

## SHOP PACKET - EASW

REFERENCE	BW34E700	ODR. QTY (PCS)	5,000	RS(2) QC(2)	ISSUED DATE	28/01/2022
ITEM CODE	BW010002	PACK SIZE	50/Box		LOT NO.	A22830
ITEM DESCRIPTION	Bactiguard Woundcare 250ml (Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
		ODR. NO	A193		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 28/01/2022		INT. ORDER	IO/BD/270122/01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton		N/A		
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-PI NO. (2nd Packaging) - Carton		N/A		
PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION				Ryandan (893)	wah	Tank 1000L/T6 03HB290122025
TIME START : DATE : TIME COMPLETE : DATE :	7:00pm 29-01-22 9:00pm 30-01-22	5004	5004	N/A	9:00AM 28/01/2022	Tank 1000L/T7 03HB290122024
UDI PRINTING (Label/Box/Carton)						UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
SOLUTION FILLING & CAPPING				Kyu (887) Farah (1051)	wah 7:00PM 3-2-22	N/A
TIME START : DATE : TIME COMPLETE : DATE :	10:00 AM 03-02-22 7:00 PM 03-02-22	5004	5004	N/A		
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	9:00 AM 04-02-22 5:30 PM 04-02-22	5004	5004	N/A	unay (1049) Netra (1103)	wah 5:30PM 4-2-22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :	10:30 AM 03-02-22 2:00 PM 04-02-22	5004	5004	N/A	Era (982) Viki	wah 2:00PM 4/2/22
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	9:00 AM 04-02-22 5:30 PM 04-02-22	5004	5004	N/A	Netra (1103) Era (932) unay (1049)	wah 6:00PM 4-2-22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	9:40 am 04-02-22 12:45 pm 05-02-22	100 ctn	100 ctn	N/A	FATLI 1053 Rabin 1088 Tehdi 1054	Nurin 5/2/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 5008 btl  
 QUANTITY FOR QC / RETAIN SAMPLE : 4+4 btl  
 SHIPMENT QUANTITY PCS / CTNS : SUTO (145) / (10) ctns  
 FINAL SHIPMENT DATE :  
 COMPLETED / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>Note</i>	Approved by (QA), Signature : <i>JM8</i>	Released by (QC), Signature : <i>MARTINS</i>
Name : RAJINNEKA Date : 7/2/22	Name : Roshana Osman Date : 8/2/2022	Name : MARTINS Designation : QC DEPT Date : 7/2/2022 Stamp :
Remarks: TO PRODUCE WITHOUT LABEL		
 RELEASED BACTIGUARD (S.E.A) SDN BHD QUALITY CONTROL		

**VIGILENZ®**
**CHECKLIST FOR LINE CLEARANCE OF  
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)**

 Doc. No      QC-LC002  
 Rev.            00

<b>Item Description</b>	<i>Bactiguard Woundcare 250 ml (Spray Mist)</i>		
<b>Reference</b>	<i>BW 34E700</i>		
<b>Lot No.</b>	<i>A 22830</i>		

No.	Checklist	Yes	No	Performed by (Signature / Date)	Verified by QC (Signature / Date)	Remarks	Responsibility
1	Flush machine HD-01 with approximately 20L of RODI water & 10L of EASW solution before each production batch	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Kyandeh 03/02/22</i>	<i>work 3.2.22</i>	N/A	Technician
2	All machine components which are directly in contact with the product materials are thoroughly cleaned and free from rust / dirt / dust and foreign particles					N/A	Technician
i)	Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
ii)	Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
iii)	Stopper Inserter	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
iv)	Cap Dispenser	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
v)	Cap Pusher	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>. Kyan 03/02/22</i>	<i>work 3.2.22</i>	N/A	Production
4	All finished goods, materials and rejected items related to previous lot are cleared and removed from working area	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>1 Kyan 03/02/22</i>	<i>work 3.2.22</i>	N/A	Production

Title:

## QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Document type:  
FORM

Doc Id:  
QC-IP002-09

Issue Date:  
15/11/2021

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		 Bactiguard	
Reference / Lot No.	BW 34E 700 / A22830	Order Qty	5000

Item Description	Bactiguard Woundcare 250ml (Spray mist)		
Reference / Lot No.	BW 34E 700 / A22830	Order Qty	5000
Volume Specification	255	±	5 ml

A. Filling Process

Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition
10/10	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS

B. Labelling, Lot No, Manufacturing Date and Expiry Date Process

Sampling / Frequency	Label printing is clear and legible (inclusive of special printing when applicable)	Reference No, Lot No, Manufacturing Date and Expiry Date are corresponding to Shop	Correct Position of Labelling on Packaging	Correct UDI number printing on labelling (Product Code, Manufacturing Date, NP)	Test Disposition

Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bacteriostatic Water	Issue Date: 15/11/2021	Page: 1(3)
Document type: FORM	Doc Id: QC-IP002-09			

Item Description	Bactiguard woundcare 250 ml (spray mist)		
Reference / Lot No.	BUN 34E 700	/	A 22830
Order Qty	5000		
Volume Specification	255	±	5 ml

## A. Filling Process

### B. Labelling, Lot No., Manufacturing Date and Expiry Date Process

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
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Bactiguard

Item Description	Bactiguard woundcare 250ml (spray mist)		
Reference / Lot No.	BW 34E 700	/	A 22830
Order Qty	5000		
Volume Specification	255	±	5 ml

A. Filling Process

Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition
1/300	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
1/300	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
1/300	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
1/300	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
1/198	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
						<input type="checkbox"/>
						<input type="checkbox"/>
						<input type="checkbox"/>

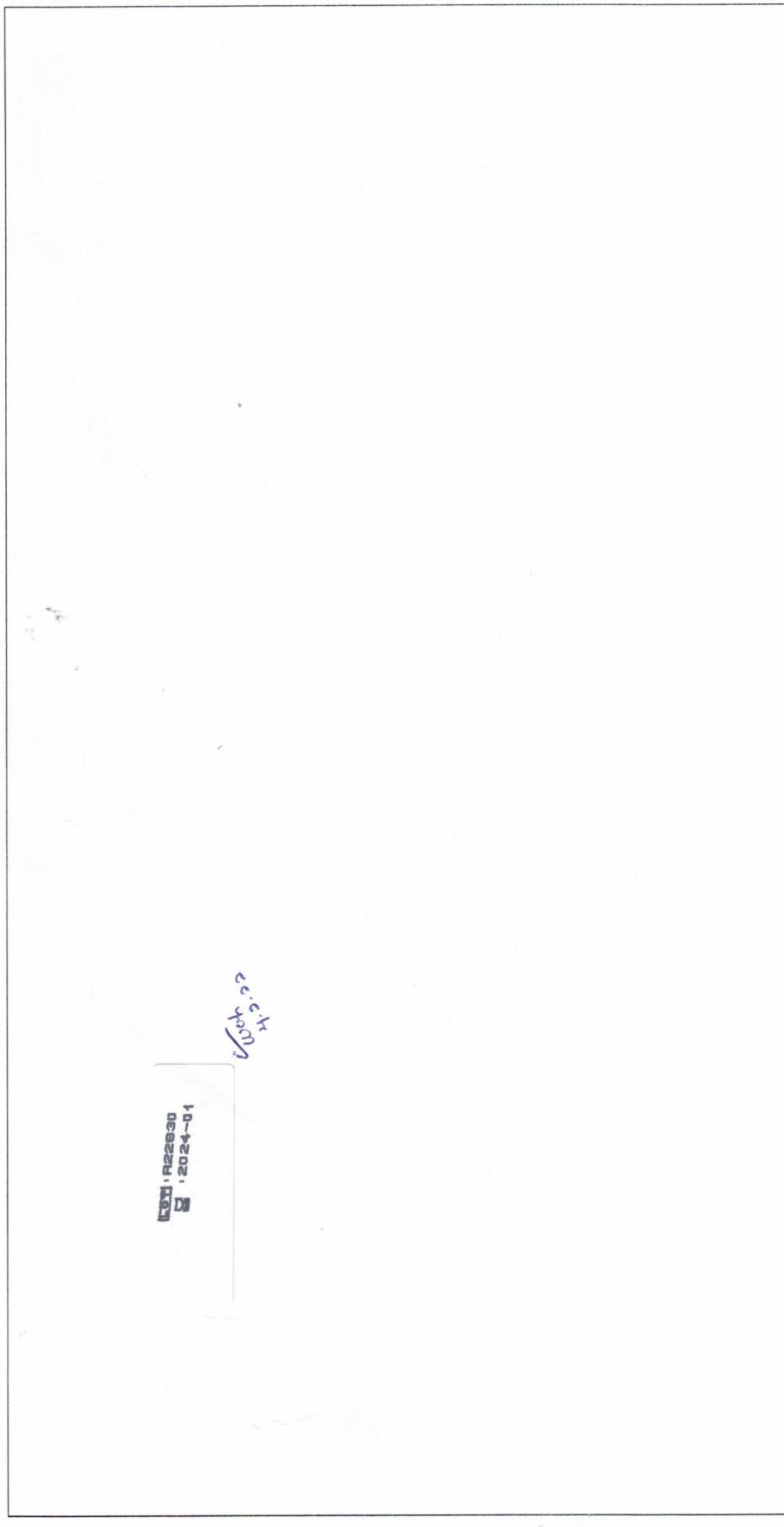
Yours  
Sai

B. Labelling, Lot No, Manufacturing Date and Expiry Date Process

Sampling / Frequency	Label printing is clear and legible (inclusive of special printing when applicable)	Reference No, Lot No, Manufacturing Date and Expiry Date are corresponding to Shop	Correct Position of Labelling on Packaging	Correct UDI number printing on labelling (Product Code, Manufacturing Date, Manufacturing Date, Expiry Date)	Test Disposition
					<input checked="" type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
Document type:	Doc Id:	Issue Date:	
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**C. Attachment (First Printed Label)**

