

NO LABEL



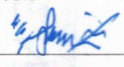

Bactiguard

SHOP PACKET - EASW

REFERENCE	BW34E700	ODR. QTY (PCS)	2,150	RS: 2+2 (QC TEST)	ISSUED DATE	29/01/2022
ITEM CODE	BW010002	PACK SIZE	50/Box	+2+2	LOT NO.	A22903
ITEM DESCRIPTION	Bactiguard Woundcare, 250ml (Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	29/01/2022
		ODR. NO	A202		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA 8P. DATE : 29/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 29/01/2022		INT. ORDER	10/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	IPOC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START: 11:30 Am	2158	2158	Nil	Kyanden (893)	Wah 4/3/22	Tank 500L IT5 03HB040322064 Tank 500L IT1 03HB040322067
DATE: 04-03-22						
TIME COMPLETE: 3:00 Pm						
DATE: 04-03-22						
UDI PRINTING (Label/Box/Carton)						
TIME START:				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE:						
TIME COMPLETE:						
DATE:						
SOLUTION FILLING & CAPPING						
TIME START: 9:08 am	2158	2158	NIL	VICKY(1090)	Wah 8/3/22	N/A
DATE: 08-03-22						
TIME COMPLETE: 12:05 pm						
DATE: 08-03-22						
LABELLING						
TIME START:				N/A		
DATE:						
TIME COMPLETE:						
DATE:						
PRINTING LOT NUMBER						
TIME START: 12:30 pm	2158	2158	NIL	PARAH (1080) LINA (1131)	Wah 8/3/22	N/A
DATE: 08-03-22						
TIME COMPLETE: 04:00 pm						
DATE: 08-03-22						
CAP SEALING (Applicable for 100mL)						
TIME START: 9:15 am	2158	2158	NIL	ET9 (932) LINA (1131)	Wah 8/3/22	N/A
DATE: 08-03-22						
TIME COMPLETE: 12:30 pm						
DATE: 08-03-22						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START:			N/A			
DATE:						
TIME COMPLETE:						
DATE:						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START: 12:30 pm				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE: 08-03-22						
TIME COMPLETE:						
DATE:						
FINAL CONTROL						
TIME START: 12:30 pm	2158	2158	NIL	PARAH (1080) LINA (1131)	Wah 4:00pm 8/3/22	N/A
DATE: 08-03-22						
TIME COMPLETE: 04:00 pm						
DATE: 08-03-22						
CARTON PACK						
TIME START: 9:20 am	43 ctn	43 ctn	Nil	Rabin (1088) Fati (1054) Kendi (1053)	Nurin 9/3/2022	FIRBANS 815 9/3/22
DATE: 09-03-22						
TIME COMPLETE: 11:20 am						
DATE: 09-03-22						
UDI LABELLING						
TIME START:				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE:						
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED :	2158 Lts
QUANTITY FOR QC / RETAIN SAMPLE :	RS 41 46H
SHIPMENT QUANTITY PCS / CTNS :	2150 Lts / 43 ctn
FINAL SHIPMENT DATE :	
COMPLETE / PARTIAL :	COMPLETE

Checked by (PR), Signature:  Name: Ratnasegaran Date: 9/3/22	Approved by (QA), Signature:  Name: Ratnasegaran Date: 15/3/2022	Released by (QC), Signature:  Name: MARTINI Designation: IPQC SUP Date: 9/3/2022 Stamp: 
Remarks:		

VIGILENZ®

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

Doc. No


QC-LC002

Rev.

00

Item Description	Bactiguard Wundare 250ml (spray mist)
Reference	BCU34E70B
Lot No.	A22903

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>[Signature]</i> 893 08/03/2022	<i>[Signature]</i> 08/03/2022	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 i) Starwheel ii) Nozzle iii) Stopper Insertor iv) Cap Dispenser v) Cap Pusher	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>[Signature]</i> 893 08/03/2022	<i>[Signature]</i> 08/03/2022	N/A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>[Signature]</i> 08/08/22	<i>[Signature]</i> 8/3/22	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>[Signature]</i> 08/08/22	<i>[Signature]</i> 8/3/22	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	Page: 1(3)

