

GREECE
LABEL


SHOP PACKET - HYDROCYN AQUA GEL

REF :	BW42C900	ODR. QTY :	288	RS 3 + 6 (QC TEST)	ISSUED DATE	3-Feb-22
ITEM CODE :	BW010009	PACK SIZE :	12/BOX		LOT NO	B20307
ITEM :	Bactiguard Woundcare, Gel Tube (50g)	CUSTOMER	Bactiguard AB (Lifecyn)		MFG. DATE	3-Feb-22
		ORD. NO	B245 8008 2- 5/22		EXP DATE:	2023-08

PROCESS		START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPOC APPROVAL	RESULTS
HYDROCYN AQUA GEL PREPARATION							
TIME START:	6:36 pm	297	297	Nil	Conjano (790)	Rashmi 6:44pm 07/02/2022	2/2
DATE:	07-02-22						
TIME COMPLETE:	6:44 pm						
DATE:	07-02-22						
CHECK: pH / VISCOSITY / FAC							
Refer attachment: PR-HR001 QC-HR003							
LABELLING GEL TUBE							
TIME START:	8:45 pm	297	297	Nil	Conjano (790)	Wah 11:30 am 8.2.2022	5/5
DATE:	08-02-22						
TIME COMPLETE:	11:30 pm						
DATE:	08-02-22						
GEL FILLING							
TIME START:	2:40 pm	297	297	Nil	HNAUNG (1049)	Rashmi 4:30 pm 8/02/22	5/5
DATE:	08-02-22						
TIME COMPLETE:	4:30 pm						
DATE:	08-02-22						
SEALING AND CUTTING GEL TUBE							
TIME START:	2:40 pm	297	296	1	FARAH (1051)	Rashmi 4:50 pm 08/02/2022	1 Tube reject replace with new Tube 5/5
DATE:	08-02-22						
TIME COMPLETE:	4:30 pm						
DATE:	08-02-22						
LOT NUMBER AND EXPIRY DATE PRINTING							
TIME START:	9:20 am	291	291	Nil	HNAUNG 1049 Dewi 11:26	Wah 10:11 am 18.2.22	5/5
DATE:	08-02-22						
TIME COMPLETE:	10:11 am						
DATE:	08-02-22						
BOX PACKING & FINAL CONTROL							
TIME START:	8:40 pm	291	290+1	Nil	Chow (885) HNAUNG (1049)	Wah 8:30 pm 22.2.22	Refer FCTR
DATE:	08-02-22						
TIME COMPLETE:	9:35 pm						
DATE:	08-02-22						
CARTON PACKING							
TIME START:	10:10 am	24 box 4ctn	24 box 4ctn	Nil	Vister (1123)	Jinda 22/02/2022	23/02/2022
DATE:	08-02-22						
TIME COMPLETE:	10:15 am						
DATE:	08-02-22						

QUANTITY PRODUCED		297 pcs	
QUANTITY FOR QC/RETAIN SAMPLE		3+6 pcs	
SHIPMENT QUANTITY PCS / CTNS :		285 pcs 2 boxes / 4ctn	
FINAL SHIPMENT DATE			
COMPLETE/PARTIAL :		COMPLETE	

Checked by (PR),		Approved by (QC),	
Signature :		Signature :	
Name :	APARNA CHAKRA	Name :	Poornima Chakraborty
Date :	22/02/22	Date :	23/02/2022




Doc: MFG-SP013 Rev: 01

LABEL APPROVAL

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

Συστατικά: Καθαρισμένο ύδωρ, Υποχλωριώδες νάτριο (0,05%), Αίθιο-Μαγνήσιο-Νάτριο Πυρρικό και Χλωριούχο Νάτριο.

 Bactiguard (South East Asia) Sdn. Bhd.
(formerly known as VIGILENZ Medical Devices Sdn. Bhd.)
308B, Penang Science Park, 14100 Penang, Malaysia.

WOUND CARE

Καταπραυντική &
Βακτηριοστατική δράση

CE 2292

REF BW42C900

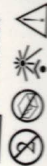
Διανομέας: LIFEQYN AE
Καζαντζή 4 & Α', Πεν-
3361 Άγιοι Ανδρέας,
Τηλ.: +30 210 8313616
email: info@lifesyn.com
Αρ. Γνωστοποίησης ΕΟΦ:



LOT: B20307
EXP: 2023-06

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

REF BW42C900



CE 2292

Bactiguard[®]



WOUND CARE

Καταπραυντική & Βακτηριοστατική δράση

Γέλη 50g

 Bactiguard (South East Asia) Sdn. Bhd.
(formerly known as VIGILENZ Medical Devices Sdn. Bhd.)
308B, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia.

