

SHOP PACKET - EASW

REFERENCE	BW34E700	ODR. QTY (PCS)	4,350	RS(2) QC(2) +2 +2 28/01/22	ISSUED DATE	28/01/2022
ITEM CODE	BW010002	PACK SIZE	50/Box	+2 28/01/22	LOT NO.	A22832
ITEM DESCRIPTION	Bactiguard Woundcare, 250ml (Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/01/2022	VERIFIED BY	A195		EXP. DATE	2024-01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton	NAME : RATNASEGARAN DATE : 28/01/2022	Not	INT. ORDER	IO/BD/270122/01
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 : DATE : TIME COMPLETE : DATE :	5:35pm 01-03-22	4358	4358	Nil	Kyandar (883)	Poshni 8:40pm 01/03/2022
UDI PRINTING (Label/Box/Carton)						TANK 500L/T5 03H2010322061 03H2026322060
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	8:30 AM 03-03-22	4358	4338	20	INA (1131) SOFIA (138)	Poshni 3:30pm 03/03/2022
LABELLING						- 20 Bottles reject replace with new Bottles
TIME START : DATE : TIME COMPLETE : DATE :						
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	3:45 PM 03-03-22	4358	4338	Nil	Sofya (1138) Era (982)	Poshni 11:50am 04/03/22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :	9:00am 03-03-22	4358	4358	Nil	FARAH (1051) RINA (1266)	Poshni 7:45pm 03/03/2022
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 :	3:45 PM 03-03-22	4358	4358	Nil	Era (932)	Poshni 11:57am 04/03/2022
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	12:00 PM 04-03-22	87 etc	87 etc	Nil	FAELI (1054) Rabin (1088)	Nurin 4/3/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 4858 Vts
 QUANTITY FOR QC / RETAIN SAMPLE : 4rst abn + 2 Rps
 SHIPMENT QUANTITY PCS / CTNS : 4850 Vts
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : MUNIB ARIFUDDIN Date : 8/3/22	Name : Mohamad Osman Date : 8/3/2022	Name : MARTINI Designation : IPAC DEPT Date : 8/3/2022 Stamp :
Remarks:		



VIGILENZ®

ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No	QC-LC002
Rev.	00

Item Description	<i>Baigund wundur 250 ml (Spray m'st)</i>		
Reference	<i>BW34E700</i>		
Lot No.	<i>122833</i>		

No.	Checklist	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Performed by (Signature / Date) <i>Rash 03/03/2022</i>	Verified by QC (Signature / Date) <i>Praj 03/03/2022</i>	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>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Technician
i)	Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Technician
ii)	Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Technician
iii)	Stopper Insertor	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Technician
iv)	Cap Dispenser	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Technician
v)	Cap Pusher	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	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>Rash 03/03/2022</i>	<i>Praj 03/03/2022</i>	<i>NP</i>	Production

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

Item Description	Banigard woundtop 250 ml (spray mist)
Reference / Lot No.	Bu 84700 / A 02833
Order Qty	A 02833 (4850
Volume Specification	255 ± 5 ml

A. Filling Process

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

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

Item Description	Bacitracin wound and spray mist		
Reference / Lot No.	BW34E700 / A00830		
Order Qty	4350		
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)		 Bactigard	Issue Date: 15/11/2021	Page: 1(3)
Document type: FORM	Doc id: QC-IP002-09			

