

28/2

SHOP PACKET - HYDROCYN AQUA GEL

REF 1 : HW40F900	ODR. QTY : 900	RS 3 + 7 (QC TEST)	ISSUED DATE : 14-Feb-22
ITEM CODE : H0100016	PACK SIZE : 20/BOX		LOT NO : B21429
ITEM : Hydrocyn Aqua Wound Gel (15g)	CUSTOMER : VMD		MFG. DATE : 14-Feb-22
	ORD. NO : B090		EXP DATE : 2023-08

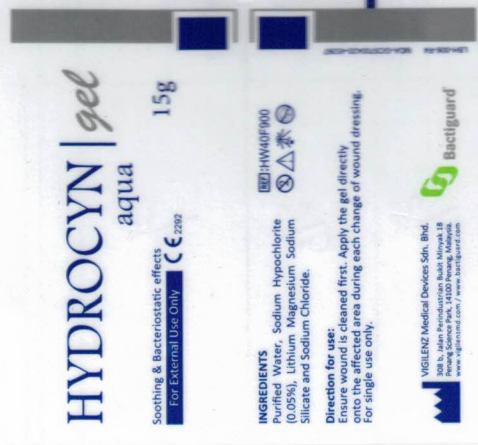
PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 1:35pm	910	910	NIL	DEWI (1126)	Pashini 14:3 pm 26/02/2022	2/0
DATE : 216-03-22						
TIME COMPLETE : 1:43pm						
DATE : 216-03-22						
CHECK : pH / VISCOSITY / FAC Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 9:40 am	910	910	NIL	hashini (1117)	boah 01/03/22	5/5
DATE : 011-03-22						
TIME COMPLETE : 11:00 am						
DATE : 011-03-22						
GEL FILLING						
TIME START : 3:05pm	910	910	NIL	INA (1131)	Pashini 01/03/22	5/5
DATE : 011-03-22						
TIME COMPLETE : 5:35pm						
DATE : 011-03-22						
SEALING AND CUTTING GEL TUBE						
TIME START : 3:05pm	910	896	14	FARAH (1051)	Pashini	-14 Tube reaching the set replace with new Tube
DATE : 011-03-22						
TIME COMPLETE : 5:35 pm						
DATE : 011-03-22						
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 3:08pm	903	903	NIL	Ambiga (1129) RINA (1136)	luch 02/03/22	5/5
DATE : 022-03-22						
TIME COMPLETE : 4:15pm						
DATE : 022-03-22						
BOX PACKING & FINAL CONTROL						
TIME START : 4:25pm	903	903	NIL	Ambiga (1129) RINA (1136)	luch 02/03/22	Refer FCTR
DATE : 022-03-22						
TIME COMPLETE : 5:20pm						
DATE : 022-03-22						
CARTON PACKING						
TIME START : 12:20pm	45 box 4ctn	45 box 4ctn	NIL	Rabin (1088)	Junno- 02/03/22	5/5 03/03/2022
DATE : 022-03-22						
TIME COMPLETE : 12:30pm						
DATE : 022-03-22						

QUANTITY PRODUCED	910 pcs
QUANTITY FOR QC/RETAIN SAMPLE	3 pcs + 7 pcs
SHIPMENT QUANTITY PCS / CTNS	900 pcs 45 box / 4ctn
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR), Signature : <i>[Signature]</i>	Approved by (QC), Signature : <i>[Signature]</i>
Name : KUNINGKARIN	Name : MARTINI
Date : 3/3/22	Date : 4/3/2022



LABEL APPROVAL



Wound
1/3/22

✓
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Hydrocyn aqua[®] gel

[REF] HW40F900
[LOT] B21429
Qty 20 pcs / box
Weight 15g / pc

VANI
2/3/22
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Wound
1/3/22

VIGILENZ[®]

HYDROCYN aqua® GEL - RECORDS OF PREPARATION

Doc. No.	PR-HR001
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Rev. 04

Date _____

26/2/2022

	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.	HW40F900 / B21429
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)
G1B2602209	G9	9.81	comply	9945	✓	pass
G1B2602210	G110	9.81	comply	9945	✓	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

Title: 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	17.06 g	16.98 g	16.95 g	17.21 g	17.63 g	17.16 g	✓	pass
1/5	17.21 g	17.39 g	17.18 g	17.17 g	17.21 g	17.23 g	✓	pass
2/5	17.31 g	17.17 g	17.62 g	17.08 g	17.02 g	17.24 g	✓	pass
3/5	17.45 g	17.15 g	17.21 g	17.18 g	16.95 g	17.18 g	✓	pass
4/5	17.17 g	17.39 g	17.39 g	17.01 g	16.98 g	17.18 g	✓	pass
5/5	17.09 g	17.45 g	17.07 g	16.98 g	17.42 g	17.20 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	
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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 : Poly
 Name : PESHNE
 Date : 01/12/2022

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

REF : HW40F900 QTY PRODUCED (pcs) : 903

LOT NO : B21429 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	:	<u>Wah</u>	Approved By	:	<u>[Signature]</u>
Name	:	<u>Wah Wah</u>	Name	:	<u>MARTINI</u>
Date	:	<u>02/03/22</u>	Date	:	<u>3/3/2022</u>

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

DATE : 16/02/2022
REF : HW40P900
LOT NO. : B21429

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

RS 10

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 Kanyana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	grm	800	800	1 Kanyana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1 Kanyana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	grm	20	20	1 Kanyana
5	N/A	STOCK SOLUTION	N/A	61B2602209 61B2602210	ltr	20	20	1 Kanyana

(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 Kanyana
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	911	1 Kanyana
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 Kanyana
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 Kanyana
5	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	1 Kanyana
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	1 Kanyana
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 50M/LRI 50 (BC FLUTE)	H114211101	4	1 Kanyana
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 : LATINUSRECATAN
Date : 2/3/22

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

Description	Hydrocyn Aqua Wound Gel	Reference No.	HW405900	Date of Inspection	02/03/2022
	Tube (15g)	Lot No.	B31429	Sample Size	2PCS x 15g

Release Criteria:

Correct and legible printing of label	Packing Integrity			Visual Inspection	Chemical Testing		Test Disposition
	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)	
✓	✓	✓	✓	✓	✓	9.67	comply
							pass

✓ = Pass, X = Fail

Remarks: NA

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : Ray
 Name : ROSHNI
 Date : 02/03/2022

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

