

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	940 900	ISSUED DATE	15-Jan-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX	LOT NO	A21525
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	15-Jan-22
		ORD. NO	A121	EXP. DATE:	2040-01 2023-07

PROCESS		START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION							
TIME START :	2:32 PM	910	910	NIL	Sarah (1102)	Pashni 2:40 PM 28/01/22	1/2
DATE :	28-01-22						
TIME COMPLETE :	2:40 PM						
DATE :	28-01-22						
CHECK : pH / VISCOSITY / FAC							
Refer attachment: PR-HR001 QC-HR003							
LABELLING GEL TUBE							
TIME START :	8:30 AM	910	910	NIL	Vik (1099)	Pashni	5/5
DATE :	28-01-22						
TIME COMPLETE :	1:00 PM						
DATE :	31-01-22						
GEL FILLING							
TIME START :	3:40 PM	910	910	NIL	Sarah (1102)	Pashni 7:20 PM 31/01/22	5/5
DATE :	31-01-22						
TIME COMPLETE :	7:20 PM						
DATE :	31-01-22						
SEALING AND CUTTING GEL TUBE							
TIME START :	3:40 PM	910	910	NIL	NURUL (1095)	Pashni 7:20 PM 31/01/22	5/5
DATE :	31-01-22						
TIME COMPLETE :	7:20 PM						
DATE :	31-01-22						
LOT NUMBER AND EXPIRY DATE PRINTING							
TIME START :	11:40 AM	903	903	NIL	Viki (1094)	Fath 3:10 PM 05/02/2022	5/5
DATE :	05-02-22						
TIME COMPLETE :	3:00 PM						
DATE :	05-02-22						
BOX PACKING & FINAL CONTROL							
TIME START :	11:50 AM	903	903	NIL	SHEVA (10244) Ranaga (1045)	Fath 4:10 PM 05/02/2022	5/5
DATE :	04-02-22						
TIME COMPLETE :	3:55 PM						
DATE :	05-02-22						
CARTON PACKING							
TIME START :	3:40 PM	4 Ctn	4 Ctn	NIL	Herdi (1053) PASLI (1054)	Nurin 7/12/2022	08/02/2022
DATE :	07-02-22						
TIME COMPLETE :	3:52 PM						
DATE :	07-02-22						


QUANTITY PRODUCED	910 PCS
QUANTITY FOR QC/RETAIN SAMPLE	3 + 7
SHIPMENT QUANTITY PCS / CTNS :	900 PCS 6 Ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE
	PARTIAL

Checked by (PR),	Signature : <i>[Signature]</i>	Approved by (QC),	Signature : <i>[Signature]</i>
Name :	UTAMA MISCAMAH	Name :	RASTIN I
Date :	8/2/22	Date :	8/2/2022

VIGILENZ[®] HYDROCYN aqua[®] GEL - RECORDS OF PREPARATION	Doc. No.	PR-HR001
	Rev.	04

	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	
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Reference / Lot No.	H1040F900 / D21525
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)
G1B2801207	G1A	9.88	comply	9976	✓	pass
G1B2801208	G1B	9.88	comply	9976	✓	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		
9/5	16.97g	17.49g	17.57g	17.39g	17.33g	17.35g	✓	pass
1/5	17.67g	16.79g	16.84g	17.60g	17.01g	17.18g	✓	pass
2/5	17.23g	17.40g	17.02g	17.69g	17.64g	17.39g	✓	pass
3/5	17.22g	16.66g	17.52g	17.26g	17.48g	17.25g	✓	pass
4/5	17.02g	17.40g	17.62g	17.23g	17.47g	17.35g	✓	pass
5/5	17.51g	17.58g	17.24g	17.54g	17.35g	17.44g	✓	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 : Liif.
 Name : Lin Man Aye
 Date : 05/02/2022

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

REF : HW40F900 QTY PRODUCED (pcs) : 903

LOT NO : A21525 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 : N/A

Inspected By : L. N. Man Aye
 Name : 05/02/2022
 Date : 05/02/2022

Approved By : [Signature]
 Name : N. A. R. T. W. I.
 Date : 05/02/2022

RAW MATERIAL LOADING FORM (RMLF)

DATE : 19/01/2022

REF : HW40F900

LOT NO. : A21525

SHOP PACKET QTY (pcs) : 900

CUSTOMER : VMD (MALAYSIA)

LO NO. : IOVMD/13012201

RS : 10

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 Canjaya
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gmm	800	800	800	1 Canjaya
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	200	1 Canjaya
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gmm	20	20	20	1 Canjaya
5	N/A	STOCK SOLUTION	N/A	61828012207 61828012208	ltr	20	20	20	1 Canjaya

(2) PRODUCT PACKAGING					RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
1	P0100397	LBH-006-R4 - Hydrocyn Tube Label, Size: 65mm x 62mm, Material: Transparent PE	L220211202	911	1 Canjaya
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	1 Canjaya
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB222112072	1821	1 Canjaya
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 HGBL-001-R3 (4 colors), Rev: 3	H076210801	911	1 Canjaya
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	1 Canjaya
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1 Canjaya
7		#N/A			

(3) OVER WRAPPING AND CARTON PACK					RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LRI 500M/LRI 50 (BC FLUTE)	H114210801/2	4	meluk
2		#N/A			
3		#N/A			

(4) SPECIAL REQUIREMENT					RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
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 : LOVIN

Name : LOVIN

Date : 19/01/2022

VERIFIED BY (PR) :

Signature : VMD/MS-CRM

Name : VMD/MS-CRM

Date : 8/2/22

VIGILENZ[®]		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	5.02.2022
		Lot No.	A21525	Sample Size	2 x 15g

Release Criteria:

Packing Integrity				Chemical Testing		Test Disposition
Correct and legible printing of label	Proper sealing	Ability to dispense	Free from contamination/deformed/damaged	No leakage	Visual Inspection Free from contamination / particles / foreign matters	
✓	✓	✓	✓	✓	pH (9.00 – 10.50) 9.57 FAC (100 – 200 ppm) comply	PASS / FAIL pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : Wah
 Name : Wah wah
 Date : 5.02.2022

Approved By : [Signature]
 Name : HAZIM
 Date : 5/2/2022

