

SHOP PACKET - HYDROCYN AQUA GEL

REF :	Bactiguard Woundcare Gel Tube (100g) BW010010	ISSUED DATE	4-Feb-22
ITEM CODE :	BW010010	LOT NO	B20401
ITEM :	Bactiguard Woundcare Gel Tube (100g)	MFG. DATE	4-Feb-22
		EXP. DATE:	2023-08

PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 4:17pm						
DATE : 09-02-22	153	153	NIL	Farah 1051	9/2/22	2/2
TIME COMPLETE : 4:25pm						
DATE : 09-02-22	153	153	NIL	Viki (1094)	12/2/22	5/5
CHECK : pH / VISCOSITY / FAC						
Refer attachment: PR-HR001 QC-HR003						
LABELLING GEL TUBE						
TIME START : 10:00 AM						
DATE : 12-02-22	153	153	NIL	Ewa (932)	14/2/22	5/5
TIME COMPLETE : 3:00 pm						
DATE : 12-02-22	153	147	6	Farah (1051)	14/2/22	5/5
TIME START : 3:35 pm						
DATE : 14-02-22	147	147	NIL	Bashim (1117)	22/2/22	5/5
TIME COMPLETE : 4:35 pm				Susi (1125)		
DATE : 14-02-22	147	24 box 4 ctn	H11	Kyu (887)	23/2/22	Refer FCTR
SEALING AND CUTTING GEL TUBE						
TIME START : 3:35 pm						
DATE : 14-02-22	147	24 box 4 ctn		chaw (885)	24/02/2022	
TIME COMPLETE : 4:35 pm						
DATE : 14-02-22	147	24 box 4 ctn				
LOT NUMBER AND EXPIRY DATE PRINTING						
TIME START : 9:00 am						
DATE : 22-02-22	147	24 box 4 ctn				
TIME COMPLETE : 9:23 am						
DATE : 22-02-22	147	24 box 4 ctn				
BOX PACKING & FINAL CONTROL						
TIME START : 4:40 pm						
DATE : 21-02-22	147	24 box 4 ctn				
TIME COMPLETE : 5:15 pm						
DATE : 21-02-22	147	24 box 4 ctn				
CARTON PACKING						
TIME START : 4:00 pm						
DATE : 24-02-22	147	24 box 4 ctn				
TIME COMPLETE : 4:30 pm						
DATE : 24-02-22	147	24 box 4 ctn				

QUANTITY PRODUCED	153 tubes
QUANTITY FOR QC/RETAIN SAMPLE	3TG PCS
SHIPMENT QUANTITY PCS / CTNS :	153 tubes 2500/2500
FINAL SHIPMENT DATE	
COMPLETE/PARTIAL :	COMPLETE

Checked by (PR),	Approved by (QC),
Signature : [Signature]	Signature : [Signature]
Name : [Name]	Name : [Name]
Date : 25/2/22	Date : 25/2/2022

LABEL APPROVAL

Οδηγίες χρήσης Βεβαιωθείτε πρώτα ότι έχει καθαριστεί η πληγή. Εφαρμόστε τη γέλη απευθείας στην πληγή σε κάθε αλλαγή επιδέσμου του τραύματος. Μόνο για εξωτερική χρήση. Μετά το άνοιγμα της συσκευασίας, θα πρέπει να χρησιμοποιείται το σύνολο του περιεχομένου.

Συστατικά Κεκαθαρισμένο ύδωρ, Υποχλωρίνη 0,05% (Libio-Marghono-Nátrio) ή Χλωριούχο Νάτριο.

Bactiguard (South East Asia) Sdn. Bhd.
(formerly known as VIGILENZ Medical Devices Sdn. Bhd.)
308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 141000 Penang



Αρ. Γνωστοποίησης ΕΟΦ:
130619/23-12-2021.

REF BW4CB900



CE 2292

U-111 : B20401
E : 2023-08



Bactiguard[®]

Bactiguard[®]
WOUND CARE
GEL

100g

Bactiguard[®]

WOUN
Καταπραύνου
Γέλη



✓ 32049 03/23

✓ 32049 03/23

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308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia.