Item Description	Bactiguard Woundcare 250ml (spray mist)		
Reference / Lot No.	BW34E700 / A22903		
Order Qty	2150		
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	
						PASS	FAIL
10/10	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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,	Test Disposition	
					PASS	FAIL
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>

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



Document type:
FORM

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
1(3)


Item Description	Bactiguard woundcare 250ml (spray mist)		
Reference / Lot No.	BW34E700	/	A22903
Order Qty	2150		
Volume Specification	255	±	5 ml

A. Filling Process

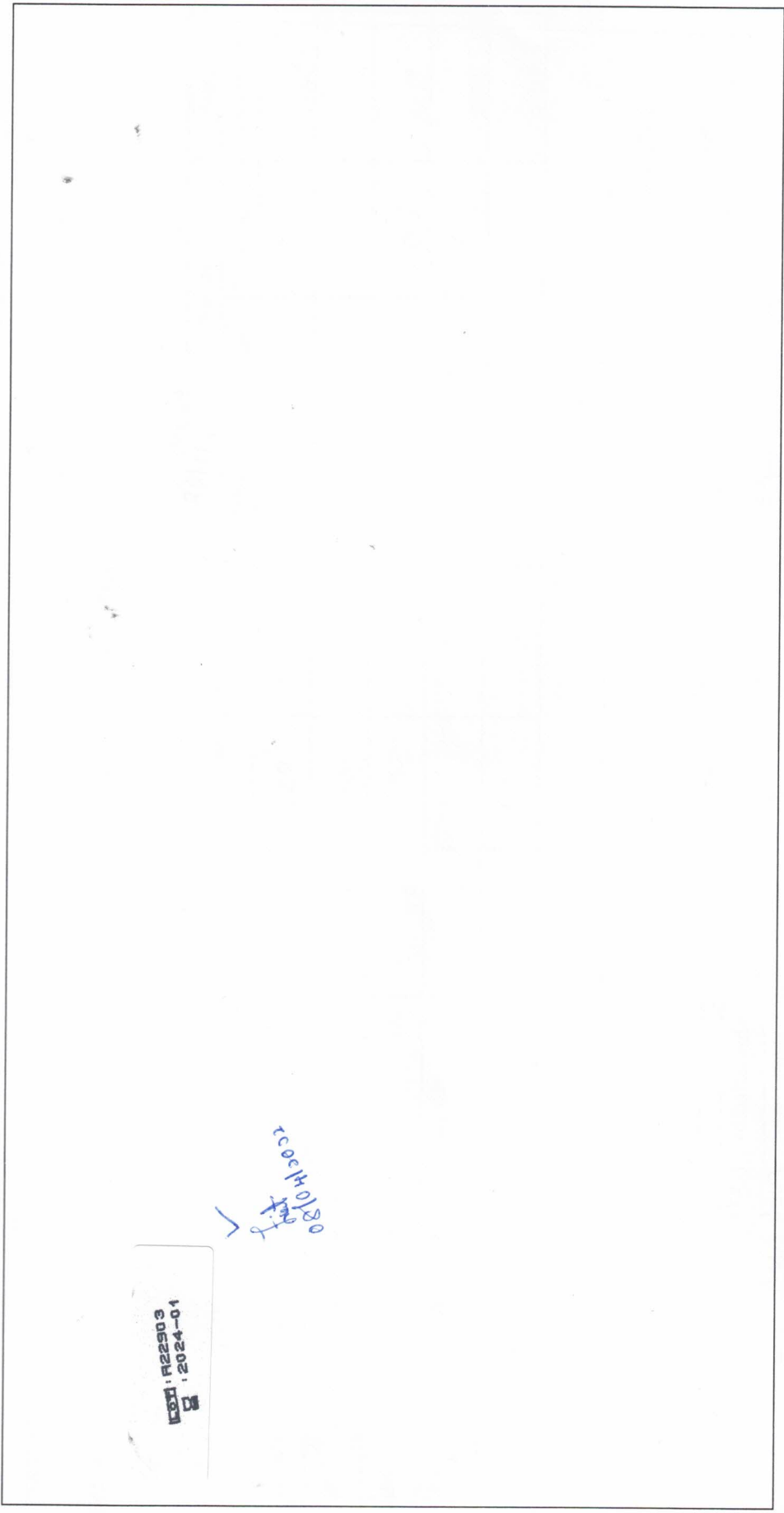
Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition	
						PASS	FAIL
1/348	260ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>

