

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	900	ISSUED DATE	14-Feb-22
ITEM CODE :	H0100016	PACK SIZE :	20/BOX	LOT NO	B21426
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD	MFG. DATE	14-Feb-22
		ORD. NO	B087	EXP DATE:	2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 11:49 am						
DATE : 26-02-22	910	910	NIL	DEWI (1126)	Pashini 11:57 am 26/02/2022	9/5
TIME COMPLETE : 11:57 am						
DATE : 26-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 09:00 am						
DATE : 28-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
TIME COMPLETE : 5:40 pm						
DATE : 28-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
GEL FILLING						
TIME START : 2:55 pm						
DATE : 28-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
TIME COMPLETE : 5:40 pm						
DATE : 28-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
SEALING AND CUTTING GEL TUBE						
TIME START : 2:55 pm						
DATE : 28-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
TIME COMPLETE : 5:40 pm						
DATE : 28-02-22	910	910	NIL	DEWI (1126)	Pashini 5:40 pm 28/02/22	9/5
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 10:00 am						
DATE : 01-03-22	903	903	NIL	ERA (932)	Pashini 4:20 pm 01/03/22	5/5
TIME COMPLETE : 4:20 pm						
DATE : 01-03-22	903	903	NIL	Ambiga (1129)	Pashini 4:20 pm 01/03/22	5/5
BOX PACKING & FINAL CONTROL						
TIME START : 10:50 am						
DATE : 01-03-22	903	903	NIL	ERA (932)	Pashini 4:20 pm 01/03/22	5/5
TIME COMPLETE : 4:20 pm						
DATE : 01-03-22	903	903	NIL	Ambiga (1129)	Pashini 4:20 pm 01/03/22	5/5
CARTON PACKING						
TIME START : 10:30 am						
DATE : 02-03-22	45 box 4 ctn	45 box 4 ctn	NIL	HERDI (1053)	Pashini 4:20 pm 01/03/22	5/5
TIME COMPLETE : 10:40 am						
DATE : 02-03-22	45 box 4 ctn	45 box 4 ctn	NIL	HERDI (1053)	Pashini 4:20 pm 01/03/22	5/5

QUANTITY PRODUCED	910 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3257 pcs
SHIPMENT QUANTITY PCS / CTNS :	900 pcs 45 box / 4 ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR):	Signature :	Approved by (QC):	Signature :
Name : KUNINSELEMAN	Date : 2/3/22	Name : MARTINI ROBINSON	Date : 3/3/2022



LABEL APPROVAL



Hydrocyn aqua[®] gel	
[REF]	HW40F900
[LOT]	B21426
Qty	20 pcs / box
Weight	15g / pc
VIGILENZ[®] MALAYSIA	




Doc. No.	PR-HR001
Rev.	04

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$$\therefore \frac{26}{22}$$

	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.	HN40F900 / B21426
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)
G1826022203	G13	9.42	comply	9900	✓	pass
G1826022204	G14	9.42	comply	9900	✓	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)
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	16.95 g	17.07 g	17.21 g	17.17 g	17.07 g	✓	pass
1/5	17.07 g	17.09 g	17.52 g	17.63 g	17.19 g	17.03 g	✓	pass
2/5	17.15 g	17.26 g	17.39 g	17.35 g	17.43 g	17.32 g	✓	pass
3/5	17.41 g	17.21 g	17.24 g	17.28 g	17.18 g	17.21 g	✓	pass
4/5	17.26 g	17.07 g	17.19 g	17.09 g	17.39 g	17.02 g	✓	pass
5/5	17.39 g	17.18 g	17.36 g	17.16 g	17.26 g	17.27 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
2/5	✓	✓	✓	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
2/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

G. Conclusion

Overall in – process inspection: (PASS / ~~FAIL~~)

Inspected By : Poly
 Name : POHNE
 Date : 01/08/2022

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

REF : HW40F900 QTY PRODUCED (pcs) : 903

LOT NO : B21426 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/P

Inspected By : Pony

Name : POSHI

Date : 10/2/2022

Approved By : M. J. J. J.

Name : MARTIN

Date : 3/3/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

DATE : 16/02/2022
REF : HW40F900
LOT NO. : B21426

SHOP PACKET QTY (pcs) : 900
CUSTOMER : VMD (MALAYSIA)
LO NO. : IO/VMD/110222/01

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(2 layers), Open End, Gloss Finishing	H022210902	pcs	910	910	1 Cayana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gsm	800	800	1 Cayana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Cayana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	1 Cayana
5	N/A	STOCK SOLUTION	N/A	C02602203 H08022204	ltr	20	20	1 Cayana

(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 Cayana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	1 Cayana
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23220101	1821	1 Cayana
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 Cayana
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	1 Cayana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1 Cayana
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 LRI50M/LRI50 (BC FLUTE)	H114211101	4	1 Cayana
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	1 Cayana
2		#N/A			

ISSUED BY (MM) :

Signature : 
Name : LOVIN
Date : 16/02/2022

VERIFIED BY (PR) :

Signature : 
Name : M. A. A. S. F. C. A. M.
Date : 27/3/22

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

Description	Hydrocyn Aqua, wound care 15g	Reference No.	HWP01900	Date of Inspection	03/03/2022
		Lot No.	B01420	Sample Size	2PCS 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)
✓	✓	✓	✓	✓	✓	9.71	comply
							PASS / FAIL
							PASS

✓ = Pass, X = Fail

Remarks: N/P

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : P. Jay
 Name : P. CHANE
 Date : 03/03/2022

Approved By : [Signature]
 Name : MARTIN
 Date : 3/3/2022