Διανομέας: LIFECYN AE
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EC REP ORELS SA, BD, GENERAL WAHIS 53, 1030 BRUSSELS, BELGIUM

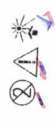
WOUND CARE

Καταπραύντική & Βακτηριοστατική δράση

Γέλη 100 g

REF	BW4CB900
LOT	B20401
Qty	6 pcs / box
Weight	100 g / pc

Bactiguard[®]



ecar/co/b0

	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]

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL

Document type:
FORM



Doc Id:
QC-IP004-01

Issue Date:
15/11/2021

Page:
1(3)

Reference / Lot No.	8W4C900 / 830401
Order Qty.	144

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)
9807032207	67	9.86	comply	9950	✓	pass
9807032208	68	9.86	comply	9950	✓	pass
			N/A			

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


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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	103.28 g	102.97 g	104.28 g	104.30 g	103.57 g	103.68 g	✓	
1/5	103.63 g	104.47 g	103.38 g	103.03 g	103.63 g	103.63 g	✓	
2/5	103.02 g	103.35 g	102.80 g	102.86 g	103.95 g	103.20 g	✓	
3/5	103.68 g	103.59 g	104.59 g	104.06 g	103.03 g	103.75 g	✓	
4/5	103.51 g	103.82 g	103.67 g	103.89 g	103.33 g	103.54 g	✓	
5/5	103.01 g	103.14 g	103.64 g	103.78 g	106.60 g	103.43 g	✓	
							✓	

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

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
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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 : Wah
 Name : Wah Wah
 Date : 23/2/2024

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

REF : Bw4CB900 QTY PRODUCED (pcs) : 153

LOT NO : B20401 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>AARTINI</u>
Date	:	<u>23/2/2022</u>	Date	:	<u>25/2/2022</u>

VIGILENZ®

Doc. No. PR-RM001
Rev. 06

DATE : 05/02/2022
REF : BW4C0900
LOT NO. : 120401

SHOP PACKET QTY (pcs) : 144
CUSTOMER : BACTIGUARD AB (LIFECYN)
I.O. NO. : IO/CYN/060505/01

RS : 9

144
BACTIGUARD AB (LIFECYN)
IO/CYN/060505/01

NO	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		CONSUMPTION	RECEIVED BY
						REQUIRED	ISSUED		
1	P0100727	100g Tubes with D40 White Color Screw-on Cap	Diameter 40 x 135 mm, White Colour Tube + neck, 5mm Tube Orifice with Aluminium Foil Seal, Open End	H11G210501	pcs	153	153	153	Kanyang
2	P0100804	White Nozzle Cap	0	H12G210701		306	306	306	Kanyang
3	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gsm	800	800	800	Kanyang
4	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	G023210701	ml	200	200	200	Kanyang
5	C0100024	Pure Dry Vacuum Salt (25kg)	-	G021210601	gsm	20	20	20	Kanyang
6	N/A	STOCK SOLUTION	N/A	61807022207 61807022208	ltr	20	20	20	Kanyang

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100896	LBWC-012-GR-RO (100G - Gel Tube- GREECE), VIGILENZ0132, 110MM X 125MM, IN ROLL, TRANSPARENT PE, 4C + WHITE	LBES421101	154	Kanyang
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22210801	307	Kanyang
3	P0100806	LDPE ZIPPER BAG, Size: 0.05mm x 2" (opening) x 3" (L) USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	154	Kanyang
4	P0100916	BWC - GEL INNER BOX - GREECE 100g	BGR2220201		
5	P0100790	V09-BX024-00 - Hydrocyn Gel 100g (outer box) 300gsm 1 Side Art Card, 237 x 84 x 168mm	PH02210701	13	Kanyang
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210801	13	Kanyang
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 LR150M/LR150 (BC FLUTE)	H114210801/2	2	Kanyang
2	P0100767	V0047-0154; POF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m, 1 roll/carton	P092210801		Kanyang
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 : 05/02/2022

VERIFIED BY (PR) :

Signature :
Name :
Date : 28/2/22

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

Description	Bactiguard Woundcare	Reference No.	BW4C B900	Date of Inspection	22/02/2022
	Gel Tube 100g	Lot No.	B20401	Sample Size	1 pcs x 100g

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		pH (9.00 – 10.50)	FAC (100 – 200 ppm)	
✓	✓	✓	✓	✓	✓	9.46	comply	pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Poly
 Name : PESHNE
 Date : 23/02/2022

Approved By : [Signature]
 Name : MARTIN
 Date : 23/2/2022