Διανομέας: LIFEQYN AE
Καζαντζή 4 & Α', Πενταπόλεως
3361 Άγιοι Ανδρέας, Αττική
Τηλ.: +30 210 8313616 email: info@lifesyn.com

REF: BW42C900

Bactiguard Wound Care Gel

REF BW42C900

LOT B20307

Qty 12 pcs / box

Weight 50 g / pc

Bactiguard[®]



✓ wch
22.2.22


VIGILENZ[®]	HYDROCYN aqua[®] GEL - RECORDS OF PREPARATION	
	Doc. No.	PR-HR001
		Rev. 04

VIGILLENZ	HYDROCYN aqua® GEL - RECORDS OF PREPARATION
	Doc. No. PR-HR001
	Rev. 04

Date	QC-56	HSM-01
02/20/2010	3.0	3.1
	20.0	20.1

	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.	Bu43c900 / B20307
Order Qty.	288

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)
G1B07022203	G13	9.70	comply	9706	✓	pass
G1B07022204	G14	9.70	comply	9706	✓	pass

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		 Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 2(3)

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	51.28 g	52.39 g	52.37 g	52.14 g	51.93 g	52.02 g	✓	pass
1/5	51.94 g	51.95 g	53.33 g	52.73 g	52.43 g	52.47 g	✓	pass
2/5	53.14 g	53.25 g	52.19 g	52.11 g	52.35 g	52.61 g	✓	pass
3/5	52.08 g	52.15 g	52.39 g	52.47 g	52.39 g	52.29 g	✓	pass
4/5	51.95 g	52.73 g	52.49 g	52.19 g	52.17 g	52.31 g	✓	pass
5/5	53.25 g	53.08 g	53.19 g	52.49 g	52.08 g	52.82 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

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

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 : 22-02-2022

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

REF : BW42C900 QTY PRODUCED (pcs) : 297

LOT NO : B 20307 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 : Wah

Name : Wah Wah

Date : 22.02.2022

Approved By : [Signature]

Name : AKRINI

Date : 23/2/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

DATE : 04/02/2022
REF : BW42C900
LOT NO. : B20307

SHOP PACKET QTY (pcs) : 288
CUSTOMER : BACTIGUARD AB (LIFECYN)
LO NO. : 10/CYN/060505/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100726	50g Tubes with D30 White Color Screw-on Cap	Diameter 30 x 120 mm, White Colour Tube + neck, 5mm Tube Orifice with Aluminium Foil Seal, Open End	H05G210901	pcs	297	297	1. Canjana
	P0100804	White Nozzle Cap	0	H12G211001		594	594	1. Canjana
2	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gms	800	800	1. Canjana
3	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	1. Canjana
4	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gms	20	20	1. Canjana
5	N/A	STOCK SOLUTION	N/A	B1B07033003 B1B07033004	ltr	20	20	1. Canjana

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100895	LBWC011-GR-R0 (50G - Gel Tube- GREECE), VIGILENZO131; 100MM X 90MM; IN ROLL, TRANSPARENT PE, 4C + WHITE	LG04220201	298	1. Canjana
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22210801	595	1. Canjana
3	P0100806	LDPE ZIPPER BAG, Size: 0.05mm x 2" (opening) x 3" (L) USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P0100806	298	1. Canjana
4	P0100916	BWC-GEL INNER BOX 50g BWC-004 GR-R0 -GREECE	BGR220201		
5	P0100788	V09-BX022-00 - Hydrocyn Gel 50g (outer box) 300gram 1 Side Art Card, 192 x 142.5 x 129mm	PH01210702	25	1. Canjana
6	P0100208	BLANK LABEL (Sharps Pad) Gauze/ Gel) SIZE: 85mm X 65mm	L190210801	25	1. Canjana
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-D.338mm X (W)293mm X (H)305mm LR150/MLR150 (BC FLUTE)	H114210801/2	4	1. Canjana
2	P0100767	V0047-0154; POF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m, 1 rolls/carton	P092210801	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)		N/A	
2		#N/A			

ISSUED BY (MM) :

Signature :
Name : ADVIN
Date : 04/02/2022

VERIFIED BY (PR) :

Signature :
Name :
Date : 20/2/2022

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

Description	Reference No.	Date of Inspection
	Lot No.	Sample Size
Bachguard Woundcare Gel Tube, 50g.	BW432900	23/2/2022
	B20207	1PCS x 50g

Release Criteria:

Packing Integrity				Chemical Testing		Test Disposition
Correct and legible printing of label	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)	PASS / FAIL
					9.77 copy	pass

✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Raj
 Name : POSHNI
 Date : 23/2/2022

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

