

25/2



SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ISSUED DATE	14-Feb-22
ITEM CODE :	H0100016	LOT NO	B21424
ITEM :	Hydrocyn Aqua Wound Gel (15g)	MFG. DATE	14-Feb-22
		EXP. DATE	2023-08

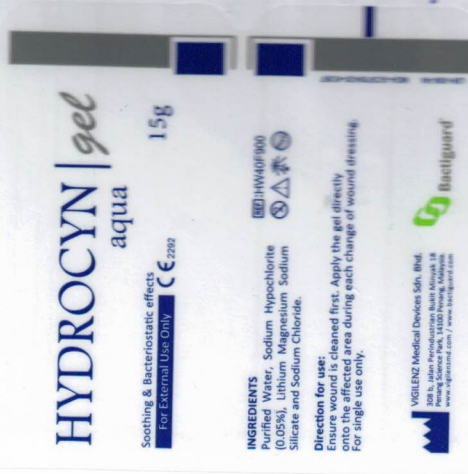
PROCESS		START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION							
TIME START :	12:30pm						
DATE :	23-02-22						
TIME COMPLETE :	12:38pm						
DATE :	23-02-22						
CHECK : pH / VISCOSITY / FAC							
PR-HR001 QC-HR003							
LABELLING GEL TUBE							
TIME START :	11:00 AM						
DATE :	23-02-22						
TIME COMPLETE :	3:40 PM						
DATE :	23-02-22						
GEL FILLING							
TIME START :	2:50 PM						
DATE :	23-02-22						
TIME COMPLETE :	5:30 PM						
DATE :	23-02-22						
SEALING AND CUTTING GEL TUBE							
TIME START :	2:50 PM						
DATE :	23-02-22						
TIME COMPLETE :	5:30 PM						
DATE :	23-02-22						
LOT NUMBER AND EXPIRY DATE PRINTING							
TIME START :	10:32						
DATE :	23-02-22						
TIME COMPLETE :	12:00 PM						
DATE :	23-02-22						
BOX PACKING & FINAL CONTROL							
TIME START :	5:30						
DATE :	23-02-22						
TIME COMPLETE :	2:00 PM						
DATE :	23-02-22						
CARTON PACKING							
TIME START :	2:40 PM						
DATE :	23-02-22						
TIME COMPLETE :	2:50 PM						
DATE :	23-02-22						

QUANTITY PRODUCED	910 PCS
QUANTITY FOR QC/RETAIN SAMPLE	3 PCS + 1 PCS
SHIPMENT QUANTITY PCS / CTNS :	900 PCS
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	PARTIAL

Checked by (PR),	Approved by (QC),
Signature : <i>P. Patel</i>	Signature : <i>P. Patel</i>
Name : <i>M. Nairaga</i>	Name : <i>M. Nairaga</i>
Date : <i>26/2/2022</i>	Date : <i>26/2/2022</i>



LABEL APPROVAL



HYDROCYN aqua gel 15g

Soothing & Bacteriostatic effects
For External Use Only **CE** 2292



HYDROCYN aqua gel



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.vigilenzmd.com / www.bactiguard.com

Bactiguard

VIGILENZ Medical Devices Sdn. Bhd.
308 b, Jalan Perindustrian Bukit Minyak, 18,
Penang Science Park, 14100 Penang, Malaysia.
www.vigilenzmd.com / www.bactiguard.com

HGBL-001-R3

MDA-GC9700420-45397

Page 26/2022




Page 25/2022

Hydrocyn aqua gel

[REF] HW40F900
[LOT] B21424
Qty 20 pcs / box
Weight 15g / pc

VIGILENZ
MALAYSIA

NA

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.	HW40400 / B01424
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)
B1B2302207	017	9.95	compy	9743	✓	pass
B1B2302208	018	9.95	compy	9745	✓	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

Title QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 2(3)

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	17.20 g	17.22 g	17.20 g	17.16 g	16.90 g	17.16 g	✓	pass
1/5	16.99 g	17.27 g	17.21 g	17.23 g	17.16 g	17.19 g	✓	pass
2/5	17.21 g	17.33 g	17.26 g	17.21 g	17.24 g	17.23 g	✓	pass
3/5	17.26 g	17.16 g	17.28 g	17.22 g	17.24 g	17.25 g	✓	pass
4/5	17.32 g	17.28 g	17.16 g	17.51 g	17.37 g	17.35 g	✓	pass
5/5	17.48 g	17.41 g	17.41 g	17.61 g	17.56 g	17.49 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

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)
4/c	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/c	✓	✓	✓	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 : Polly
 Name : ROSHNE
 Date : 25/2/2022

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

REF : H21401900 QTY PRODUCED (pcs) : 903

LOT NO : B21424 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/D

Inspected By :	Approved By :
Name :	Name :
Date :	Date :

Ray
Reshmi
26/2/2022

[Signature]
M A R T I N I
26/2/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

DATE : 16/02/2022
REF : HW-40F900
LOT NO. : B2142/4 44 d 22

SHOP PACKET QTY (pcs) : 900
CUSTOMER : VMD (MALAYSIA)
LO NO. : IOVMD/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(3 layers), Open End, Gloss Finishing	H022210902	pcs	910	910	'Gaujauq
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gsm	800	800	'Gaujauq
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	'Gaujauq
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gsm	20	20	'Gaujauq
5	N/A	STOCK SOLUTION	N/A		ltr	20	20	'Gaujauq

(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	'Gaujauq
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	'Gaujauq
3	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23220101	1821	'Gaujauq
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	'Gaujauq
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	'Gaujauq
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	'Gaujauq
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/MLR150 (BC FLUTE)	H114211101	4	'Gaujauq
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 : 16/02/2022

VERIFIED BY (PR) :
Signature :
Name :
Date : 20/2/2022

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	26/02/2022
		Lot No.	B21424	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)
✓	✓	✓	✓	✓	✓	9.60
						FAC (100 – 200 ppm)
						PASS / FAIL
						pass

✓ = Pass, X = Fail

Remarks: N/P

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : Pasji
 Name : Pasime
 Date : 26/2/2022

Approved By : [Signature]
 Name : KARTINI
 Date : 26/2/2022

