			SHOP PACKE	T - EASW		Guglesh	
REFERENCE	HW4CG800		ODR. QTY	162	RS 2 +1 (QC TEST)	ISSUED DATE	22/02/2022
!TEM CODE	H0100030	1	PACK SIZE	54/BOX		LOT NO.	B22204
		2010 400	CUSTOMER	VMD (MALAYSIA)	)	MFG. DATE	22/02/2022
ITEM DESCRIPTION	Hydrocyn Aqua Gel Spray (I	BOV) 100g	ODR. NO	B138		EXP. DATE	2023-08
	NAME: UDHAYESREE 6	00	15 13514	NAME : RATNASI	EGARAN A		
PREPARED BY	DATE : 22/02/2022	-	VERIFIED BY	DATE : 22/02/2022	1100	INT. ORDER	IO/VMD/220222/01
UDI-DI NO.			17 6 175	UDI-DI NO.	1		
(1st Packaging) -		N/A		(2nd Packaging) -		N/A	
Bottle/Box/Bag UDI-PI NO.		_		Carton UDI-PI NO.			
(1st Packaging) -		N/A		(2nd Packaging) -		N/A	
Bottle/Box/Bag				Carton			
PROC	F66	INPUT	OUTPUT	REJECT	OPERATOR	IPQC	REMARKS
		BOTTLE	BOTTLE			APPROVAL	
STOCK SOLUTION PREPAI TIME START:	4:00 pm				FARAH	ovah	3/3
DATE	26-00-00	165	165	NIL			/3
TIME COMPLETE:	3 16 - 10 3 - 13 3 408 bu			1470	(1051)	26/02/22	
EDM PRINTING (Label/Box/				•		20 102172	
TIME START:							UDI NOT REQUIREI
DATE:		_			N/A		FOR THIS LOT
TIME COMPLETE:							
SOLUTION FILLING & CAL					FARAHIINCI)	Deal .	- 2 Cour reject
TIME START:	10:15QM	115	163	2	FARAH(1051) SOEIA CI(38)	Foshmi h. bogm	replace with
DATE: TIME COMPLETE:	09 - 03 - 22 11:00am	165	163	2	Salar Livey	11.00010	
DATE:	09-03-22					09/03/2033	new eary
LABILLING					FARAH (1051) SOFIA (1138) FARAH (1051) SOFIA (1138)		
TIME START:	1:00 pm	1.65	165	NIL	FAFATORES	Roshm	NA
TIME COMPLETE:	1:13 pm		.03	74.0	30FIA( 1138)	1-13pm	1
DATE:	09-03-22					1-13 pm	
PRINTING LOT NUMBER TIME START:	1:00pm				CARAH(1051)		
DATE:	09-03-22	165	165	NIL	7	Roshm	
TIME COMPLETE:	1:13 pm	3			SOFTACII38)	/ H3pm	AN
DATE :  CAP SEALING (Applicable for	09-03-00					09/03/2622	A 1980
TIME START	or rough)				4.1	/	
DATE:		¥1		NP			The state of
TIME COMPLETE:			TANTA THE	/0/	,		
BOX PACKING & PRINTIN	G				-		
TIME START:							
DATE : TIME COMPLETE :					NA —		1100
DATE:					NH	1.5	,
MANUAL UDI LABELLING							
TIME START : DATE :					N/A		UDI NOT REQUIRED
TIME COMPLETE :					, inco	7	FOR THIS LOT
DATE:							
FINAL CONTROL TIME START:	1:00pm				FARAL	Roshm!	
DATE:	09-03-22	165	165	NIL	(1051)	/ 2.50 pm	
TIME COMPLETE :	0 9 - 0 3 - 2 2				(105.)	09/03/202	NA
DATE : CARTON PACK				-		1/05/2000	
TIME START :	12:10 p m	2	3	44.5	FASLI (1054)	Nurin	Figures 865
DATE:	10-03-122	3 ctn	ctn	HII	(1054)	in to to a	10/02-
TIME COMPLETE : DATE :	10-03/22	UIN			(, ,	10/3/2022	1678120
UDI LABELLING							
TIME START : DATE :					2774		UDI NOT REQUIRED
TIME COMPLETE:					N/A		FOR THIS LOT
DATE:							
	· • -				11.200	Released by	(OC)
QUANTITY PRODUCED	: 165		Checked by (F		oproved by (QA),	Released by	10
OHANDER SON		¢	Signature:	Sig	gnature :	Signature :	3 Auns
QUANTITY FOR QC / RETAIN SAMPLE	: 2611		( N	1-	Ama		ARTINI
			Name: Mul	n AKIRWHEN	(1110	D :	IPAC SUP
SHIPMENT QUANTITY	110/0	daa	Date: 62/2	1	ame Rohamsa O	Date: 12	
PCS / CTNS	: 167 / 30	the	17/3	1.0	121312077	Stamp:	
			_				ENISO
						6	3
FINAL SHIPMENT DATE	: -	-	Remarks:			(3)	(50)
			_			[3]	SEED S
COMPLETE/ PARTIAL	: COMPLETE	PARTIAL				15	
						1	· QUILLO
						7110451	
							AN LINE STORY

