DATE :						
CHECK : pH / VISCOSITY / FAC Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START :	910	910	Nil	Khira CG47	Poshmi	5/5
DATE :						
TIME COMPLETE :						
DATE :						
GEL FILLING						
TIME START :	910	910	Nil	Siti C1099	Poshmi 5:30 pm 24/1/22	5/5
DATE :						
TIME COMPLETE :						
DATE :						
SEALING AND CUTTING GEL TUBE						
TIME START :	910	910	Nil	KALI (1078)	Poshmi 5:30 pm 24/1/2022	5/5
DATE :						
TIME COMPLETE :						
DATE :						
LOT NUMBER AND EXPIRY DATE PRINTING BP-01						
TIME START :	903	903	Nil	SHEVA (1044)	Poshmi 2:35pm 28/01/2022	5/5
DATE :						
TIME COMPLETE :						
DATE :						
BOX PACKING & FINAL CONTROL						
TIME START :	903	903	Nil	Tilamal (079)	Poshmi 3:00pm 28/01/22	
DATE :						
TIME COMPLETE :						
DATE :						
CARTON PACKING						
TIME START :	45 box	45 box	Nil	Herdi (1053)	NUVIN 20/1/2022	29/01/2022
DATE :						
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED	910	Approved by (QC),	Signature : <i>[Signature]</i>
QUANTITY FOR QC/RETAIN SAMPLE	3 pcs / 7 pcs	Signature : <i>[Signature]</i>	Name : <i>[Name]</i>
SHIPMENT QUANTITY PCS / CTNS :	900 pcs / 45 box / 4 ctn	Name : <i>[Name]</i>	Date : <i>[Date]</i>
FINAL SHIPMENT DATE		Name : <i>[Name]</i>	Date : <i>[Date]</i>
COMPLETE/PARTIAL :	COMPLETE	Name : <i>[Name]</i>	Date : <i>[Date]</i>

LABEL APPROVAL

<div data-bbox="215 1592 693 2046"><p>HYDROCYN[®] gel aqua</p><p>15g</p><p>Soothing & Bacteriostatic effects For External Use Only</p><p>CE 2292</p><p>INGREDIENTS Purified Water, Sodium Hypochlorite (0.05%), Lithium Magnesium Sodium Silicate and Sodium Chloride.</p><p>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.</p><p>BactiGuard</p><p><small>VIGILENZ Medical Devices Sdn. Bhd. 308 D, Jalan Perindustrian Bukit Minyak, 18, Penang Science Park, 14100 Penang, Malaysia. www.vigilenzmd.com</small></p></div> <div data-bbox="215 973 369 1249"><p>9 555468 912422</p></div> <div data-bbox="215 597 369 973"><p>Manufactured by: VIGILENZ Medical Devices Sdn. Bhd. [a subsidiary of BactiGuard] 308 D, Jalan Perindustrian Bukit Minyak, 18, Penang Science Park, 14100 Penang, Malaysia. www.vigilenzmd.com / www.bactiGuard.com</p><p>MDA-GC9700420-45397</p><p>HGBL-001-R3</p><p>HW40F900</p><p>2023-07-15</p><p>2023-07-15</p></div> <div data-bbox="400 1294 600 1415"><p>HYDROCYN[®] aqua gel</p></div> <div data-bbox="400 884 600 1249"><p>HYDROCYN[®] aqua gel</p><p>WOUND</p><p>Soothing & Bacteriostatic effects For External Use Only</p><p>CE 2292</p><p>15g</p><p>BactiGuard</p><p>VIGILENZ[®]</p></div> <div data-bbox="400 442 600 873"><p>HYDROCYN[®] aqua gel</p><p>WOUND</p><p>Soothing & Bacteriostatic effects For External Use Only</p><p>CE 2292</p><p>15g</p><p>BactiGuard</p><p>VIGILENZ[®]</p></div>	<div data-bbox="847 265 1262 829"><p>Hydrocyn aqua[®] gel</p><table><tr><td>[REF]</td><td>HW40F900</td></tr><tr><td>[LOT]</td><td>A21521</td></tr><tr><td>Qty</td><td>20 pcs / box</td></tr><tr><td>Weight</td><td>15g / pc</td></tr></table><p>VIGILENZ[®] MALAYSIA</p></div> <div data-bbox="877 1216 1016 1880"><p>9 555468 912422</p></div> <div data-bbox="1155 1681 1201 1747"><p>NP</p></div>	[REF]	HW40F900	[LOT]	A21521	Qty	20 pcs / box	Weight	15g / pc
[REF]	HW40F900								
[LOT]	A21521								
Qty	20 pcs / box								
Weight	15g / pc								

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 / A21521
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)
G1B24012207	G17	9.03	comply	9967	✓	pass
G1B24012208	G18	9.03	comply	9967	✓	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


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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	17.73 g	17.68 g	17.58 g	17.21 g	17.72 g	17.58 g	✓	pass
1/5	17.63 g	16.95 g	16.98 g	17.38 g	17.27 g	17.23 g	✓	pass
2/5	17.80 g	17.79 g	17.38 g	17.55 g	17.51 g	17.60 g	✓	pass
3/5	16.89 g	17.39 g	17.56 g	17.56 g	17.44 g	17.37 g	✓	pass
4/5	17.31 g	17.46 g	17.61 g	17.30 g	17.51 g	17.44 g	✓	pass
5/5	17.61 g	17.54 g	17.47 g	17.29 g	17.66 g	17.52 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

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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. S. S.
 Name : DASHAN
 Date : 28/01/2022

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

REF : HW 405900 : 910

LOT NO : A21521 : 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 : P. Raj
 Name : P. RAJINI
 Date : 28/01/2022

Approved By : [Signature]
 Name : M. ARTHI
 Date : 08/01/2020

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

SHOP PACKET QTY (pcs) : 900 RS 10
CUSTOMER : VMD (MALAYSIA)
LO NO. : IOVMD/130122/01

19/01/2022
HW40F900
A21521

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	Karyana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gms	800	800	Karyana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	Karyana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gms	20	20	Karyana
5	N/A	STOCK SOLUTION	N/A	61324012408 61324012007	ltr	20	20	Karyana

(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	Karyana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	Karyana
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB22210801/3	1821	Karyana
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	Karyana
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	Karyana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	Karyana
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)	H114210801/2	4	Karyana
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	
2		#N/A			

ISSUED BY (MM) :

Signature :
Name : LOVIN
Date : 19/01/2022

VERIFIED BY (PR) :

Signature :
Name : KARYANA
Date : 29/1/22

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

Description	Hydrocyn Aqua, wound Gel (15g)	Reference No.	HW4DF900	Date of Inspection	29/01/2022
		Lot No.	A21521	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)
✓	✓	✓	✓	✓	✓	9.57	comply
							pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE
☐ ON-HOLD

Inspected By : Poly
Name : POSHNI
Date : 29/01/2022

Approved By : [Signature]
Name : MARTINI
Date : 3/2/2022