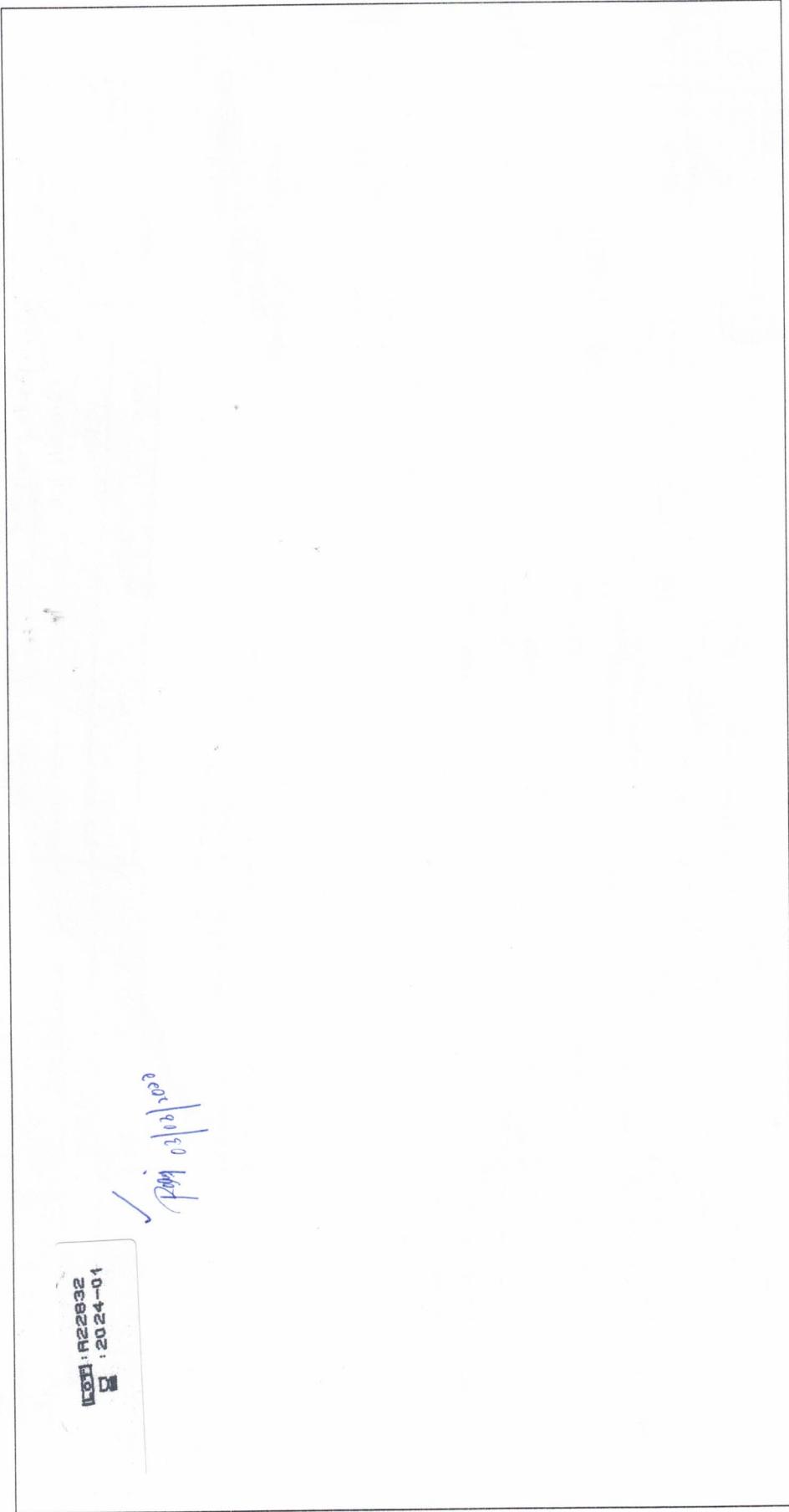
Item Description	Bacitracin wound care 250 ml (spray mist)		
Reference / Lot No.	BW34E700		
Order Qty	4350	±	5
Volume Specification	255	ml	

A. Filling Process

Manufacturing Date and Expiry Date Process

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
Document type:	Doc Id:	Issue Date:	
FORM	QC-IP002-09	15/11/2021	
Page: 2(3)			

