



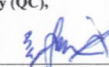

## SHOP PACKET - EASW

NO LABEL

SHIP PACKET - EASW						
REFERENCE	BW35D100	ODR. QTY (PCS)	2280 4008	RS(2) QC(1) +1	ISSUED DATE	29/01/2022
ITEM CODE	BW010007	PACK SIZE	24/Box	+2	LOT NO.	A22906
ITEM DESCRIPTION	Bactiguard Woundcare 500ml (Cap Closure)	CUSTOMER	BACTIGUARD AB		MFG. DATE	29/01/2022
		ODR. NO	A205		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN		INT. ORDER	10/BD/270122/01
	DATE : 29/01/2022		DATE : 29/01/2022			
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
<b>STOCK SOLUTION PREPARATION</b>						
TIME START:						
DATE:	25-02-22	4011+3	4011+3	Nil	Kyandam (293)	wah
TIME COMPLETE:	8:15 AM					
DATE:	25-02-22					
<b>UDI PRINTING (Label/Box/Carton)</b>						
TIME START:						
DATE:				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE:						
DATE:						
<b>SOLUTION FILLING &amp; CAPPING</b>						
TIME START:						
DATE:	28-02-22	4014	4014	Nil	Bashim (1113)	wah
TIME COMPLETE:	5:30 PM				Ambiga (1129)	5:30 PM
DATE:	28-02-22					28/2/22
<b>LABELLING</b>						
TIME START:						
DATE:				NO	LABEL	
TIME COMPLETE:						
DATE:						
<b>PRINTING LOT NUMBER</b>						
TIME START:						
DATE:	28-02-22	4014	4014	Nil	Bashim (1113)	wah
TIME COMPLETE:	8:40 PM				Era (932)	8:40 PM
DATE:	28-02-22					28/2/22
<b>CAP SEALING (Applicable for 100mL)</b>						
TIME START:						
DATE:				N/A		
TIME COMPLETE:						
DATE:						
<b>BOX PACKING &amp; PRINTING (Applicable for 100ml only)</b>						
TIME START:						
DATE:				N/A		
TIME COMPLETE:						
DATE:						
<b>MANUAL UDI LABELLING (Applicable for 100 mL &amp; Bags only)</b>						
TIME START:						
DATE:				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE:						
DATE:						
<b>FINAL CONTROL</b>						
TIME START:						
DATE:	28-02-22	4014	4014	Nil	Maleasing (909)	wah
TIME COMPLETE:	8:40 PM				Aye (884)	8:45 PM
DATE:	28-02-22					28/2/22
<b>CARTON PACK</b>						
TIME START:						
DATE:	01-03-22	167	167	Nil	Rabm (1088)	Nurin
TIME COMPLETE:	5:15 PM	Ctn	Ctn		Fahri (1054)	
DATE:	01-03-22				Herdi (1053)	1/3/2022
<b>UDI LABELLING</b>						
TIME START:						
DATE:				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED :	4014 btl
QUANTITY FOR QC / RETAIN SAMPLE :	4+2 btl
SHIPMENT QUANTITY PCS / CTNS :	4008 btl / 167 ctn
FINAL SHIPMENT DATE :	
COMPLETE / PARTIAL :	COMPLETE

Checked by (PR), Signature:  Name: Ratnasegaran Date: 1/3/22	Approved by (QA), Signature:  Name: Ratnasegaran Date: 1/3/2022	Released by (QC), Signature:  Name: RATINI Designation: IPQC SUP Date: 1/3/2022 Stamp: 
Remarks:		


VIGILENZ®	CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		QC-LC002
			00
	Doc. No		
	Rev.		

