

SHOP PACKET - EASW

REFERENCE	BW34E700	ODR. QTY (PCS)	4,350	RS(2) QC(2) +2	ISSUED DATE	28/01/2022
ITEM CODE	BW010002	PACK SIZE	50/Box	+2	LOT NO.	A22833
ITEM DESCRIPTION	Bactiguard Woundcare, 250ml (Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
		ODR. NO	A196		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						
TIME START : DATE : TIME COMPLETE : DATE :	1:15 PM 03-03-22	4357+1	4357+1	N:1	Roshni (893)	TANK 1000L/T 03/03/2022 6:10 pm OBHR03032065 TANK 500L/T/ 03/03/2022
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT 03/03/2022
SOLUTION FILLING & CAPPING	4358	4341	17	Eta (931) Desi (1137)	Roshni 4:40 pm 04/03/2022	NP
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						
PRINTING LOT NUMBER	4358	4358	N:1	FARAH (1051)	Roshni 8:40 pm 04/03/2022	NP
CAP SEALING (Applicable for 100mL)	4858	4538	N:1	Leah (1078) Ling (1031)	Roshni 5:00pm 04/03/2022	NP
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)				N/A		UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL	4358	4858	N:1	FARAH (1051)	Roshni 8:40 pm 04/03/22	NP
CARTON PACK	87 ctn	87 ctn	N:1C	RUBIN (1088) FATHI (1054)	Linda 07/03/22	7/3/2022
UDI LABELLING				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						

QUANTITY PRODUCED	4358
QUANTITY FOR QC / RETAIN SAMPLE	4287 961
SHIPMENT QUANTITY PCS / CTNS	4350
FINAL SHIPMENT DATE	
COMPLETE/ PARTIAL	COMPLETE

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : Mohd Arifuddin Date : 8/3/22	Name : Rohamiza Othman Date : 8/3/2022	Name : MARTINI Designation : IPQC SUP Date : 8/3/2022 Stamp :
Remarks:		

VIGILENZ®

ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No	QC-LC002
Rev.	00

Item Description	<i>Bacigard woundcare 250 ml (spray mist)</i>		
Reference	<i>BuB346700</i>		
Lot No.	<i>A22835</i>		

No.	Checklist	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Performed by (Signature / Date) <i>Kyle 893</i> 04/03/2022	Verified by QC (Signature / Date) <i>Poly</i> 04/03/22	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>Kyle 893</i> 04/03/2022	<i>Poly</i> 04/03/22	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Kyle 893</i> 04/03/2022	<i>Poly</i> 04/03/22	N/A	Technician
i)	Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
ii)	Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
iii)	Stopper Insertor	<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>Cayenne</i> 04/03/22	<i>Cayenne</i> 04/03/2022	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>Cayenne</i> 04/03/22	<i>Cayenne</i> 04/03/2022	N/A	Production

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
Document type:			
FORM	Doc Id:	QC-JP02-09	Issue Date:
		15/11/2021	Page: 1(3)

Item Description	<i>Bactiguard woundcare 250ml (spray mist)</i> <i>BW34ET700 / A3383</i>	
Reference / Lot No.		
Order Qty	4350	
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	260ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/200	260ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/200	300 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	300 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	300 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	300 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	300 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	300 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, NP)	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"/>

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 2% ointment 250 ml (spray mist)		
Reference / Lot No.	BW24E700 / A00833		
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)		Bactiguard
Doc Id: QC-IP002-09	Issue Date: 15/11/2021	Page: 1(3)

Document type:
FORM

Item Description	Bactiguard woundcare 250ml (Spray mist)		
Reference / Lot No.	BW34E TOO / A00833		
Order Qty	4350		
Volume Specification	255	± 5	ml