C. Attachment (First Printed Label)

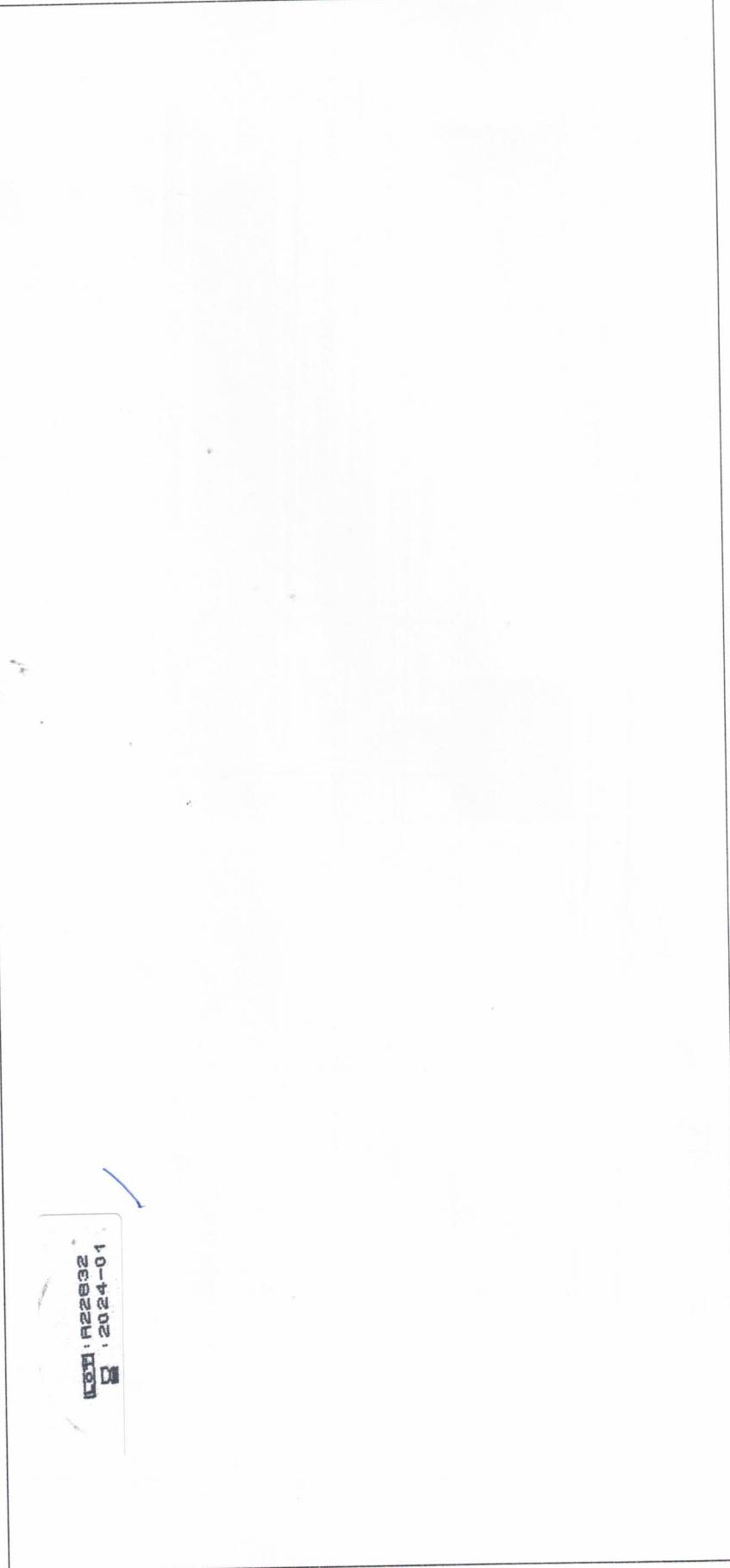


Disposition of the Lot : PASS FAIL

Inspected by : Polly
Name : Bosnal
Date : 07/09/2023

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	Page: 3(3)

D. Attachment (Last Printed Label)



Inspected by : Poly
 Name : Roshni
 Date : 04/03/2023

Disposition of the Lot : PASS FAIL

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

ITEM DESCRIPTION : Bottled water 250 ml

REFERENCE : BW31E100

LOT NO. : A20832

QTY. PRODUCED (pcs) :

4858

RETAIN SAMPLE QTY. (pcs) :

2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results	Status
				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>
2	Free from contamination, deformed or damaged on packaging.	<u>S4, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</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>
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>
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>

Remarks :