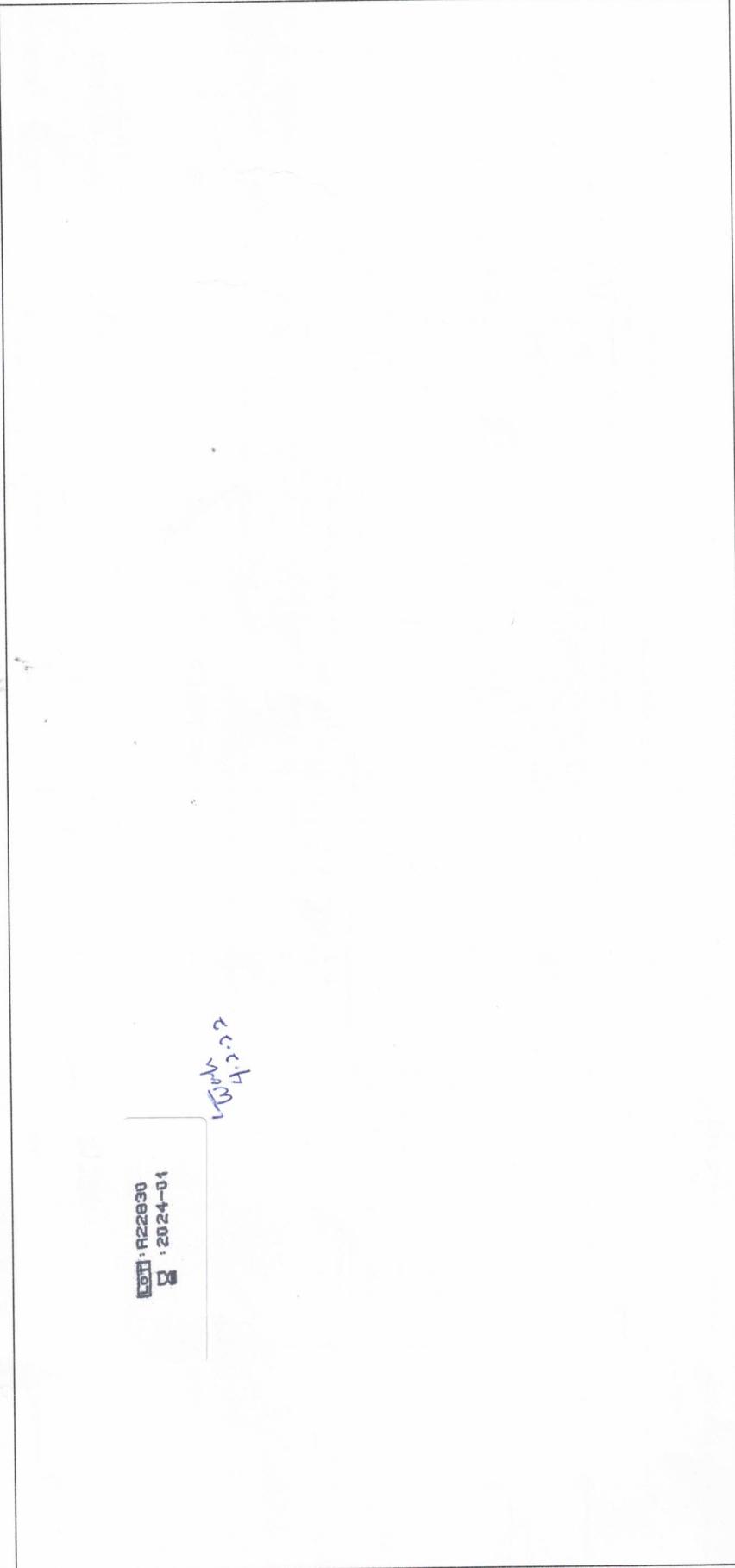


Disposition of the Lot :  PASS  FAIL  
 Inspected by : Woh  
 Name : Woh wick  
 Date : 4.02.2022

Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	 Bactiguard
Document type: FORM	Issue Date: 15/11/2021