A. Filling Process

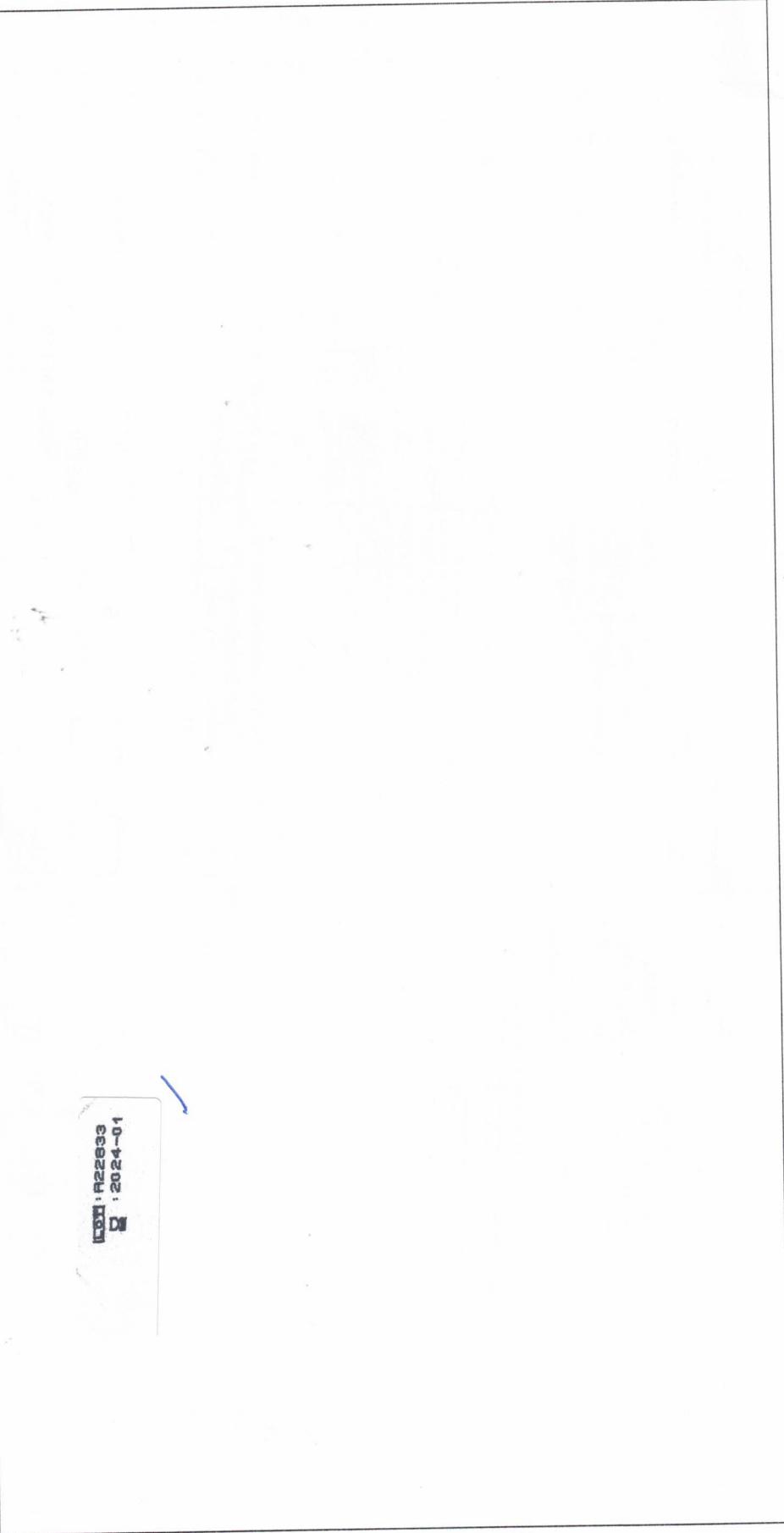
Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition
			PASS			FAIL
1/300	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
1/140	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>
		N/A	N/A			

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"/>
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					<input type="checkbox"/>
					<input type="checkbox"/>
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					<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:	Page:
FORM	QC-IP002-09	15/11/2021	2(3)

C. Attachment (First Printed Label)



Inspected by : By
 Name : Postini
 Date : 09/11/2023

PASS FAIL

Disposition of the Lot :

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

D. Attachment (Last Printed Label)

Disposition of the Lot : PASS FAIL
 Inspected by : *N/A*
 Name : *N/A*
 Date : *N/A*

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
ITEM DESCRIPTION	Refrigerated woundcare 250 ml	Doc. No.	QC-FC004

REFERENCE : BW34E700

QTY. PRODUCED (pcs) :

4358

LOT NO. : A22 Q33

RETAIN SAMPLE QTY. (pcs) :

4

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results	Status
				Accept	Reject		
1	Legible and clean printing of label.	23, 0.15	80	0	1	80	0
2	Free from contamination, deformed or damaged on packaging.	23, 0.15	80	0	1	80	0
3	Proper sealing and no leaking.	23, 0.15	80	0	1	80	0
4	Free from contamination / particle / foreign materials on product solution.	23, 0.15	80	0	1	80	0
5	Correct volume filled (against reference sample).	23, 0.15	80	0	1	80	0

Remarks :

N/A

Inspected By : Poly
Name : Roshni
Date : 04/31/2022

Approved By : Hari
Name : HARI
Date : 4/3/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc.
Rev.

