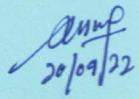


SHOP PACKET - GEL TUBE

REF : HW41F900	ODR. QTY : 60	RS: 3 + QC: 6	ISSUED DATE : 12/09/2022
ITEM CODE : H0100044	PACK SIZE : 20/Box	LOT NO	121204
ITEM : Hydrocyn Aqua Gel Tube, 30g	CUSTOMER : VMD	MFG. DATE	12/09/2022
	ORD. NO : 1071	EXP DATE	2024-03

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCCYN AQUA GEL PREPARATION						
TIME START : 3:50 PM DATE : 12-09-22	69	69	NIL	IRMA	SYAMINI 12/09/2022	2/2
TIME COMPLETE : 3:58 PM DATE : 12-09-22						
CHECK : pH / Refer attachment: VISCOSEITY / FAC PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 10:13 AM DATE : 13-09-22	69	69	NIL	YATI 1157	HANA 13/09/2022	5/5
TIME COMPLETE : 10:50 AM DATE : 13-09-22						
GEL FILLING						
TIME START : 3:15 PM DATE : 13-09-22	69	69	NIL	IRA YATI	HANA 13/09/2022	5/5
TIME COMPLETE : 3:40 PM DATE : 13-09-22						
SEALING AND CUTTING GEL TUBE						
TIME START : 3:15 PM DATE : 13-09-22	69	69	NIL	IRA YATI	HANA 13/09/2022	5/5
TIME COMPLETE : 3:40 PM DATE : 13-09-22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 10:30 AM DATE : 14-09-22	63	63	NIL	LIANA	DEVA 14/09/2022	5/5
TIME COMPLETE : 10:45 AM DATE : 14-09-22						
BOX PACKING INSERT IFU & FINAL CONTROL						
TIME START : 10:45 AM DATE : 14-09-22	63	63	NIL	AZIAH 1167	DEVA 14/09/2022	Refer: FCTR
TIME COMPLETE : 11:10 AM DATE : 14-09-22						
CARTON PACKING						
TIME START : 2:30 P.M DATE : 20-09-22	3 BOX 1 CTN	3 BOX 1 CTN	NIL	Rabin (1088)	KIRAH 20/09/2022	 20/09/22
TIME COMPLETE : 2:40 P.M DATE : 20-09-22						

QUANTITY PRODUCED

69

QUANTITY FOR QC / RETAIN SAMPLE

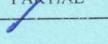
RS: 3+6

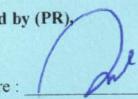
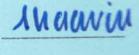
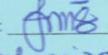
SHIPMENT QUANTITY PCS / CTNS

60 / 2 BOX
1 CTN

FINAL SHIPMENT DATE

COMPLETE/ PARTIAL

COMPLETE  PARTIAL

Checked by (PR), Signature :  Name : MULFIYA KHALID 22/09/2022	Released by (QC), Signature :  Name : SHAAMIM 22/09/2022	Approved by (QA), Signature :  Name : BISHANNA OLEMAN Designation : QM8 Manager Date: 22/09/2022
Remarks:		



LABEL APPROVAL

HYDROCYN | *gel* aqua

Soothing & Bacteriostatic effects
For External Use Only

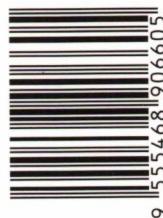
30g

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.

Bactiguard®
 Bactiguard Medical Devices Sdn. Bhd.
308 b, Jalan Perindustrian Batu Melayu 18
Penang Science Park, 14100 Penang, Malaysia.
www.vigilenzmd.com / www.bactiguard.com

HYDROCYN aqua *gel*



MDA-GC9700420-45397
HBL-002-R1

Manufactured by
VIGILENZ Medical Devices Sdn. Bhd.
(a subsidiary of Bactiguard)
308 b, Jalan Perindustrian Batu Melayu 18,
Penang Science Park, 14100 Penang, Malaysia.
www.vigilenzmd.com / www.bactiguard.com

