

SHOP PACKET - HYDROCYN AQUA GEL

REF :	HW40F900	ODR. QTY :	760	ISSUED DATE	15-Jan-22
ITEM CODE :	H01000016	PACK SIZE :	20/BOX	LOT NO	A21523
ITEM :	Hydrocyn Aqua Wound Gel (15g)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	15-Jan-22
		ORD. NO	A119	EXP DATE:	2023-07

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START:	770	770	Nil	Sardh (102)	Wch 1:59 pm 28-01-22	2/2
DATE:						
TIME COMPLETE:						
DATE:						
CHECK: pH / VISCOSITY / FAC Relier attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START:	770	770	Nil	Khin (647)	Wch 5:40 pm 28-01-22	5/5
DATE:						
TIME COMPLETE:						
DATE:						
GEL FILLING						
TIME START:	770	770	Nil	Viki (1094)	Wch 6:45 pm 29/01/22	5/5
DATE:						
TIME COMPLETE:						
DATE:						
SEALING AND CUTTING GEL TUBE						
TIME START:	770	770	Nil	Farah (1051)	Pdmini 5:45 pm 29/01/2022	5/5
DATE:						
TIME COMPLETE:						
DATE:						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START:	763	763	Nil	122041 (1106)	Pdmini 3:37 pm 3-2-2022	5/5
DATE:				Sardh (1102)		
TIME COMPLETE:						
DATE:						
BOX PACKING & FINAL CONTROL						
TIME START:	763	763	Nil	Huang (1049)	Wch 4:30 pm 3-2-2022	Refer FCTR
DATE:				Sardh (1102)		
TIME COMPLETE:						
DATE:						
CARTON PACKING						
TIME START:	38 box 4ethn	38 box 4ethn	Nil	Fahri (1054)	Jinda 04/02/2022	04/02/2022
DATE:						
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED	770 pcs
QUANTITY FOR QC/RETAIN SAMPLE	325 + 7 pcs
SHIPMENT QUANTITY PCS / CTNS :	760 pcs 38 box / wch
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR),	Signature : <i>[Signature]</i>
Name :	PRATIKA MANI
Date :	01/2/22
Approved by (QC),	Signature : <i>[Signature]</i>
Name :	HAATIWI RAGIMPA
Date :	4/2/2022



LABEL APPROVAL

HYDROCYN | *gel*
aqua 15g

Soothing & Bacteriostatic effects
For External Use Only

INGREDIENTS
Purified Water, Sodium Hypochlorite
(0.05%), Lithium Magnesium Sodium
Silicate and Sodium Chloride.

DIRECTION FOR USE:
Ensure wound is cleaned first. Apply the gel directly
onto the affected area during each change of wound dressing.
For single use only.



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

MDA-GC9700420-45397



9 555468 912422

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.viglenzmd.com / www.bactiguard.com

LOT: A21523
EXP: 12/2023-07

HYDROCYN
aqua
gel

HYDROCYN
aqua
gel

Soothing & Bacteriostatic effects

For External Use Only

CE 2292

15g



Bactiguard VIGILENZ

HGBL-001-R3

MDA-GC9700420-45397

HW40F900



3.2.1
1/2023

NA

Hydrocyn aqua[®] gel

[REF]

HW40F900

[LOT]

A21523

Qty

20 pcs / box

Weight

15g / pc

VIGILENZ[®]
MALAYSIA




NA
25/1/22

NA
25/1/22

cc 10.10.2023
40037



A21523 01/243

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.	Hw40F900 / A21523
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)
6B28012203	613	9.97	comply	9829	✓	pass
6B28012204	614	9.97	comply	9829	✓	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

File:


QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
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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	17.57 g	17.45 g	17.59 g	17.54 g	17.57 g	17.549	✓	pass
1/5	17.47 g	17.51 g	17.40 g	17.39 g	17.50 g	17.459	✓	pass
2/5	17.00 g	17.75 g	17.63 g	17.25 g	17.53 g	17.489	✓	pass
3/5	17.73 g	17.37 g	17.56 g	17.53 g	17.36 g	17.519	✓	pass
4/5	17.45 g	17.30 g	16.73 g	17.01 g	17.34 g	17.169	✓	pass
5/5	17.63 g	17.34 g	17.48 g	17.16 g	17.63 g	17.449	✓	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 : Woh
 Name : Woh woh
 Date : 3.2.2022

VIGILENZ®

FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

Doc. No. QC-FC006

Rev. 03

REF

H1640 F900

QTY PRODUCED (pcs) :

770

LOT NO

A21523

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

Wach

Name

Wach Wach

Date

3.2.2022

Approved By

Wach Wach

Name

Wach Wach

Date

3/2/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

19/01/2022
HW40F900
A21523

SHOP PACKET QTY (pcs) :

760

RS 10

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, Glass Finishing	H022210902	pcs	770	770	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	GR808012203 GR828012204	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	771	Kanjana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	771	Kanjana
3	P0100349	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB2321201	1541	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	771	Kanjana
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	38	Kanjana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	38	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 LRI 500M/LRI 150 (BC FLUTE)	H114210801/2	3	Kanjana
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)		N/A	
2		#N/A			

ISSUED BY (MM) :

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

VERIFIED BY (PR) :

Signature :
Name :
Date :

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

Description	Hydrocyn Aqua Wound Gel (15g)	Reference No.	Hlu 40 F 900	Date of Inspection	4.02.2022
		Lot No.	A 21523	Sample Size	2 x 15 g

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)
✓	✓	✓	✓	✓	✓	9.77	comply
							Pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : Wah
 Name : Wah Wah
 Date : 4.02.2022

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