@	
1	1
/	~
	-
I	ļ
-	4
-	4
(	)
	4
-	
-	

# QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

 Doc. No
 QC-IP006

 Rev.
 00

Reference / Lot No.	HW4CG 800 /	Вэээон
Order Qty.	162	

## A. Before Filling

		Weh 9/3/22	way	woh	413122
Test Disposition	(PASS / FAIL)	pass	poss	6088	
Gel is Clear and Free from	Contamination	7	1	7	
Viscosity (8,000 - 10,000 cps)	Instrument No.: & c-96 Calibration due date: 01/07/1003	9865	9865	4146	
FAC (100 – 200 ppm)	Instrument No.: 1980074 Calibration due date: N/b	comply 9865	comply 9865	comply 9717	NA -
pH $(9.00-10.50)$	Instrument No.: & 1-78 Calibration due date: 1403/1032	19.51	9.51	9.65	
Container No.		611	6,12	G 14	
Batch No.	d	GB36023211	GB 26017212	G1826022214	

# B. Gassing Process

			, ,					10
Test Disposition	(PASS/FAIL)		poss	poss	0085	8500	SFOO!	98800
			MPA	Mpa	mpa	mpa	mpa	mou
		S	6.0	8.0	6.0	∞-0	6.0	0.9
	2003		ndu	mpa	Mon	mpa	mpa	mpor
Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)	Calibration due date: $(6/0)/203$	4	8.0	0.9 mpa	6.0	6.0	∞, ⊙	6.0
; canister: (	alibration due		mpa	mpa	mpa	mpa	word	mple
Pressure .9 mPa/ 100g	Cč	3	0.9 mpa	٥ %	0,0	8.0	6.0	7,0
ister: 0.7-0			Mor	mpa	mpa,	mpa	mpa	mpa
(50g can		2	8.0	6.0	0.8	4.0	8.0	6-0
	Qr- 130		mpa	maa	mpa	mpa	mpa	mpa
	Instrument No.: & r- 130	1	0.9 mpa	0.9 mpa	0.8 mpa	6.0	6.0	0.8 mph
Sampling /		X	5/5	1/5	2/5	3/5	4/5	5/5

N / / E	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	1
	L	4
_	_	1
_	Ξ	1
	_	4
	>	-

# QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

QC-IP006 00 Doc. No Rev.

