

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	1,040	RS 3 + 7 (QC TEST)	ISSUED DATE	15-Jan-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX		LOT NO	A21522
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	15-Jan-22
		ORD. NO	A118		EXP DATE:	2023-07

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 1:36 PM						
DATE : 28-01-22						
TIME COMPLETE : 1:44 PM						
DATE : 28-01-22						
CHECK : pH / VISCOSITY / FAC						
Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 6:35 AM						
DATE : 28-01-22						
TIME COMPLETE : 1:30 PM						
DATE : 28-01-22						
GEL FILLING						
TIME START : 9:30 AM						
DATE : 29-01-22						
TIME COMPLETE : 2:30 PM						
DATE : 29-01-22						
SEALING AND CUTTING GEL TUBE						
TIME START : 9:30 AM						
DATE : 29-01-22						
TIME COMPLETE : 2:30 PM						
DATE : 29-01-22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 11:45 AM						
DATE : 30-01-22						
TIME COMPLETE : 2:00 PM						
DATE : 30-01-22						
BOX PACKING & FINAL CONTROL						
TIME START : 8:56 AM						
DATE : 30-01-22						
TIME COMPLETE : 3:00 PM						
DATE : 30-01-22						
CARTON PACKING						
TIME START : 9:30 AM						
DATE : 30-01-22						
TIME COMPLETE : 9:40 AM						
DATE : 30-01-22						

QUANTITY PRODUCED	1050 PCS	QUANTITY FOR QC/RETAIN SAMPLE	3+7 PCS
SHIPMENT QUANTITY PCS / CTNS :	1040 PCS 52 box / 5 ctn		
FINAL SHIPMENT DATE			
COMPLETE/PARTIAL :	COMPLETE		

Checked by (PR),	Signature : <i>[Signature]</i>	Approved by (QC),	Signature : <i>[Signature]</i>
Name : <i>[Name]</i>	Date : <i>[Date]</i>	Name : <i>[Name]</i>	Date : <i>[Date]</i>



LABEL APPROVAL



28.10.22
Cuch

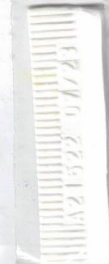


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Hydrocyn aqua® gel

[REF] HW40F900 *Ng Riin 25/1/22*
[LOT] A21522 *Poh 25/1/22*
Qty 20 pcs / box
Weight 15g / pc
VIGILENZ® MALAYSIA

NA




28.10.22
Cuch



ccoe.10.8c

	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.	Flow40F900 / A21522
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)
GB28012201	G 1	9.89	comply	9525	✓	pass
GB28012202	G 2	9.89	comply	9525	✓	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)							
	1	2	3	4	5	Average		
5/5	16.94 g	17.05 g	17.07 g	17.04 g	16.93 g	17.01 g	✓	
1/5	17.22 g	17.39 g	17.30 g	17.15 g	17.48 g	17.31 g	pass	
2/5	17.02 g	17.22 g	17.43 g	17.05 g	16.92 g	17.13 g	pass	
3/5	16.63 g	16.79 g	17.58 g	17.52 g	17.09 g	17.12 g	pass	
4/5	17.08 g	17.37 g	17.48 g	17.00 g	17.38 g	17.26 g	pass	
5/5	17.29 g	17.42 g	17.50 g	17.34 g	17.35 g	17.38 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 : Wah
 Name : Wah Wah
 Date : 3.2.2022

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

REF :	Hlw4DF900	QTY PRODUCED (pcs) :	910
LOT NO :	A215222	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 :	Wah
Name :	Wah Wah
Date :	3.2.2022

Approved By :	MA RTINI
Name :	MA RTINI
Date :	3/2/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

DATE : 19/01/2022
REF : HW40F900
LOT NO. : A21522

SHOP PACKET QTY (pcs) : 1040
CUSTOMER : VMD (MALAYSIA)
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, Gloss Finishing	H022210902	pcs	1050	1050	Kanjana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gms	800	800	Kanjana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	Kanjana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gms	20	20	Kanjana
5	N/A	STOCK SOLUTION	N/A	JTB28012201 JTB28012202	ltr	20	20	Kanjana

(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	1051	Kanjana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	1051	Kanjana
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23211201	2101	Kanjana
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	1051	Kanjana
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	52	Kanjana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	52	Kanjana
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 LR150N/LR150 (BC FLUTE)	H114210801/2	4	melich
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)			
2		#N/A			

ISSUED BY (MM) :

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

VERIFIED BY (PR) :

Signature :
Name : RAHMAN SUCATMAN
Date : 19/1/2022

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

Description	Hydrocyn Aqua Wound Gel C 152g	Reference No.	HW40F900	Date of Inspection	4.02.2022
		Lot No.	A21522	Sample Size	2 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)
✓	✓	✓	✓	✓	✓	9.74	comply
							PASS / FAIL
							pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : Woh
 Name : Woh Woh
 Date : 4.2.2022

Approved By : [Signature]
 Name : MARTINI
 Date : 04/02/2022

