

SHOP PACKET - EASW						
REFERENCE	BW34E100	ODR. QTY (PCS)	4,500	RS(2) QC(2)	ISSUED DATE	28/01/2022
ITEM CODE	BW010006	PACK SIZE	50/Box		LOT NO.	A22826
ITEM DESCRIPTION	Bactiguard Woundcare 250ml (Cap Closure)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 28/01/2022		EXP. DATE	2024-01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton			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	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	10:00 AM 03-02-22	4504	4504	Nil	Wah 3-2-2022	Tank 1000L/T 03HB030222028
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :	10:00 AM 03-02-22			N/A		UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	1:00 PM 05-02-22	4504	4463	41	Farah (1051) 5-2-22	-41 white cap reject replace with new cap
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	3:42 PM 04-02-22	4504		Nil	Viki (1094) Farah (1051) 7-2-22	Wah 2:45 PM
CAP SEALING (Applicable for 100mL )						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	3:42 PM 04-02-22	4504	4463	Nil	Viki (1094) Netra (1103) 7-2-22	Wah 2:50PM
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	5:00 PM 07-02-22	90 ctn	90 ctn	Nil	FASLI (1054) HERDI (1053) PABN (1088)	Jinda 08/02/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 4504 bts  
 QUANTITY FOR QC / RETAIN SAMPLE : 2+2 btl  
 SHIPMENT QUANTITY PCS / CTNS : 4500 bts / 90 ctn  
 FINAL SHIPMENT DATE :    
 COMPLETE / PARTIAL :  COMPLETE   PARTIAL

Checked by (PR), Signature : <i>Netra</i>	Approved by (QA), Signature : <i>Jmz</i>	Released by (QC), Signature : <i>Netra</i>
Name : <i>RATNA SEGERAN</i> Date : <i>8/2/2022</i>	Name : <i>Rahamiza Ghani</i> Date : <i>8/2/2022</i>	Name : <i>A&amp;ETINI</i> Designation : <i>QC DEPT</i> Date : <i>8/2/2022</i> Stamp : <i>GR</i>
Remarks: TO PRODUCE WITHOUT LABEL		



VIGILENZ®	CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	Doc. No QC-LC002
Item Description	Bottleguard Woundcare 250 ml C cap closure	Rev. 00

Reference	Btu34E-H00
Lot No.	A 22 826

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"/>	Kiranay 05/02/22	Woh 5.02.22	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 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"/> <input type="checkbox"/>	Kiranay 05/02/22	Woh 5.02.22	N/A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Lekyanday 05/02/22	Woh 5.02.22	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"/>	Carlyano 05/02/22	Woh 5.02.22	N/A	Production

Title:

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

Document type:  
FORM

Bactiguard

Issue Date:  
15/11/2021Page:  
1(3)

Item Description	Bactiguard woundcare 250ml Ccap closure
Reference / Lot No.	BW34E100 / A22826
Order Qty	4500
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	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□

## 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
					□	□
					□	□
					□	□
					□	□
					□	□
					□	□
					□	□
					□	□

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

<b>Item Description</b>	Bactiguard Woundcare 250ml Capp closed
<b>Reference / Lot No.</b>	BW 34E100 / A 22826
<b>Order Qty</b>	4500
<b>Volume Specification</b>	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	✓	✓	✓	✓	□
1/300	260 mL	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	□
1/300	260 mL	✓	✓	✓	✓	□

## **B. Labelling, Lot No, Manufacturing Date and Expiry Date Processes**

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	Bactiguard Woundcare 250ml (cap closure)		
Reference / Lot No.	BW 34E 100	/	A 22826
Order Qty	4500		
Volume Specification	25.5	±	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)	 Backguard
Document type: FORM	Doc Id: QC-IP002-09
Issue Date: 15/11/2021	Page: 2(3)

C. Attachment (First Printed Label)

Lot : P222826  
Date : 2024-01

KW  
5.2.22

Inspected by : Wach  
Name : wach wach  
Date : 5.02.2022

Disposition of the Lot :  PASS  FAIL

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

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


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Disposition of the Lot :  PASS  FAIL