# C. Crimping Process

Depth Specifications: $\geq 5.1  \text{mm}$   Depth Specifications: $\geq 27.1  \text{mm}$   Instrument No.: $\approx C - 1.2  \text{g}$   Calibration due date: $\sim 1.0  \text{g}$   Calibration du
Depth Specifications: ≥ 5.1 mm   Instrument No.:
Depth Specifications: ≥5.1 mm
Depth Specifications:  Instrument No.: Q.C128  Calibration due date: N/R  1 2 3  5.24 mm 5.19 mm 5.25 mm 5.24 mm 5.15 mm 5.27 mm
Depth Spe  Instrument No.:
Instrument No Calibration du 1 5.24 mm 5.24 mm 5.24 mm

## D. Filling Process

50g : 76.0g – 83.0g 100g: 139.0 – 154.0g Weight Specifications:

	П	
	П	
	- 1	
	- 1	
	- 1	
	- 1	
	-1	
	1	
	- 1	
	- 1	
	н	
	п	
	п	
	н	
	-1	
	н	
	-1	
	н	
	н	
	-1	
	н	
	-1	
	-1	
	-1	
	-1	
	1	
	1	
	1	
	1	
	1	
	J	
	1	
	н	
	н	
	н	
	1	
	н	
	1	
	1	
	1	
	-1	
	1	
	ı	
	I	
	ı	
	ı	
	ı	
	ı	
	ı	
	ı	
	ı	
	ı	
	ı	
	ı	
	ı	
	l	
	l	
	l	
	l	
	l	
	l	
	l	
	l	
	l	
	l	

_				_		_		
	Test Disposition	(PASS / FAIL)	p048	DOCS	2500	OMS	00%	2004
		w	151.5 9	140.1 9	142.9 9	0 C.H.	144-9 9	149.0 3
	te: \$105/011	4	p 1.041	143.1 9	146.× 9	P C. 1111	146.3 9	147.0 9
Weight of Sample (g)	Calibration due date: \$105/1011	8	p 9.44.	146-3 9	P C.F.K1	148.0 9	147.3 9	45.2 g
		2	6 9.841	142.0 9	143.5 9	149.1 9	151.5 9	152-1 9
	Instrument No.: Ar- w B-01	1	6 5.050	145.6 9	146.8 4	149.8 9	146.1 9	145.9 3
	Sampling /	famahari	5/5	1/5	3/s	3/5	4/5	5/5

VIGILENZ®

# QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

 Doc. No
 QC-IP006

 Rev.
 00

3	Actuators are properly fixed onto the canister	Functionality of actuator	Caps are properly fit onto the canister	Test Disposition (PASS / FAIL)
	\	1	>	35000
	>	7	7	pacs
- 1	>	>		pags
	>	>	>	5000
	>		1	Soug
	\	1	1	2000

# F. Labelling & Printing Process

Test Disposition (PASS / FAIL)	pass	pass	bucs ,	PMS	8000	BUS
Correct Printing Position	`	7	7	>	7	>
Correct Label Position	7	1	>	1	1	>
Ref No., Lot No. & Expiry Date Corresponds to Shop Packet and Approved Artwork	3	>	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	\	7	>
Print Information must be Clear / Legible and Conforms to Specifications as Stated in Approved Artwork	`	7	\	5	\	/
Sampling / Frequency	3%	1/5	2/5	3/5	4/5	3/5

# VIGILENZ®

# QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

QC-IP006 00 Rev.

Doc. No

### moist wound environment that supports wound healing. The gel also increases the moisture within the wound which assists the debridement and desloughing process especially in dry wounds. The ingredients in the hydrogel prevent any bacterial growth on the hydrogel and preserve it after HYDROCYN aqua aerosol hydrogel is a clear amorphous hydrogel that helps maintain a

DESCRIPTION

### OCYN® adna

### **DIRECTION FOR USE**

Clean the wound before application of hydrogel. Spray the hydrogel continuously to maintain optimal moisture on the from the wound bed for even application. Use hydrogel between dressing changes wound. Saturation of the dressing with on the wound; maintain a 10-15cm distance Cover with appropriate wound dressing. hydrogel will assist with dressing removal. The hydrogel can be used as debriding agent if necessary. Consult doctor if required

### CAUTION

**Aerosol Hydrogel** for Wound Care

surgical wounds, burns (1st - 2nd degree) and bed sores.

