VIGILENZ®

24/01/2622 -5 pcs tube reject replace Jos 2 - 0-4 with new Cabe RESULTS Rober FCTR 2/2 3/5 1 3 A21616 15-Jan-22 5-Jan-22 2040-01 40x 10/b1 6601/10/01 8 601/10/18 23/01/2021 riopin wy 1.50pm 4.30 DM Fostini 8.00pm 1.30pm 110c/2017 ad 91.5 APPROVAL Roshin Restmi Roshin Roshin ISSUED DATE Roshmi - White MFG. DATE EXP DATE: LOT NO RS 3 + 7 (QC TEST) Sarah (102) OPERATOR Netra (1103) (ra (782) FASLI (1054 HEEDI (1653) (ra (832) (1089) Chandra 1 aghe FARAH (1601) SHOP PACKET - HYDROCYN AQUA GEL VMD (MALAYSIA) REJECT TUBE 201 N 000 -010 Vi! 51 7.2 Ē 5 20/BOX A111 45 b 6X 900 +5 4040 OUTPUT TUBE 903 903 910 25 910 9110 ODR. QTY: CUSTOMER ORD. NO START QTY TUBE 45 box 4 chn 903 903 PH P 016 910 016 960 Hydrocyn Aqua Wound Gel (15g) 2 : 6 5 pm 21-01-22 20-06-22 10:15 qm 21-01-22 2 (- 0 (- 2 2 22-01-22 6 7 2 2 4 -0 1 -22 1 9 - 0 1 - 32 26 -01 -2 2 2 - 0 (- 2 1 1:00 pm 3:00 pm 10:15 am 30 pm 2:00 pm 00 00 1 0 - 6 1 5:15 pm 5:10 pm Refer attachment: PR-HR001 QC-HR003 2 2 - 0 1 0 DATE PRINTING HW40F900 H0100016 10 HYDROCYN AQUA GEL PREPARATION PROCESS 7 EALING AND CUTTING GEL TUBE OX PACKING & FINAL CONTROL CHECK: pH / VISCOSITY / FAC OT NUMBER AND EXPIRY QUANTITY PRODUCED ABELLING GEL TUBE CARTON PACKING (4) 22 TIME COMPLETE FIME COMPLETE IME COMPLETE : TIME COMPLETE IME COMPLETE IME COMPLETE TIME COMPLETE ITEM CODE IME START: IME START: IME START TIME START TIME START **LIME START** IME START TEM DATE: DATE:

Approved by (QC) Signature : Name Date Memoriala 24(1/20)2 Checked by (PR), Signature: Name Date

Schools Brings

RELEASED

Bull

100 pcs COMPLETE

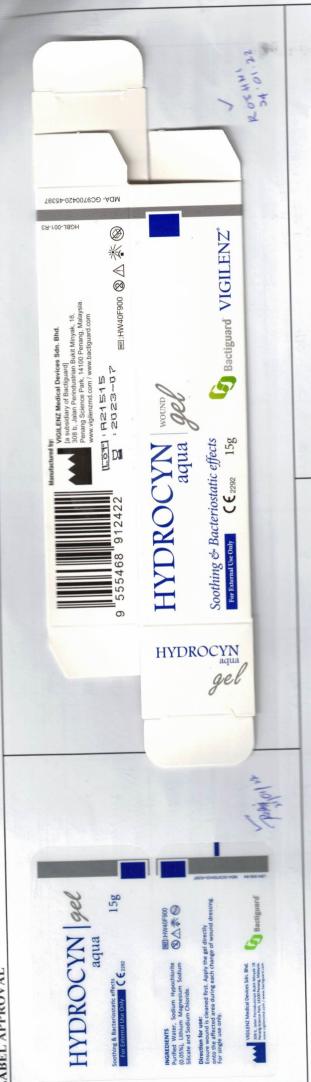
PARTHAI

3 45 +7 008 QUANTITY FOR QC/RETAIN SAMPLE SHIPMENT QUANTITY PCS FINAL SHIPMENT DATE

COMPLETE/PARTIAL :

VIGILENZ® MEDICAL DEVICES







HW40F900 Oty 20 pcs / box Weight 15g / pc Oth Color

troil 10 1 to Most

VIGILENZ®



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Doc. No: PR-SP013 Rev:01

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HYDROCYN aqua® GEL - RECORDS OF PREPARATION

PR-HR001	04
Doc. No.	Rev.