REF : 124204
LOT : 2024-03
REF : HW41F900 ☒ △ ☺

14/09/2022

WOUND
gel

HYDROCYN
aqua

Soothing & Bacteriostatic effects
For External Use Only

30g

Bactiguard VIGILENZ®

Jugumai
14/09/2022

Hydrocyn aqua® *gel*

REF	HW41F900
LOT	121204
Qty	20 pcs / box
Weight	30 g / pc
VIGILENZ®	
MALAYSIA	

Hydrocyn aqua® *gel*

13/09/2022

(III) RECORDS OF PREPARATION

Medium Type
1000N

(iii) RECORDS OF PREPARATION		Bacitguard	Page: 1(1)
Functional Title	Doc Id: PR-HR001-05	Issue Date: 04/07/2022	
FORM			

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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

Document type: FORM	Doc Id: QC-IP004-02	Issue Date: 07/07/2022	Page: 1(3)
Title: QC IN-PROCESS INSPECTION RECORD – GEL TUBE	 Bactiguard		

Reference / Lot No.	Hwy1FG00 / Hwy
Order Qty.	60

A. Before Filling

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

QC IN-PROCESS INSPECTION RECORD – GEL TUBE

Document type:
FORM

Doc Id:
QC-IP004-02

Bactiguard

Issue Date:
07/07/2022

Page:
2(3)

C. Filling Process

Sampling / Frequency	Weight of Sample					Leak Test	Test disposition (PASS / FAIL)
	1	2	3	4	5		
5/5	32.73	32.63	32.67	33.30	32.82	32.83	pass
1/5	32.69	32.69	32.83	32.67	32.66	32.71	pass
3/5	32.69	32.77	32.81	32.72	32.69	32.71	pass
5/5	33.16	33.22	32.58	32.14	32.98	32.81	pass
4/5	33.01	32.07	32.62	32.99	32.76	32.89	pass
5/5	32.10	32.85	33.30	32.78	33.03	33.01	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)
✓	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

Title: QC IN-PROCESS INSPECTION RECORD – GEL TUBE

Document type:
FORM

Doc Id:
QC-PP004-02

Issue Date:
07/07/2022

Page:
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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 IFU in the primary box	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 : Dev A
Name : DEVA
Date : 20/7/22

Reviewed By : martini
Name : MARTINI
Date : 22/09/2022

FINAL CONTROL TEST REPORT : GEL TUBE

Instrument Type:
FORMDoc Id:
QC-FC006-04Issue Date:
07/07/2022Page:
1(1)

REF	<u>HW41F900</u>	Sampling Details	Sample Size	AQL	Results	Status
LOT NO	<u>I-1204</u>	No	Sampling Criteria	Accept	Reject	(PASS/FAIL)
		1	Legible and correct printing of label.	S3,0,15	<u>69</u>	<u>0</u>
		2	Availability of Hologram and Secure Sticker.	S3,0,15	<u>69</u>	<u>0</u>
		3	Availability of IFU inside the inner box	S3,0,15	<u>N/A</u>	
		4	Free from contamination, deformed or damaged on packaging.	S3,0,15	<u>69</u>	<u>0</u>
		5	Proper sealing and no leakage.	S3,0,15	<u>69</u>	<u>0</u>
		6	Correct quantity in secondary box packaging.	S3,0,15	<u>69</u>	<u>0</u>

REF

LOT NO

QTY PRODUCED (pcs)

RETAIN SAMPLE QTY (pcs)

693

No	Inspection Criteria	Sampling Details	Sample Size	AQL	Accept	Reject	Accept	Reject	Status
1	Legible and correct printing of label.	S3,0,15	<u>69</u>	<u>0</u>	<u>1</u>	<u>69</u>	<u>0</u>	<u>Pass</u>	
2	Availability of Hologram and Secure Sticker.	S3,0,15	<u>69</u>	<u>0</u>	<u>1</u>	<u>69</u>	<u>0</u>	<u>Pass</u>	
3	Availability of IFU inside the inner box	S3,0,15		<u>N/A</u>					
4	Free from contamination, deformed or damaged on packaging.	S3,0,15	<u>69</u>	<u>0</u>	<u>1</u>	<u>69</u>	<u>0</u>	<u>Pass</u>	
5	Proper sealing and no leakage.	S3,0,15	<u>69</u>	<u>0</u>	<u>1</u>	<u>69</u>	<u>0</u>	<u>Pass</u>	
6	Correct quantity in secondary box packaging.	S3,0,15	<u>69</u>	<u>0</u>	<u>1</u>	<u>69</u>	<u>0</u>	<u>Pass</u>	

