1/66 PR

VIGILENZ®

MEDICAL DEVICES

may my Refer FLTR Approved by (QC), 29 101 2002 10-5000 RESULTS 2/2 2/2 S 3 15-Jan-22 **A21520** 15-Jan-22 R 2040-04 tosisam 9135 am 13:00 PDM 28 (or ) 202 27.101.22 27.101.22 2:15pm 28.1.22 28.1.33 and Sing 27.1.72 IPQC APPROVAL Coop ISSUED DATE way Checked by (PR), wer won Imola Dochus MFG. DATE 503 EXP DATE: (th9) KAL1 (1078) Hramy (1049) Heroi (1053) 61099 Huang (1049) RS 3 + 7 (QC TEST) Viles (1094) Viki Cloqu) OPERATOR , Canjanes (061) Lin SITI SHOP PACKET - HYDROCYN AQUA GEL 1111 20/BOX VMD (MALAYSIA) REJECT TUBE 7-8 NIC 1/2 112 」 え 76 A116 45 bex T OF OUTPUT TUBE 0/6 903 CUSTOMER ORD. NO 410 910 903 PACK SIZE : ODR. QTY START QTY TUBE 45 box 5 016 903 016 908 016 016 Hydrocyn Aqua Wound Gel (15g) 2 7 - 0 1 - 2 2 77-01-2 28-01-24 2 7 - 0 1 - 1 2 2 2 2 3 2 5 PM 2 3 3 - 10 1 - 3 3 0 1 2 2 24-01-22 24-01-22 7 7 1 0 2171-1011 -122 12:00 pm 2 - 0 - 2 2 4:60 pm 8.30 am 4.30pm 35 P W 36 90 am Md 00: 8 9-50 Am 3+7 7:25 pm 28-01 CHECK: pH / VISCOSITY / FAC | Refer attachment: 2.20 OT NUMBER AND EXPIRY DATE PRINTING HW40F900 7 3 -H0100016 HYDROGYN AQUA GEL PREPARATION PROCESS QUANTITY FOR QC/RETAIN SAMPLE SEALING AND CUTTING GEL TUBE BOX PACKING & FINAL CONTROL QUANTITY PRODUCED ABELLING GEL TUBE CARTON PACKING TIME COMPLETE : IME COMPLETE: TIME COMPLETE TIME COMPLETE TIME COMPLETE TIME COMPLETE *FIME COMPLETE* TEM CODE GEL FILLING FIME START: LIME START: TIME START: TIME START **LIME START** TIME START *FIME START* TEM: DATE DATE

ce-1-to

Er1-40

Page 1 of 2

KARTINI 2/2/2022

Name

Name : PATHINGECHRAM

Date

Signature :

los / polis

g

9000g

SHIPMENT QUANTITY PCS FINAL SHIPMENT DATE PARTIAL

COMPLETE

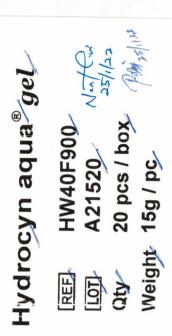
COMPLETE/PARTIAL:

Signature : Lange

Doc. No.: PR-SP013 Rev: 01

#### LABEL APPROVAL





VIGILENZ®

Doc. No: PR-SP013

@	
1	V
1	Z
1	Ų
H	
(	5
1	_
۲	

1	M	VIGIL FN7				1	IYDROC	VN agna	® CEL R	PECOPI	COFPDI	HYDROCYN agina® GFL - RECORDS OF PDEPAPATION	NC			Doc. No.	PR-HR001
			]									EL ANALI					04
4		111111111111111111111111111111111111111										Equipm OC-56	Equipment ID				
Date		34/01/23	123					Purified Wat	Purified Water (L)			3.0 - 3.1	20.0 - 20.1				
								Lithium Mag	nesium Sodiun	n Silicate (g)		120 ± 1	800 ± 1				
								Sodium Hyph	nochlorite (ml)			$30.0 \pm 0.05$	200.0 ± 0.5				
								PDV Salt (g)				3.0 ± 0.1	20.0 ± 0.1				
				1:1													
No.	Batch No.	No. Batch No. Equipment	Purified	Cased	Lithium Magnesium Sodium Silicate	ım Sodium Sil	icate		Sodium Hypochlorite	pochlorite			PDV Salt	alt			
		<u>e</u>	Water (L)	(LDM)	Amount (g)	Ctort	Time	Speed	Amount (ml)		- 1	Speed	Amount (a)	Time	ne	Prepared	Checked
-	(4 Bay612)	10000				Start	End	(rpm)		Start	End	(rpm)	(g) mnome.	Start	End	By	Ву
_	Copycolo	G. Ozyolos G. Ozyolos	20	005)	800	4:17	06:£	800	200	7:20	7:21	008/	20	7:21	¥, 25	remo(mos)	Logy ,
					~ ?												
		w.															
					-				NA.								
		3 3							The state of the s	THE PARTY OF THE P		Contraction and					