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,	Test Disposition	
					PASS	FAIL
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input 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)		 Bactiguard	
Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/11/2021	Page: 2(3)

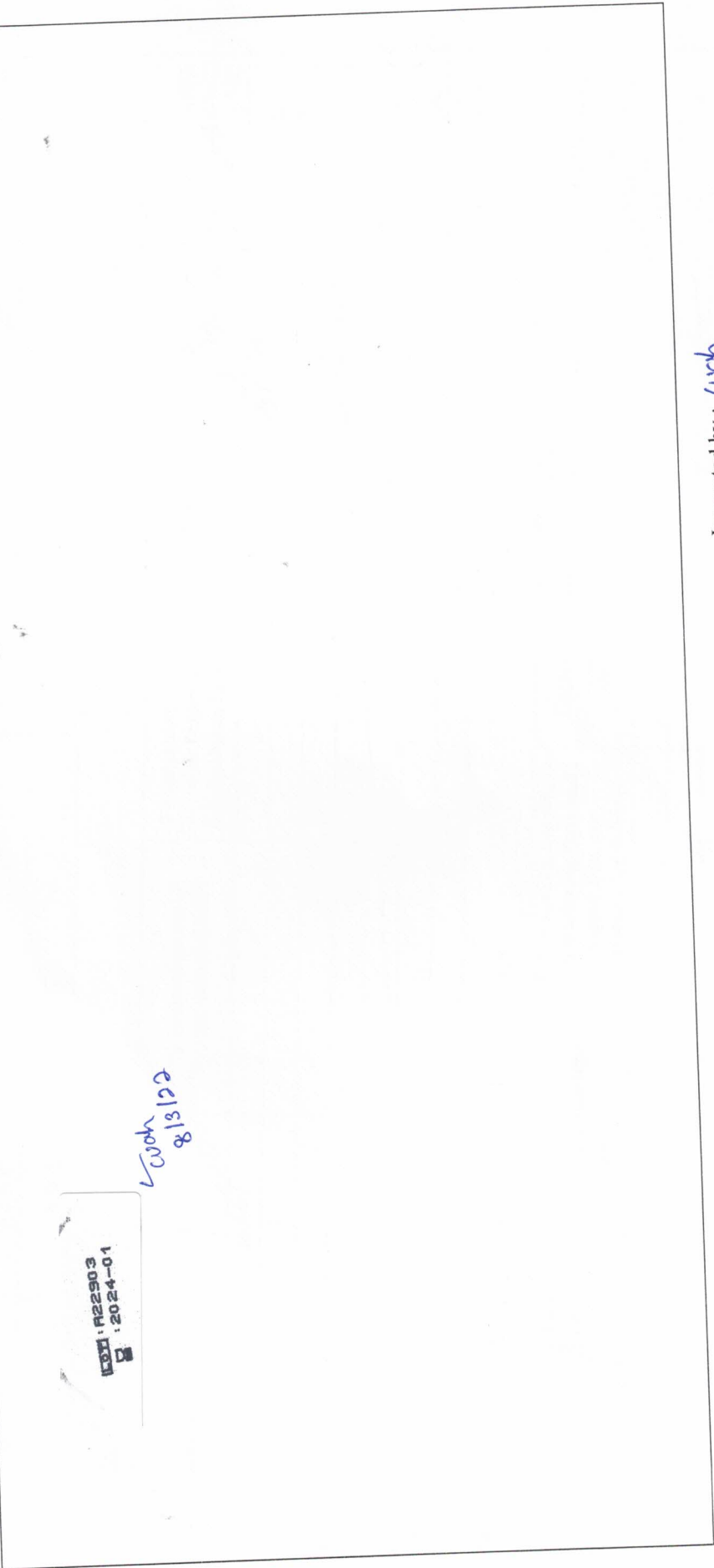
C. Attachment (First Printed Label)



Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL
	Inspected by : <u>Wah</u>	
	Name : <u>Wah Wah</u>	Date : <u>8/3/22</u>

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

D. Attachment (Last Printed Label)



Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL	Inspected by : <u>Woh</u>
			Name : <u>Woh Woh</u>
			Date : <u>8/13/22</u>