Inspected by : Woh  
 Name : Woh Woh  
 Date : 7.2.22

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

ITEM DESCRIPTION : Buflguard Woundcare 250 ml  
 REFERENCE : BW 34 E 100  
 LOT NO. : A 22826

QTY. PRODUCED (pes) : 4504  
 RETAIN SAMPLE QTY. (pes) : 2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	<u>S<sub>3</sub></u> , <u>80</u> , <u>0.15</u>	<u>Ø-80</u>	<u>+ 0</u>	<u>-80</u>	<u>80</u>	<u>0</u>	<u>pass</u>
2	Free from contamination, deformed or damaged on packaging.	<u>S<sub>3</sub></u> , <u>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>S<sub>3</sub></u> , <u>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>S<sub>3</sub></u> , <u>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>S<sub>3</sub></u> , <u>0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>pass</u>

Remarks :

N/A

Inspected By : Woh Woh  
 Name : Woh Woh  
 Date : 7. 2. 2022

Approved By : M. A. KETTINI  
 Name : M. A. KETTINI  
 Date : 8/2/2022

## RAW MATERIAL LOADING FORM (RMLF)

Doc. No.  
Rev.

DATE :	03/02/2022
REF :	JLH 34/20 HW44500 BW34€100
LOT NO. :	A2826

SHOP PACKET QTY (pcs) : 4500  
 CUSTOMER : BACTIGUARD AB  
 I.O. NO. : IO/BD/27/122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H01221101	pcs	4504	4504	4504	✓ Cognac
2	P0100814	White Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woundau	0	H020210601	pcs	4504	4504	4504	✓ Cognac
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	4504	4504	4504	✓ Cognac
4		STOCK SOLUTION		234B000222028	ltr	1171	1171	1171	✓ Cognac

## (2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1		#N/A				1	P0100566	DSN-H-009(A) - VIG-403-CTN-HYDROCYN 250ML(Cap Closure) Size: 330x330x 305mm, Mat: T180/M/T180 BA Flute	H060210601	90	✓ Cognac
2		#N/A				2	P0100567	DSN-H-009(B) - VIG-901-ASY, HYDROCYN 250ml, NL & NS:312 x 90mm(4pos each), Mat:T150/T150 B Flute	H069200101	180	✓ Cognac
3		#N/A				3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 12mm, Mat: T150/T150 B Flute	H070201201	90	✓ Cognac
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 (pcs)	RECEIVED BY	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1		#N/A				1	P0100566	DSN-H-009(A) - VIG-403-CTN-HYDROCYN 250ML(Cap Closure) Size: 330x330x 305mm, Mat: T180/M/T180 BA Flute	H060210601	90	✓ Cognac
2		#N/A				2	P0100567	DSN-H-009(B) - VIG-901-ASY, HYDROCYN 250ml, NL & NS:312 x 90mm(4pos each), Mat:T150/T150 B Flute	H069200101	180	✓ Cognac
3		#N/A				3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 12mm, Mat: T150/T150 B Flute	H070201201	90	✓ Cognac
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	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1		#N/A				1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	N/A		
2		#N/A				2		#N/A			
3		#N/A									
4		#N/A									
5		#N/A									
6		#N/A									
7		#N/A									

ISSUED BY (MM):

Signature :   
 Name : LOVIN  
 Date : 03/02/2022

VERIFIED BY (PR):

Signature :   
 Name : MURALI GOPAL  
 Date : 01/02/2022

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Bactiguard wondcare 250mL	Reference No.	BW34E100	Date of Inspection	08/03/2022
Lot No.	A03826	Sample Size	250 x 250mL		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	FAC (ppm)	Test Disposition ( PASS / FAIL )		
Spec: 6.50 - 9.00	Spec: ≥ 850	Spec: 95-140			
Result	Instrument	Result	Instrument	Result	Instrument
7.14	QC-78	870	QC-C7	105	QC - 80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : *Rosy*  
 Name : *Rosy*  
 Date : *08/03/2022*

Approved By : *MM*  
 Name : *MM*  
 Date : *08/03/2022*