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

Reference / Lot No.	DESIZU/ OOD JOHNH	
Order Qty.	900	

#### A. Before Filling

Batch No.	Container No.	$^{ m pH}_{(9.00-10.50)}$	FAC (100 – 200 ppm)	$\begin{array}{c} \text{Viscosity} \\ \text{(8,000} - 10,000 \text{ cps)} \end{array}$	FAC Viscosity Gel is clear and free (100 - 200 ppm) (8,000 - 10,000 cps) from contamination	Test disposition (PASS / FAIL)
18 340 12305	(MS	9.03	Viomo!	4554	7	2008
61624012366	940)	9.12	(emply	456	)	7300
						(0.00)
		AN				

#### 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	7	)	7	Spin
1/5	7	7	7	DOLY.
3/5	7	2	. 3	LORGE
3/5-	7	7	7	) OPW
1/5	7	7	2	0000
5/5	7	77	>	000

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL         Doc Id:         Bactiguard         Page:           Document type:         Poc IN-000 doc Id:         Issue Date:         Page:           FORM         QC-IP004-01         15/11/2021         2(3)	, itle:			
type:   Doc Id:   Issue Date:	QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		Bactiguard	
OC-IP004-01 I5/11/2021	Door many trees.			
QC-IP004-01 15/11/2021	Cocument type:	Doc Id:	Issue Date:	Page:
	FORM	QC-IP004-01	15/11/2021	2(3)

#### C. Filling Process

Sampling /	Specification	Weight of Sample Specification: 15g (16.5 – 17.8g) / 30g (31.6 – 33.3g) / 50g (51.9 – 53.4g) / 100g (102.8 – 104.7g)	Weight of Sample () / 30g (31.6 – 33.3g) / 50g (	Sample   3g)   50g (51.9 –	53.49) / 1009 (10	12.8 – 104.70)	E	Test disposition
Frequency	1	2	6	4	2	Average	Leak lest	(PASS/FAIL)
5/5	16.72	17.13	17.19	13.36	64.61	691.El	7	Brek
181	13.49	17.38	17.55	(7.3)	17.53	17.43 9	2	Day o
3/2	bh.t1	17.31	11.51	17.45	17.62	12.W. 9.	<i>y.</i> 3	Carl Carl
3/5	19.61	17.50	17.50	65.11	17.34	17.52 9	7	2000
Ys.	13.81	86.91	5h. £1	14:33	16.91	17.33 9	7	
3/5	14.31	17.33	17:11	13.26	17.16	17 61 9	7	Cass

#### D. Sealing and Cutting

slanted after sealing and cutting	Lot no. and expiry date on tube is correct as in Shop Packet and legible	Specification: (15g : 4-6mm) (30g/ 50g/ 100g : 6-8mm)	Leak Test	Test disposition (PASS / FAIL)
7	7	)		SMO
7	\	\	)	and show
7	\	)	)	and the same
7	)	7	\	0000
7	>	)	\	1800
7	\	`	)	LOSS

	Bactiguard	Issue Date: Page: 3(3)
Title: QC IN-PROCESS INSPECTION RECORD — HYDROCYN SOME CET	dua OEL	FORM QC-IP004-01

### E. Printing on Primary Packaging

			_		_		_		_		_		
	Test disposition	(FASS/FAIL)		SHIO	Carlo	2000	1000	Seg.	11-0	0000	100	200	2
	Correct position of	9		7		7		7	*	7		7	1
	Lot no. and expiry date are corresponding to Shop Packet and approved artwork			3	.7			2		2	1	2	7
Print information must be clear / legible			7	77			7		7		7		4
Samuling /	Frequency	2	3	1/2		1/2	15	3/4	7.5	4/1	15	2/1/2	(2)

#### F. Primary Packaging

Test disposition (PASS / FAIL)			2000	1	2000	1	,0835	1000	Juro	ma	Sand I
Presence of hologram sticker on the primary box	L. Francis DOA		7	\	2	1	7	\	2	7	>
Presence of secure stickers on both opening sides of the primary box		,	7	/		7		7	1	١	7
Special requirement printing is clear and legible		7		)		\	1		\		\
Ref. no., lot no. and expiry date on primary box is correct and legible		7		7		7		2	)		\
Product is properly pack in primary packaging		7	7		1	)	7		7	\	٥
Sampling / Frequency	N	1	3	200	2/2	2	1/2	4,	SA	N	12

#### G. Conclusion

Overall in – process inspection: (PASS / FAIL)

Inspected By: Woh

Name : (1904, 1204) Date : 28 · 01 - 312

VIGILENZ®

FINAL CONTROL TEST REPORT: HYDROCYN aqua® GEL

QC-FC006 03 Doc. No. Rev.