Item Description	Bactiguard wandare 500ml Cap closure
Reference	BW350100
Lot No.	A22906

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"/>	Rashid 28/02/2022	Wah 28/2/22	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 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"/>	Rashid 28/02/2022	Wah 28/2/22	N/A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rashid 28/02/2022	Wah 28/2/22	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"/>	Rashid 28/02/2022	Wah 28/2/22	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 500ml Cap closure		
Reference / Lot No.	BW350100 / A22906		
Order Qty	4008		
Volume Specification	515	±	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	515 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	515 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	515 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	515 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	515 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	515 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/404	515 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"/>
		NA			<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>

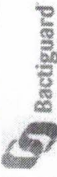
Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bactiguard	
Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/11/2021	Page: 2(3)

C. Attachment (First Printed Label)

 15001A22906 2024-04 Woh 28.3.22
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Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL
	Inspected by : <u>Woh</u>	
	Name : <u>Wohleberh</u>	
	Date : <u>28/2/22</u>	

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



Document type:

FORM

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## D. Attachment (Last Printed Label)

LOT: A22906  
Q: 2024-01

Wach  
28.2.22

Disposition of the Lot :



PASS



FAIL

Inspected by : Wach

Name : Wach Wach

Date : 28.2.22



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

ITEM DESCRIPTION : Bactiguard Woundcare 500ml

REFERENCE : BW35D100

LOT NO. : A22906

QTY. PRODUCED (pcs) : 4014

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>S<sub>3</sub>, 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>S<sub>3</sub>, 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>, 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>, 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>, 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 : Wch  
 Name : Wch Wch  
 Date : 28.2.2022

Approved By : [Signature]  
 Name : KLARTIN S  
 Date : 1/3/2022

# RAW MATERIAL LOADING FORM (RMLF)

VIGILENZ®

DATE :	09/02/2022	SHOP PACKET QTY (pcs)	4008
REF :	BW3SD100	CUSTOMER :	BACTIGUARD AB
LOT NO. :	A22906	LO NO. :	IO/BD/270122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECE
						REQUIRED	ISSUED	
1	P0100242	500ml HDPE Plastic Container ( New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	4010220101	pcs	4011	4011	4011
2	P0100814	White Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woun	0	4010220101	pcs	4011	4011	4011
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	4011	4011	4011
4		STOCK SOLUTION		034825020056 034825020057	ltr	2085	2085	2085

## (3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECE
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H165211201	167	167
2	P0100680	500ml nesting short and long-	H065220101	167	167
3		#N/A			


## (4) SPECIAL REQUIREMENT

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECE
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)		24	
2		#N/A			


## (2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1					
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 : 09/02/2022

VERIFIED BY (PR) :

Signature :   
 Name : LOVIN  
 Date : 1/3/22



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

Description <i>Bactiguard Bactiguard Woundcare 500 ml (cap closure)</i>	Reference No.	<i>BW 350100</i>	Date of Inspection	<i>01/03/2022</i>
	Lot No.	<i>A22906</i>	Sample Size	<i>1611 X 500ml</i>

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					Test Disposition (PASS / FAIL)
pH Spec: 6.50 - 8.00		ORP (mV) Spec: $\geq 850$		FAC (ppm) Spec: 95 - 140	
Result	Instrument	Result	Instrument	Result	Instrument
<i>7.19</i>	<i>QC-78</i>	<i>853</i>	<i>QC-67</i>	<i>112</i>	<i>QC-80</i>
					<i>PASS</i>

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks: *Tank 1000 L/76 03HB2502220057*

Disposition of the Lot: ☒ RELEASE ☐ ON-HOLD

Analyzed By: *Praj*  
Name: *Prajna*  
Date: *01/03/2022*

Approved By: *M. J. Singh*  
Name: *MARTIN*  
Date: *01/03/2022*



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

Description	Background wastewater Bacteria for 01/03/2022 500ml (cap closure)	Reference No.	BW 350100	Date of Inspection	01/03/2022
		Lot No.	A22906	Sample Size	16H X 500ml

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: $\geq 850$		Spec: 95 - 140		
Result	Instrument	Result	Instrument	Result	Instrument	pass
7.19	QC-78	857	QC-67	112	QC-80	

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000.1/77 03HB250000056

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Paul  
Name : DASHNI  
Date : 01/03/2022

Approved By : [Signature]  
Name : MARTIN  
Date : 01/03/2022