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

ITEM DESCRIPTION : Balghuard woundcare 350ml

REFERENCE : BW34E700

LOT NO. : A22903

QTY. PRODUCED (pcs) : 2158

RETAIN SAMPLE QTY. (pcs) : 4

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

Remarks : N/P

Inspected By : Wah

Name : Wah Wah

Date : 8/3/22

Approved By : MARTINI

Name : MARTINI

Date : 8/3/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

DATE : 07/03/2022

REF : BW34E700

LOT NO. : A22903

SHOP PACKET QTY (pcs) : 2150

CUSTOMER : BD (MALAYSIA)

LO NO. : IO/BD/270122/01

NO. SYSTEM CODE

ITEM DESCRIPTION 1

DESCRIPTION 2

LOT NO.

UOM

REQUIRED

ISSUED

QUANTITY (pcs)

CONSUMPTION

RECEIVED BY

1

P0100578

271-24410(VG)

H090211201

pcs

2154 +4

2154 +4

2158

1

2158

1

2

P0100563

JQ-24A-PP (11cm)

H091220101

pcs

2154 +4

2154 +4

2158

1

2158

1

3

STOCK SOLUTION

03HB040322064
03HB040322067

ltr

560

560

560

560

1

NO. SYSTEM CODE

ITEM DESCRIPTION 1

LOT NO.

QTY REQUIRED (pcs)

RECEIVED BY

1

Secure Capsel (For 100ml /250ml Hydrocyn) - Size: 47 x 0.04 x 55 mm (1C+P)

H019211201

2155 +4

1

2

NO LABEL

3

#N/A

4

#N/A

5

#N/A

6

#N/A

7

#N/A

NO. SYSTEM CODE

ITEM DESCRIPTION 1

LOT NO.

QTY REQUIRED (pcs)

RECEIVED BY

1

P0100560

Printed Carton (Hydrocyn 250ml, Spray, Mist) - Size: 330 x 330 x 365mm, Material: AB Flute DW 175/M/M/M/175G

H060211103

43

1

2

P0100567

DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS-312 x 90mm(4pcs each), Mat: T150/T150 B Flute

H069220301

86

1

3

P0100568

DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute

H070220301

43

1

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

1

2

#N/A

ISSUED BY (MM) :

SIGNATURE :

NAME :

DATE :

VERIFIED BY (PR) :

SIGNATURE :

NAME :

DATE :

VIGILENZ®	PRODUCT RELEASE TEST REPORT – ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc No.	QC-PC007
			Rev.	06

Description	Background woundcare 250 ml (spray mist)	Reference No.	BW34E700	Date of Inspection	09.03.22
		Lot No.	A22903	Sample Size	250 ml X 250 ml

Release Criteria:


Analysis of Electro Activated Super-Oxidized Water (EASW)						Test Disposition (PASS / FAIL)
pH		ORP (mV)		FAC (ppm)		
Spec: 6.50 - 8.00		Spec: ≥ 850		Spec: 95 - 140		
Result	Instrument	Result	Instrument	Result	Instrument	pass
7.18	QC-78	861	QC-67	112	QC-80	

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks: Tank 500 L/15 OBH B040322064

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Wuch
Name : Wuch Wuch
Date : 9.3.22

Approved By : 
Name : MARTINI
Date : 9/3/2022



VIGILENZ®	PRODUCT RELEASE TEST REPORT – ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc No.	QC-PC007
			Rev.	06

Description	Backguard wound care 250ml (spray mist)	Reference No.	BW 34E700	Date of Inspection	09.03.22
		Lot No.	A 22903	Sample Size	2b11 x 250 ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)						Test Disposition (PASS / FAIL)
pH		ORP (mV)		FAC (ppm)		
Spec:	6.50 - 8.00	Spec:	≥ 850	Spec:	95 - 140	
Result	Instrument	Result	Instrument	Result	Instrument	
7.17	QC-78	868	QC-67	123	QC-80	pass

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks: Tank 500L/1' 03HB040322067

Disposition of the Lot: ☒ RELEASE ☐ ON-HOLD

Analyzed By : Wah
Name : Wah Wah
Date : 9.3.22

Approved By : [Signature]
Name : A. K. TINI
Date : 9/3/2022