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

INGREDIENTS

MDA-GC9700420-45397 REF HW4CG800

For moistening and debridement of acute and chronic wounds such as stage I-IV ulcers, venous stasis and diabetic ulcerations,

INDICATION

application on the wound.

or incinerate even when empty. Keep out of reach of children. Store in a cool, dry sunlight. Product has a shelf life of 18 place at room temperature. Do not expose the product to high temperature or direct months from the date of manuiacture. For external use only, notify your health Content under pressure. Do not puncture



LBH-015-R1



care specialist in case of any adverse effect.



100g CE 2292

Bactiguard VIGILENZ

VIGILENZ Medical Devices Sdn. Bhd. 18 subsidiary of Bactguard 198 b, Jalan Perindustran Bukit Minyak 18 Penang Science Park, 14100 Penang Malaysia www.vigilenznd.com / www.bactguard.com

## F. Conclusion

Overall in-process inspection: PASS / FAIL

Inspected by: Woh

: Woh wich Name

Date

PR-HR001 Checked By (3) Prepared By Doc. No. (101) Rev. wdsoch und hoch End Time Start PDV Salt Amount (g)  $200.0 \pm 0.5$  $20.0 \pm 0.1$ 20.0 - 20.1 HSM-01  $800 \pm 1$ 00C Equipment ID HYDROCYN aqua® GEL - RECORDS OF PREPARATION QC-56 3.0 - 3.1  $30.0 \pm 0.05$  $3.0 \pm 0.1$ 120 ± 1 Speed (rpm) 1900 md hoch End 4:13 pm Lithium Magnesium Sodium Silicate (g) S Start Sodium Hypochlorite Sodium Hyphochlorite (ml) Amount (ml) 200ml Purified Water (L) PDV Salt (g) Speed (rpm) 1500 4:63pm End Lithium Magnesium Sodium Silicate Time md 00:h Start Amount (g) 5000 Speed (rpm) 1500 Purified Water (L) 797 200/20/30 VIGILENZ® (181602) HSm.61 No. Batch No. Equipment ID Date

Title: FINAL CONTROL TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)	(BOV)	Bactiguard	
Document type:	Doc Id:	Issue Date:	Page:
FORM	QC-FC009-01	15/11/2021	1(1)

RETAIN SAMPLE QTY (pcs) QTY PRODUCED (pcs) Hwyegsoo REF

Bassoy

LOT NO

165 8

	ıtus	(Pass / Fail)	pass	8500
	Ste	(Pass		
	Results	Reject	0	0
	Res	Accept	08	8
	AQL	Reject	_	_
	AC	Accept	0	0
	0	Sample Size	08	08
	Sampling	Details	83,0.15	53, 0.15
4	The state of the s	inspection Criteria	Legible and correct printing of label.	Free from contamination, deformed or damage on packaging.
	2	INO.	1.	2.

	Test Disposition	(PASS/FAIL)		pwss
Pressure	(50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)	Calibration due date: 16/03/2003	Sample 2	pdw8.0
Pre	(50g canister: 0.7-0.9 mPa	Instrument No: Q(- /30	Sample 1	6de 6.0

REMARKS:

NA

ROSHNE Inspected By

Name Date

Approved By :

9/3/2022 MARTINI Name

Date

RAW MATERIAL LOAI HW4CG800 23/02/2022 VIGILENZ® DATE REF

B22204

LOT NO.

=			
DING FORM (RMLF)	SHOP PACKET QTY (pcs)	CUSTOMER	LO NO.

