

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	900	RS 3 + 7 (QC TEST)	ISSUED DATE	15-Jan-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX		LOT NO	A21516
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	15-Jan-22
		ORD. NO	A112		EXP. DATE	2040-04

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 5:40 PM						
DATE : 19-01-22						
TIME COMPLETE : 5:35 PM						
DATE : 19-01-22						
Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 4:30 PM						
DATE : 20-01-22						
TIME COMPLETE : 10:06 AM						
DATE : 21-01-22						
GEL FILLING						
TIME START : 2:00 PM						
DATE : 21-01-22						
TIME COMPLETE : 5:00 PM						
DATE : 21-01-22						
SEALING AND CUTTING GEL TUBE						
TIME START : 2:00 PM						
DATE : 21-01-22						
TIME COMPLETE : 5:00 PM						
DATE : 21-01-22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 4:00 PM						
DATE : 22-01-22						
TIME COMPLETE : 5:00 PM						
DATE : 22-01-22						
BOX PACKING & FINAL CONTROL						
TIME START : 9:00 PM						
DATE : 22-01-22						
TIME COMPLETE : 5:00 PM						
DATE : 22-01-22						
CARTON PACKING						
TIME START : 2:40 PM						
DATE : 24-01-22						
TIME COMPLETE : 2:50 PM						
DATE : 24-01-22						

QUANTITY PRODUCED	910 PCS
QUANTITY FOR QC/RETAIN SAMPLE	325 + 7 PCS
SHIPMENT QUANTITY PCS / CTNS :	900 PCS
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR), Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : 25/01/2022	Approved by (QC), Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : 26/01/2022
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LABEL APPROVAL

<div data-bbox="223 1636 685 2090"><p>HYDROCYN[®] gel aqua 15g</p><p>Soothing & Bacteriostatic effects For External Use Only 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[®] VIGILENZ Medical Devices Sdn. Bhd. 308 b, Jalan Perindustrian Bukit Minyak, 18, Penang Science Park, 14100 Penang, Malaysia www.vigilenz.com / www.bactiguard.com</p></div> <div data-bbox="254 1006 654 1294"><p>9 555468 912422</p><p>HYDROCYN[®] aqua</p><p>WOUND gel</p><p>Soothing & Bacteriostatic effects For External Use Only CE 2292 15g</p><p>HYDROCYN[®] aqua</p><p>gel</p></div> <div data-bbox="254 409 654 1006"><p>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</p><p>LOT : A21516 EXP : 2023-07</p><p>MDA-GC9700420-45397</p><p>HGBL-001-R3</p><p>MDA-GC9700420-45397</p><p>HW40F900</p><p>Bactiguard[®] VIGILENZ[®]</p></div>	<div data-bbox="839 1404 1008 2001"><p>A21516 9/12/23</p></div> <div data-bbox="854 1205 1054 1338"><p>✓ 21/01/22</p></div>	<div data-bbox="854 320 1270 851"><p>Hydrocyn[®] aqua[®] gel</p><p>[REF] HW40F900</p><p>[LOT] A21516</p><p>Qty 20 pcs / box</p><p>Weight 15g / pc</p><p>VIGILENZ[®] MALAYSIA</p></div> <div data-bbox="1224 276 1255 409"><p>⑧</p></div> <div data-bbox="1224 276 1255 409"><p>△</p></div> <div data-bbox="1224 276 1255 409"><p>✱</p></div>
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10/10/2021

	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.	Hw40t900 1A21516
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)
61B19012205	675	9.22	comply	9350	✓	pass
61B19012206	676	9.22	comply	9350	✓	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


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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)				Average		
5/s	17.43	17.05	17.18	16.88	17.46	✓	pass
1/s	17.32	17.32	17.29	16.79	17.30	✓	pass
2/s	17.09	17.32	16.85	17.09	16.97	✓	pass
3/s	16.73	16.87	16.52	16.61	16.859	✓	pass
4/s	16.65	16.62	16.74	17.78	17.039	✓	pass
7/s	16.82	16.68	16.94	17.51	17.00	✓	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/s	✓	✓	✓	✓	✓	pass
1/s	✓	✓	✓	✓	✓	pass
2/s	✓	✓	✓	✓	✓	pass
3/s	✓	✓	✓	✓	✓	pass
4/s	✓	✓	✓	✓	✓	pass
7/s	✓	✓	✓	✓	✓	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 : Pasy
 Name : POSHANZ
 Date : 24/01/2021

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

REF : HW40F900 QTY PRODUCED (pcs) : 910

LOT NO : A21516 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	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 : NA

Inspected By : Pony
 Name : POSHNI
 Date : 24/01/2022

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

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

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

19/01/2022
HW40F900
A21516

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		CONSUMPTION	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	910	1 Canyano
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gsm	800	800	800	1 Canyano
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	200	1 Canyano
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	20	1 Canyano
5	N/A	STOCK SOLUTION	N/A		ltr	20	20	20	1 Canyano

(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 LR150M/LR150 (BC FLUTE)	H114210801/2	4	malysa
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			

(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 Canyano				
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm		L020210801	911	1 Canyano				
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	1 Canyano				
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 Canyano				
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back		H077210801	45	1 Canyano				
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm		L190210802	45	1 Canyano				
7		#N/A								

ISSUED BY (MM) :
Signature :
Name : LOVIN
Date : 19/01/2022

VERIFIED BY (PR) :
Signature :
Name :
Date : 25/01/2022

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

Description	Hydrocyn Aqua Wound Gel Tube (15g)	Reference No.	HW405900	Date of Inspection	24/01/2022
		Lot No.	A21516	Sample Size	9 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)
✓	✓	✓	✓	✓	✓	9.45	comply
							PASS

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Ray
 Name : ROS HANI
 Date : 24/01/2022

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