DATE :	10/02/2022
REF :	BW34E700
LOT NO. :	B22833- A12833 <i>By 4/2/2022</i>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
1	P0100578	271-2441(0VG)	250ml HDPE Round Container (Natural Color)	H070200601	pcs	4354 + 4	4354 + 4	4358	4358	<i>1. Chayang</i>
2	P0100563	JQ-24A-PP (11cm)	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP: PP, TUBE: 110mm	H091200402	pcs	4354 + 4	4354 + 4	4358	4358	<i>1. Chayang</i>
3		STOCK SOLUTION		<i>0340000005</i> <i>03400000063</i>	ltr	1/33	1/33	1/33	1/33	<i>1. Campagni</i>

(2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capsule (For 100ml Hydrocyn) - Size: 47 x 0.04 x 55 mm (I.C+P)	H019200601	4355 + 4	<i>1. Chayang</i>	1	P0100560	Printed Carton (Hydrocyn 250ml, Spray Mist) - Size: 330 x 330 x 365mm, Material: AB Flute DW 175N/M/M/M/175G	H06211103	87	<i>Male</i>
2						2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS: 31.2 x 90mm(4 pes each), Mat: TI50/TI50 B Flute	H069210601	174	<i>Male</i>
3		#N/A				3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 31.2 x 312mm, Mat: TI50/TI50 B Flute	H07210601	87	<i>Male</i>
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	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1						1	P0100560	Printed Carton (Hydrocyn 250ml, Spray Mist) - Size: 330 x 330 x 365mm, Material: AB Flute DW 175N/M/M/M/175G	H06211103	87	<i>Male</i>
2						2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS: 31.2 x 90mm(4 pes each), Mat: TI50/TI50 B Flute	H069210601	174	<i>Male</i>
3						3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 31.2 x 312mm, Mat: TI50/TI50 B Flute	H07210601	87	<i>Male</i>
4											
5											
6											
7											

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

VERIFIED BY (PR): *John*
Signature: *Multo Appuodew*
Name: *Multo Appuodew*
Date: *8/3/22*

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Background wondcare, ≥ 50 ml (Spray mist)	Reference No.	2034EF00	Date of Inspection	09/03/2023
		Lot No.	A 22833	Sample Size	2 btl x 250ml

Release Criteria:

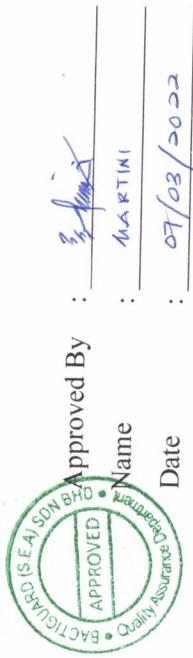
Analysis of Electro Activated Super-Oxidized Water (EASW)					
Result	Instrument	Result	ORP (mV)	FAC (ppm)	Test Disposition (PASS / FAIL)
			Spec: > 850	Spec: 95-140	
7.12	Q1-78	863	867	113	Q1-80 pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 500L/1' 04/03/2023

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Jay*
Name : *Rosmi*
Date : *09/03/2023*



Approved By : *Eduard*
Name : *MA RTINI*
Date : *07/03/2022*

VIGILENZ®

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

		Doc No.	QC-PC007
		Rev.	06

Description	
Bacteriogard woodcare 250ml (spray mist)	Reference No. <i>BW34ET700</i>

Lot No.	
<i>A00833</i>	Sample Size <i>261/250ml</i>

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
Result	Instrument	Result	Instrument	Result	Test Disposition (PASS / FAIL)
					Spec: <i>95-140</i>
<i>1.20</i>	<i>ORP</i>	<i>855</i>	<i>ORP 67</i>	<i>113</i>	<i>Pass</i>

- RO water and product bioburden meeting the acceptance criteria.

Remarks : *Jan 2000 / T6 084B03032063*Disposition of the Lot : RELEASE ON-HOLD

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



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