Remarks : N/AInspected by : Na
Name : No Fahana
Date : 20/09/2022Reviewed by : Martini
Name : Martini
Date : 20/09/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

DATE :	12/09/2022
REF :	HW41F900
LOT NO. :	121204

SHOP PACKET QTY (pes) : 60
 CUSTOMER : VMD (MALAYSIA)
 LO NO. : 10VMD/060922/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		CONSUMPTION	RECEIVED BY
							ISSUED	RECEIVED		
1	P0100725	30g Tubes with D30 White Color Screw-on Cap	Diameter 30 x 90 mm, White Colour Tube + neck, 5mm Tuf Orifice with Aluminium Foil Seal, Open End	H03G210301	pcs	69		69	69	<i>dz</i>
	P0100804	White Nozzle Cap (FOR 30, 50 & 100g GEL TUBE)		H12G210701	pcs	138		138	138	<i>dz</i>
2	C0100026	RHEOLOGICAL ADDITIVE (SUBBENT MP)	-	H080210801	gm	800		800	800	<i>dz</i>
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200		200	200	<i>dz</i>
4	C010024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20		20	20	<i>dz</i>
5	N/A	STOCK SOLUTION	N/A	618100092007	ltr	20		20	20	<i>dz</i>

(2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	ITEM DESCRIPTION 1			RECEIVED BY
						NO.	SYSTEM CODE	ITEM DESCRIPTION 1	
1	P0100758	LBH-012-R0 Tube Label 30g - 75mm x 90mm; Gloss Clear PE; Permanent; 4 colors (Roll)	LBEN3211101	70	<i>dz</i>	1	P0100661	Gel Carton - (L)388mm X (W)293mm X (H)305mm LR150/MLR150 (BC FLUTE)	H114210401
2	P0100848	"Secure-Secure" Round Sticker for Gel Tube (20mm)-Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22220101	139	<i>dz</i>	2	P0100767	POF Shrink Film CF; Size: 12mic x 12" x 1667m; - 1 rolls/carton, 5 Layer with perforation	
3	P0100806	LDPE ZIPPER BAG; Size: 0.05mm x 2" (opening) x 3' (L) - USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	70	<i>dz</i>	3		#N/A	
4	P0100870	BBWC003-EN-RL; V09-BX028-00 BWC GEL INNER BOX 30G ENGLISH-310GSM 1 SIDE ART CARD: 62 X 31 X 109MM; 4C; GLOSS LAMINATION	BEN2211101	70	<i>dz</i>				
5	P0100786	V09-BX020-00 - Hydrogen Gel 30g (outer box) - 300gsm 1 Side Art Card: 146 x 110 x 183mm	PH01210702	70	<i>dz</i>	1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	
6	P0100208	BLANK LABEL (Shraps Pad/ Gauze/ Gel) SIZE: 8.5mm X 6.5mm	L190211201	6	<i>dz</i>	2		#N/A	#N/A

ISSUED BY (MM) :

Signature : *LOVIN*
 Name : *LOVIN*
 Date : 12/09/2022

VERIFIED BY (PR) :

Signature : *Muthu April*
 Name : *Muthu April*
 Date : 02/09/2022

Title: PRODUCT RELEASE TEST REPORT – GEL TUBE

Document type:
FORM

Doc Id:
QC-PC008-03

Issue Date:
04/07/2022

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Description	Hydrocyn Aqua Gel , 30g	Reference No.	Hw41Fq00	Date of Inspection	22/09/2022
Lot No.	T21204	Sample Size	1 pcs x 30g		

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)
						Instrument no.: QC-78	PASS / FAIL
						Calibration due date: 10/10/2022	Expiry date: 10-2024
						9.53	200
							Pass

✓ = Pass, X = Fail

Remarks : N/A

CONCLUSIONS: RELEASE ON-HOLD

Inspected By : Nor Fahana
 Name : Nor Fahana
 Date : 22/09/2022

RELEASE ON-HOLD

Approved By : Martin
 Name : Martin
 Date : 22/09/2022