N/A

Inspected By : Praj
Name : MARTINI
Date : 03/03/2023

Approved By : Supriyatno
Name : MARTINI
Date : 03/03/2023

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RU
Rev. 06

DATE :	10/02/2022	SHOP PACKET QTY (pes)	: 4350
REF :	BW34E700	CUSTOMER	: BACTIGUARD AB
LOT NO. :	<u>A22832</u> / <u>A22832</u>	LO NO.	: IOBD/270122/01

SHOP PACKET QTY (pes) : 4350
 CUSTOMER : BACTIGUARD AB
 LO NO. : IOBD/270122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)	RECEIVED BY
1	P0100578	271-24410(VG)	250ml HDPE Round Container (Natural Color)	<u>H090 200601</u>	pes	4354	4354	<u>1 Cugua</u>
2	P0100563	JQ-24A-PP (11cm)	24/410 MIST SPRAYER, RIBBED 316 SPRING, HALF CAP, PP, TUBE:110mm	H091200402	pes	4354	4354	<u>1 Cugua</u>
3		STOCK SOLUTION		<u>03H0803030606</u>	ltr	<u>1132</u>	<u>1132</u>	<u>1 Cugua</u>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)	RECEIVED BY
1	P0100578	271-24410(VG)	250ml HDPE Round Container (Natural Color)	<u>H090 200601</u>	pes	4354	4354	<u>1 Cugua</u>
2	P0100563	JQ-24A-PP (11cm)	24/410 MIST SPRAYER, RIBBED 316 SPRING, HALF CAP, PP, TUBE:110mm	H091200402	pes	4354	4354	<u>1 Cugua</u>
3		STOCK SOLUTION		<u>03H0803030606</u>	ltr	<u>1132</u>	<u>1132</u>	<u>1 Cugua</u>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)	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		87	87	<u>M. Oli</u>
2	P0100567	DSN-H-009(B) - VIG-901-ASY HYDROCYN 250ml, NL & RS 31/2 x 90mm(4pos each), Mat: T150/T150 B Flute		H069210601		174	174	<u>M. Oli</u>
3	P0100568	DSN-H-009(C) - VIG-901-ASY HYDROCYN 250ml, NL & RS 31/2 x 90mm(4pos each), Mat: T150/T150 B Flute		H070210601		87	87	<u>M. Oli</u>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)	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		87	87	<u>M. Oli</u>
2	P0100567	DSN-H-009(B) - VIG-901-ASY HYDROCYN 250ml, NL & RS 31/2 x 90mm(4pos each), Mat: T150/T150 B Flute		H069210601		174	174	<u>M. Oli</u>
3	P0100568	DSN-H-009(C) - VIG-901-ASY HYDROCYN 250ml, NL & RS 31/2 x 90mm(4pos each), Mat: T150/T150 B Flute		H070210601		87	87	<u>M. Oli</u>
4		#N/A						
5		#N/A						
6		#N/A						
7		#N/A						

VERIFIED BY (PR) : M. Oli
 Signature : M. Oli
 Name : M. Oli
 Date : 01/02/2022

ISSUED BY (MM) : Lovin
 Signature : Lovin
 Name : Lovin
 Date : 10/02/2022

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Bactericidal woundcare, 250ml (spray mist)	Reference No.	13WR34E700	Date of Inspection	07/03/2022
Lot No.	A00830	Sample Size	250ml		

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
7.19	Q1-78	865	Q1-67	114	Q1-80 pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 500L/T5 03M0010322061

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Boj
Name : Roslyn
Date : 09/03/2022

Approved By : MARTIN
Name :
Date : 07/03/2022



VIGILENZ®

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

Doc No.	QC-PPC007
Rev.	06

Description	Background woundcare, 50 ml (spray mist)	Reference No.	BW 34 E700	Date of Inspection	04/03/2022
Lot No.	A22830	Sample Size	2611 x 250ml		

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
7.30	Q1-78	865	Q1-67	110	Q1-80
					Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000L/11 03MB02032063

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rony
Name : Roshni
Date : 04/03/2022



Approved By : Martini
Name : Martini
Date : 07/03/2022