F	Doc. No.	PR-X	
	Rev.	90	7
L			
	162	RS	3
	VMD (MALAYSIA)		
	IO/VMD/220222/01		

	ION RECEIVED BY	enolog,	" Garganet	Dunchay 1	making)	pandage 1	Landana	1 cardonal
	CONSUMPTION	89.	591	(65	\$00	2002	920	C
QUANTITY (pcs)	ISSUED	165	165	165	800	900	200	92
	REQUIRED	165	165	165	800	300	20	20
WOI		bcs	bcs	bcs	gm	冒	шв	扫
LOTNO		A010210401	H083210401	H029210401	H080211101	C023220201	C021211101	C166 602 62 11
DESCRIPTION 2		BOV: 100ml; Capacity: 150ml	0.46mm (Orifice)	Diameter: 35mm	ı	0	,	
ITEM DESCRIPTION 1		Aluminium can (Size:45x150mm)	Plastic Actuator (EVER BRIGHT)	Plastic Cap (Blue Color) (EVER BRIGHT)	RHEOLOGICAL ADDITIVE (SUPBENT MP)	Sodium Hypochloride, 10% Available Chlorine	Pure Dry Vacuum Salt (25kg)	STOCK SOLUTION
SYSTEM CODE		P0100723	P0100344	P0100345	C0100026	C0100048	C0100024	
NO.			2	м	4		9	7

(3) OV	ON	1	2	к	(4) SPE	ON	-	,
	RECEIVED BY	, company	v					
	QTY REQUIRED (pcs)	991					*	
	LOT NO.	L091210201 L091210202						
(2) PRODUCT PACKAGING	ITEM DESCRIPTION 1	Hydrocyn Aqua Acrosol Gel Spray Label 100gram-PP Top White (W)135mm X (H)115mm Roll/1000 (LEH -015 - R1)	#N/A	#N/A	#N/A	Y/N#	#N/A	A'N'A
) PRODUCT	NO SYSTEM CODE	P0100665						
(2	ON	-	2		4	8	9	7

5	EK WKAFFING	(3) OVER WRAPPING AND CARLON PACK			
ON	SYSTEM CODE	ITEM DESCRIPTION 1	LOTNO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H165211201	3	madilal
2	P0100692	Aerosol Gel Nesting set-Long 5pcs & Short 8pcs - 456(L)x110MM , B/Q:T150/T150 BF	H066200801	W	malle
ю		#N/A			
l) SP	(4) SPECIAL REQUIREMENT	MENT			
NO	SYSTEM CODE	ITEM DESCRIPTION I	LOTNO.	QTY REQUIRED (pcs)	RECEIVED BY
-	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour. Red (2 layers)		- N / A	
2		#N/A			

VERIFIED BY (PR):

Signature : Name:

muth Appropries 12/3/22

Date:

SUBCIAL FIRDOUS Signature :

ISSUED BY (MM):

Name : Date :

23/02/2022

Page: 1(1) Bactiguard Issue Date: 15/11/2021 Doc ld: QC-PC011-01 PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV) Document type: FORM

scription	Hydrocyn haug Gel Spicy	Reference No.	HW4CG3800	Date of Inspection	10/03/2012
		Lot No.	Вээгон	Sample Size	1 0c8 X 1000

Test Disposition	PASS / FAIL	poss
Chemical Testing	FAC (100 – 200 ppm) Instrument No.: $\psi$ & $\theta$ Calibration due date: $\delta$	hidas.
Chemica	pH (9.00 – 10.50) Instrument No.: Ωc- 38 Calibration due date: 12/01/023	ch.b
	Ability to Dispense	7
ial Inspection)	Proper Crimping and Capping	\
Packing Integrity (Visual Inspection)	Free from Contamination / Deformed / Damaged	>
	Correct and Legible Printing of Label	>

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

REMARKS:

d/V

RELEASE ON-HOLD

CONCLUSION:

Inspected By

POSHINE Name Date

10/03/1017

Approved By

MA RTINI

Name

Date

10/03/2022