REF

HWHOFGOO

QTY PRODUCED (pcs)

910

LOT NO

A21520

RETAIN SAMPLE QTY (pcs) :

3

7	1	October Dates 1	Comin o Cino	AQL	L	Results	ults	Status
ON N	inspection Criteria	Sampling Details   Sample Size	Sample Size	Accept	Reject	Accept	Reject	(PASS/FAIL)
1	1 Legible and correct printing of label.	83,0.15	80	0	1	80	0	2400
2	2 Availability of Hologram and Secure Sticker.	S3,0.15	80	0	)	80	0	puss
3	Free from contamination, deformed or damaged on packaging.	83,0.15	80	0	,	8	0	pox
4	4 Proper sealing and no leakage.	S3,0.15	80	0	,	86	0	poss
5	5 Correct quantity in secondary box packaging.	S3,0.15	80	0	J	80	0	poss

Remarks:

(vah Inspected By Name

28-01-2013 wood work

Date

Approved By Name

RA PTINI

\$ 6001/00/05

Date

## RAW MATERIAL LOADING FORM (RMLF)

 Doc. No.
 PR-RM001

 Rev.
 06

10

RS

19/01/2022 HW40F900 A21520

SHOP PACKET QTY (pcs)
CUSTOMER

VMD (MALAYSIA)

2	ON TO	A21520			LO NO.			IO/VMD/130122/01	
100								120000000000000000000000000000000000000	
							QUANTITY (pcs)		RECEIVED BY
N	NO. SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOTNO.	МОЛ	REQUIRED	ISSUED	CONSUMPTION	
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	016	016	216	, Canjana
7	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)		H080210801	mg.	\$00	800	800	, Canjano
	C0100048	Sodium Hypochlonde, 10% Available Chlonne	0	C023210701	lm «	20 200	200	200	, Caugane
4	4 C0100024	Pure Dry Vacuum Salt (25kg)		C021210601	в	20	200	20	rayand
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	s N/A	STOCK SOLUTION	N/A	Succioheosos	TI.	20	20	20	1 Caujana

5	PRODUCTI	(2) PRODUCT PACKAGING			
ON	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	911	· Caujand
2	P0100316	L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm	L020211101	116	1 Caujang
	P0100849	Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Matenal: Breakable PVC, Color: Black, Roll Form (15g only)	LB23210801/3	1821	, Cayano
4	<b>P</b> 0100399	BX002, Inner Tube Box for Hydrocyn Cel - Size: 30mm(L) x 25mm(W) x 116mm(H), Material 310gsm 1 Side Coated Art Card (4 colors), Rev: 3	H076210801	911	Canjana
8	P0100318	Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back	H077210801	45	, Caujana
9	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210802	45	· Caulano
7		#N/A			

(3) OV	ER WRAPPING	(3) OVER WRAPPING AND CARTON PACK			
ON	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	meluid
2		#N/A		v	
3		#N/A			
(4) SP	(4) SPECIAL REQUIREMENT	EMENT			
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
-	P0100324	"SAMPLE NOT FOR SALE" Slicker - Size: 35mm x 18mm, Material: Transparent PE, Colour. Red (2 layers)	}	arm -	
2		#N/A			

VERIFIED BY (PR):
Signature:
Name:

ume: PAAN PETE CALANI
ste: 98 | Par

19/01/2022

ISSUED BY (MM):
Signature:
Name:
Date:

#### **VIGILENZ®**

# PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL

02
Rev.

Description	Mydrocun saus wound (ne)	Reference No.	HWYOFGOO	Date of Inspection	econtrolpe
Coscillation	0	Lot No.	002167	Sample Size	PS1 X 8106

#### Release Criteria:

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

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

Remarks: \_\_

CONCLUSIONS: V RELEASE

ON-HOLD

Inspected By

Name Date

29/01/1033 POSHN2

Approved By: Name

Q3VOAQ4

MARTIMI

Date

3/2/2022