1/13
0/61

Date

	Equipr	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 Hyphochlorite (ml)	30.0 ± 0.05	200.0 ± 0.5
PDV Salt (g)	3.0 ± 0.1	20.0 ± 0.1

	Checked	Ву	Just		aprillo	- SPERIO			He v		
	Prepared	άq	CIOSI)								
	Time	End	6:18 pm								
alt	Tin	Start	Billipm								
PDV Salt	A ma count (ce)	Amount (g)	бое								
	Speed	(rpm)	1500	*							
	16	End	P:14pm								
pochlorite	Time	Start	513pm				4X				
Sodium Hypochlorite	Amount (m)	(mi) minomix	lmooc				1				
	Speed	(rpm)	0051								
cate	ne	End	5:13pm								
n Sodium Sili	Time	Start	E:10pm						1		
Lithium Magnesium Sodium Silicate	Amount (a)	(g) mnome	6008								
Lithi	Speed	(rpm)	1500						\	7 3	
Duniffod	Water (I.)		700								
Position on t	Equipment	1	HSM-01					34	F. S.		
	No. Batch No.		618 190123 HSM-01								
	No.		~		*						

Title: QC IN-PROCESS INSPECTION RECORD — HYDROCYN aqua GEL		Bactiguard	
Document type:	Doc Id:	Issue Date:	Page:
FORM	QC-IP004-01	15/11/2021	1(3)

Reference / Lot No.	and John H	1931515
Order Qty.		900

A. Before Filling

Test disposition (PASS / FAIL)	22 mg	boks ,		
Gel is clear and free from contamination (7	7		
Viscosity (8,000 – 10,000 cps)	bohb	bohb		
FAC (100 – 200 ppm)	Kidwas	compix		
pH (9.00 – 10.50)	4.43	61.13	Na	
Container No.	643	644		
Batch No.	61819012203	Grangensoy		

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)
3/8	7	>	7	pass
1/5	7	5	7	pass
3/5	7	7	7	pacs
3/5	7	1	>	pass
3/4	\	7	7	Page
3%	7	,	2	pass

Bactiguard	lssue Date: Page: 15/11/2021 2(3)
QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL	FORM QC-IP004-01

C. Filling Process

	Wei	ight of	Weight of Sample				
-	$Specification:\ 15g\ (16.5-17.8g)\ /\ 30g\ (31.6-33.3g)\ /\ 50g\ (51.9-53.4g)\ /\ 100g\ (102.8-104.7g)$	1.6 – 33.	.3g) / 50g (51.9-	53.4g) / 100g (10)	2.8 - 104.7g	Leak Tost	Test disposition
	2 3		4	S.	Average		(PASS/FAIL)
	8.91 630.21	608	6 28.31	16.999	brb.91	7	27.6
	15.91 608.91	639	17.14.389	61c.El	16.969.	5	2500
	17.369 17.2	600.	6 co.f1	618.91	666.91	7	06.55
	16.569 16.7	6 tt.	69c. £1	bbt.91	618.91	, 2	2000
	17.019 16.6	689.	17.269	16.759	17.089	2	Puss
	9.91 6 £s.91	669.91	6 68.91	6 hs. £1	646.91)	8500

Want was

D. Sealing and Cutting

Test disposition (PASS / FAIL)	DACK	(60)	pass	taks take	pars	Dass
Leak Test	1	,)	1		į ,) }
Seal Width Specification: (15g: 4-6mm) (30g/ 50g/ 100g: 6-8mm)	3	5	5	1	>	2
Lot no. and expiry date on tube is correct as in Shop Packet and legible	7	,	1	1	7	1
No sharp edge and not slanted after sealing and cutting	>	>	1	7	7	2
Sealing is intact	7	7	7	2	7	7
Sampling / Frequency	5/5	1/18	3/5	3/5	4/15	3/5

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

E. Printing on Primary Packaging

	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	8	5		51/0
1/5	5	5		1007
3/8	>			(LAN)
			>	DUMA
3/5			5	/ pines
s/h	5.		5	5700
8	`	`	,	1001

F. Primary Packaging

Test disposition (PASS / FAIL)	Sood	DAILOC	Chand	pars	/ pass	Jan de la constitución de la con	MAS	DUR
Test d (PAS)								
Presence of hologram sticker on the primary box	5			5	5	•	3	1
Presence of secure stickers on both opening hologram sticker sides of the primary box	5	5		5		1		>
Special requirement printing is clear and legible	5	5		S	1	2		>
Ref. no., lot no. and expiry date on primary box is correct and legible	>	1		5	>	5		`
Product is properly pack in primary packaging	7	2	2		2	>	1	2
Sampling / Frequency	sk	1/5	2/5	2	3/5	. 5/4	T	3/5

G. Conclusion

Overall in – process inspection: (PASS / FAIE)

Inspected By: Posmile

Name : Posmile

Date : allogue

3 of 3

VIGILENZ®

FINAL CONTROL TEST REPORT: HYDROCYN aqua® GEL

QC-FC006 03 Doc. No. Rev.

