

22/2

VIGI EN

SHOP PACKET - HYDROCYN AQUA GEL

REF : 14W400-900	QTY : 900	ISSUED DATE : 14 Feb 22
ITEM CODE : 14100010	PACK SIZE : 20/BOX	LOT NO : B21422
ITEM : Hydrocyn Aqua Wound Gel (16g)	CUSTOMER : VMD	MFG. DATE : 14 Feb 22
	ORD. NO : B083	EXP DATE : 2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 12:25 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						
Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 2:00 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						
GEL FILLING						
TIME START : 2:20 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						
SEALING AND CUTTING GEL TUBE						
TIME START : 2:20 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 2:20 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						
BOX PACKING & FINAL CONTROL						
TIME START : 2:20 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						
CARTON PACKING						
TIME START : 2:50 PM						
DATE : 19/02/22						
TIME COMPLETE : 19/02/22						
DATE : 19/02/22						

QUANTITY PRODUCED : 830 PCS	QUANTITY FOR QC/RETAIN SAMPLE : 3 PCS	SHIPMENT QUANTITY PCS / CTNS : 820 PCS	FINAL SHIPMENT DATE : 23/02/22	COMPLETE/PARTIAL : COMPLETE
<p>SHORT CLOSE QTY: 80PCS not enough</p>				
<p>Checked by (PR): <i>[Signature]</i> Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : <i>[Date]</i></p>		<p>Approved by (QC): <i>[Signature]</i> Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : <i>[Date]</i></p>		



LABEL APPROVAL



HYDROCYN[®] | gel
aqua 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

MDA-GC9700420-45397

HGBL-001-R3

9 555468 912422

LOT: B21422

EXP: 2023-08

MDA: HW40F900

Icons:

Hydrocyn aqua[®] gel

HW40F900

B21422

20 pcs / box

Weight 15g / pc.

VIGILENZ[®]
MALAYSIA

Not in
22/1/22


My Signat
22/2/22

Signature
22/2/22



✓
22/2/22

— N/A —

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.	HLWHPF900 / B21422
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)
G1819022207	G17	9.79	comply	9019	✓	pass
G1819022208	G18	9.79	comply	9019	✓	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		Bactiguard®	
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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	17.72 g	17.72g	17.75g	17.75 g	17.73 g	17.73g	✓	
1/5	17.67 g	17.66g	17.52 g	17.57 g	17.66 g	17.62g	✓	
2/5	17.54 g	17.70g	17.43 g	17.43 g	17.60g	17.54g	✓	
3/5	17.36 g	17.47g	17.39 g	17.45 g	17.67 g	17.47g	✓	
4/5	17.50 g	17.47g	17.52g	17.39 g	17.43 g	17.46g	✓	
5/5	17.49 g	17.46g	17.55g	17.44 g	17.57g	17.50g	✓	
							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)
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 : Raj
 Name : Roshini
 Date : 22/3/22

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

REF : HW401900 QTY PRODUCED (pcs) : 903

LOT NO : B21422 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 : Poly
 Name : ROSELINE
 Date : 22/2/22

Approved By : [Signature]
 Name : MARTINI
 Date : 22/2/2022

RAW MATERIAL LOADING FORM (RMLF)

DATE : 16/02/2022

REF : HW40F900

LOT NO. : B21422

SHOP PACKET QTY (pcs) : 900

CUSTOMER : VMD (MALAYSIA)

LO NO. : IOVMD/110222/01

PR-RM001

Rev. 06

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	gm	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	gm	20	20	20	1 Canjaya
5	N/A	STOCK SOLUTION	N/A	61819023307 61819023308	ltr	20	20	20	1 Canjaya


(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 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)	LB23220101	1821	1 Canjaya

(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 LRI 50/M/LRI 50 (BC FLUTE)	HI 14211101	4	naheem
2		#N/A			
3		#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	1 Canjaya
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			


ISSUED BY (MM) :

Signature : 

Name : LOVIN

Date : 16/02/2022

VERIFIED BY (PR) :

Signature : 

Name : RANU ARIE CAZMI

Date : 26/02/22

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

Description	Hydrocyn Aqua Wound Gel Tube (15g)	Reference No.	HU040F900	Date of Inspection	22/02/2022
		Lot No.	B21422	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)	FAC (100 – 200 ppm)
✓	✓	✓	✓	✓	✓	9.62	comply
							PASS / FAIL
							pass

✓ = Pass, X = Fail

Remarks: N/D

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Day
 Name : Reshmi
 Date : 22/2/22

Approved By : [Signature]
 Name : MARTINI
 Date : 22/2/2022