Doc Id:  
QC-IP002-09

**D. Attachment (Last Printed Label)**



Disposition of the Lot :  PASS  FAIL  
 Inspected by : Woh  
 Name : Woh Woh  
 Date : 15.02.2022

VIGILENZ®	FINAL CONTROL TEST REPORT -		Doc. No.	QC-FC004
	ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Rev.	09

ITEM DESCRIPTION : Bacteriostatic Water 250 ml

REFERENCE : BW 34E 400

LOT NO. : A22830

QTY. PRODUCED (pes) : 5008 5008

RETAIN SAMPLE QTY. (pes) : 2+2

WCH  
3.2.22

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	S3, 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S3, 0.15	80	0	1	80	0	pass
3	Proper sealing and no leaking.	S3, 0.15	80	0	1	80	0	pass
4	Free from contamination / particle / foreign materials on product solution.	S3, 0.15	80	0	1	80	0	pass
5	Correct volume filled (against reference sample).	S3, 0.15	80	0	1	80	0	pass

Remarks : N/A

Approved By : WCH  
 Name : MARTINI  
 Date : 4/2/2022

Inspected By : WCH  
 Name : WCH WCH  
 Date : 4.02.2022

## RAW MATERIAL LOADING FORM (RMLF)

Doc. No.  
Rev.

DATE :	03/02/2022
REF :	BW34E700
LOT NO. :	A22830

SHOP PACKET QTY (pcs) : 5000 RS  
 CUSTOMER : BACTIGUARD AB  
 I.O. NO. : IO/BD/27/01/22/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
1	P0100578	271-24410(VG)	250ml HDPE Round Container (Natural Color)	H018200701	pcs	5004		5004	5004	<u>Cayano</u>
2	P0100563	JQ-24A-PP (11cm)	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP, PP, TUBE:110mm	H091200402	pcs	5004		5004	5004	<u>Cayano</u>
3		STOCK SOLUTION		O3HB290122025 0511B2901221211	ltr	1300		1300	1300	<u>Cayano</u>

## (2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capsel (For 100ml Hydrocyn) - Size: 47 x 0.04 x 55 mm (L-C-P)	H019210901	5005	<u>Cayano</u>
2					
3		#N/A			
4		#N/A			
5		#N/A			
6		#N/A			
7		#N/A			

## (3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100560	Printed Carton (Hydrocyn 250ml, Spray Mist) - Size: 330 x 350 x 365mm, Material: AB Flute DW 175/MMM/M175G	H060211101	100	<u>M-oly</u>
2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS: 312 x 90mm(4ps each), Mat: TI50/TI50 B Flute	H069210601	200	<u>M-oly</u>
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: TI50/TI50 B Flute	H070211103	100	<u>M-oly</u>

## (4) SPECIAL REQUIREMENT

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	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 : LOVIN  
 Name : MAURICE LOVIN  
 Date : 03/02/2022

VERIFIED BY (PR) :

Signature : Art  
 Name : MAURICE LOVIN  
 Date : 7/2/09

VIGILENZ®

**PRODUCT RELEASE TEST REPORT –  
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)**

Doc No.	QC-PC007
Rev.	06

Description	Bactericidal woundcare 350mL (spray mist)	Reference No.	BU34ETCO	Date of Inspection	08/03/2022
Lot No.	A33830	Sample Size	10g x 350mL		

*Release Criteria:*

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	FAC (ppm)	Test Disposition ( PASS / FAIL )		
Spec: 6.50 - 8.00	Spec: ≥ 850	Spec: 95 - 140			
Result	Instrument	Result	Instrument	Result	Instrument
7.18	Q.C. - T8	871	Q.C. - 6.7	113	Q.C. - 8.0 pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000 L / T4, 03 HBB9012204

Disposition of the Lot :  RELEASE  ON HOLD

Analyzed By : Rony  
 Name : Postma  
 Date : 8/2/2022

Approved By : M. J. Murphy  
 Name : M. J. Murphy  
 Date : 8/2/2022



VIGILENZ®

**PRODUCT RELEASE TEST REPORT –  
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)**

Doc No.	QC-PC007
Rev.	06

Description	Bactericidal woundcare 150 mL (Spray Mist)	Reference No.	BW34E700	Date of Inspection	Passed
Lot No.	A33 830	Sample Size	250 mL	Approved	

*Release Criteria:*

Analysis of Electro Activated Super-Oxidized Water (EASW)				Test Disposition (PASS / FAIL)
pH	ORP (mV)	FAC (ppm)	Spec: 95-140	
Result	Instrument	Result	Instrument	Result
7.8	GC-78	867	GC-67	111
			QC - 80	pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000L / 76, 03HB90110005

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : Polly  
 Name : Roshni  
 Date : 8/2/2022



Approved By : Mr. RITIN  
 Name : Mr. RITIN  
 Date : 8/2/2022