Hw40Fgood

D31515

LOT NO

REF

QTY PRODUCED (pcs)

910

RETAIN SAMPLE QTY (pcs)

								-
				AQL		Res	Results	Status
Z	Inspection Criteria	Sampling Details Sample Size-	Sample Size	Accept	Reject	Accept Reject	Reject	(PASS/FAI
7							•	
	1 I wild and correct printing of label.	S3,0.15	80	-2	©	8		SSID
_	Legible and correct princing of							
	2 Availability of Hologram and Secure Sticker.	\$3,0.15	&		0	&	0	ball
4	Availability of Hotogram area							
	Free from contamination, deformed or damaged on	S3,0.15	80	1	0	8	٥	bass
-1	nackaging.					-		
	The second and the leakage	S3,0.15	8	-	0	8	0	paes
7	4 Proper sealing and no rearage:							

5800

0

08

0

80

\$3,0.15

Remarks:

W/A

Correct quantity in secondary box packaging.

5 cos/10/116 DOSHNIE

Inspected By

Name Date

Approved By Name

MARTINI

24/01/2022

Date

RAW MATERIAL LOADING FORM (RMLF)

PR-RM001	90
Doc. No.	Rev.

19/01/2022	HW40F900	A21515

LOT NO. :

SHOP PACKET QTY (pcs)	USTOMER	ONO
SH	CO	

RS	
006	VMD (MALAYSIA)

		RECEIVED BY	, Caryana	Dh Dhina)1	- Autland	روسامه	onolno,
		CONSUMPTION	016	800	200	8	20
	QUANTITY (pcs)	ISSUED	016	800	200	92	20
		REQUIRED	910	300%	300	2	20
	LOM		pcs	шв	П	вш	且
	LOT NO		H022210902	H080210801	C023210701	C021210601	
	DESCRIPTION 2		Diameter 22 x 80mm, White Colour Tube with Long Nozzle(5 layers), Open End, Gloss Finishing		0		N/A
	ITEM DESCRIPTION 1	の の の の の の の の の の の の の の の の の の の	15ml Long Nozzle Tube with white color screw on cap	RHEOLOGICAL ADDITIVE (SUPBENT MP)	Sodium Hypochloride, 10% Available Chlorine	Pure Dry Vacuum Salt (25kg)	STOCK SOLUTION
	NO. SYSTEM CODE		P0100225	C0100026	C0100048	C0100024	N/A
100	NO.		-	7	3	4	2

ON		(2) I NOBOCI I ACKAGING			
	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
-	P0100397	LBH-006-R4 - Hydrocyn Tube Label, Size: 65mm x 62mm, Material: Transparent PE	L220211202	116	omoline,
7	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15 0mm X 15.0mm	L020210801	116	Compano
ю	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (15g only)	LB23210801/3	1821	· Courping
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	Can Jana
S	P0100318	Outer Tube Box for Hydrocyn Gel - Sizæ. 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	Гандано
9	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	on plans
7		#N/A			

3)0	VER WRAPPING	(3) OVER WRAPPING AND CARTON PACK			
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
-	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LR150/M/LR150 (BC FLUTE)	H114210801/2	4	madikeh
2		#N/A			
		#N/A			
(4) SP	(4) SPECIAL REQUIREMENT	SMENT			
NO	SYSTEM CODE	ITEM DESCRIPTION I	LOT NO.	QTV REQUIRED (pcs)	RECEIVED BY
-	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 33mm x 18mm, Material: Transparent PE, Colour. Red (2 layers)		4/4	



ISSUED BY (MM):

VERIFIED BY (PR)

#N/A

VIGII FN7®

QC-PC008 Doc No.

					Rev.	02	
							_
		The second secon					
Description	Hydrocyn Agrus, Wound Grei	Reference No.	HWYOEgoo	Date of Inspection	34/0	Sules Loss	
Continue	(153)	Lot No.	A21515	Sample Size	3000	150 x 150	

Release Criteria:

Test Disposition		PASS / FAIL	pass
Chemical Testing		(9.00 – 10.50) FAC (100 – 200 ppm)	Kiduos
		pH (9.00-10.50)	4.6
Visual Inspection		Free from contamination / particles / foreign matters	>
		No leakage	>
egrity		Free from contamination/ deformed/ damaged)
Packing Integrity		Ability to dispense	>
		Proper sealing)
		Correct and legible printing of label	>

 $\sqrt{}$ = Pass, X = Fail

Remarks:

RELEASE CONCLUSIONS:

ON-HOLD

Inspected By :

Name

Date

24/01/2033 ROSHNE

Approved By:

MARTINI

Name Date

34/01/2022