

16/2


NO LABEL

SHOP PACKET - EASW 11/02/2022

REFERENCE	BW35D100	ODR. QTY (PCS)	1848-2568 <i>h</i>	RS(2) QC(1) +1	ISSUED DATE	29/01/2022
ITEM CODE	BW010007	PACK SIZE	24/Box	+2	LOT NO.	A22907
ITEM DESCRIPTION	Bactiguard Woundcare 500ml (Cap Closure)	CUSTOMER	Bactiguard AB		MFG. DATE	29/01/2022
		ODR. NO	A206		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA <i>h</i> DATE : 29/01/2022	VERIFIED BY	NAME : RATNASEGARAN <i>h</i> DATE : 29/01/2022		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 : 8:00 pm DATE : 23-02-22 TIME COMPLETE : 8:15 Am DATE : 24-02-22	2568+3	2571	Nil	Kyandari (893)	Roshni 8:15 am 24/2/22	TANK 1000L/T7 03HB230222054 Tank 500L/T5 03HB230222053
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : 2:30 pm DATE : 26-02-22 TIME COMPLETE : 5:00 pm DATE : 26-02-22	2574	2574	Nil	Devi (1026)	Roshni 5:00pm 26/02/22	NA
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
PRINTING LOT NUMBER						
TIME START : 2:25 pm DATE : 25-02-22 TIME COMPLETE : 5:00 pm DATE : 26-02-22	2574	2574	Nil	Fareh (1051)	Roshni 5:00pm 26/02/22	NA
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 : 2:25 pm DATE : 25-02-22 TIME COMPLETE : 5:00 pm DATE : 26-02-22	2574	2574	Nil	Fareh (1051)	Roshni 5:00pm 26/02/22	NA
CARTON PACK						
TIME START : 8:00 pm DATE : 28-02-22 TIME COMPLETE : 11:00 am DATE : 28-02-22	107 ctn	107 ctn	Nil	Rashin (1058) Vister (1023) Earli (1054) Hendi (1053)	Nurin 28/2/2022	28/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED :	2571 kls
QUANTITY FOR QC / RETAIN SAMPLE :	1/25+2 btl
SHIPMENT QUANTITY PCS / CTNS :	2568 kls / 107 ctn
FINAL SHIPMENT DATE :	
COMPLETE/ PARTIAL :	COMPLETE


Checked by (PR), Signature: <i>h</i> Name: RATNASEGARAN Date: 28/2/22	Approved by (QA), Signature: <i>h</i> Name: Rohanda Othman Date: 1/3/2022	Released by (QC), Signature: <i>h</i> Name: N. RATINI Designation: IPQC SUP Date: 01/03/2022 Stamp: 
Remarks:		

Sheet no 46

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

Item Description	Bachigand woundcare 500ml (Bottle cap closure)
Reference	BW35 D100
Lot No.	A 22907

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 25/02/2022	<i>Wach</i> 25/02/22	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 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 25/02/2022	<i>Wach</i> 25/02/22	N/A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>[Signature]</i> 25/02/22	<i>[Signature]</i> 25/02/22	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"/>	<i>[Signature]</i> 25/02/22	<i>[Signature]</i> 25/02/22	N/A	Production

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: 1(3)


Item Description	<i>Bactiguard woundcare 500ml (Bottle cap closure)</i>		
Reference / Lot No.	<i>BW352100 / A22907</i>		
Order Qty	<i>2508</i>		
Volume Specification	<i>315</i>	<i>±</i>	<i>5 ml</i>

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
<i>10/10</i>	<i>520ml</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/300</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/300</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/300</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/300</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/300</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/300</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<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"/>

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: 1(3)


Item Description	<i>Bactiguard wound care 500 ml (Bottle cap closure)</i>		
Reference / Lot No.	<i>BW550100 / A2907</i>		
Order Qty	<i>2568</i>		
Volume Specification	<i>515</i>	\pm	<i>5</i> 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
<i>1/200</i>	<i>520ml</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/500</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>1/161</i>	<i>520ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
			<i>NA</i>			<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"/>
		<i>A1P</i>			<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	Page: 2(3)
Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/11/2021	

C. Attachment (First Printed Label)


 LOT: A22907
 2024-01


✓ Woch
 25.2.22

☐ FAIL

☒ PASS

Disposition of the Lot :

Inspected by : Woch
 Name : Woch Woch
 Date : 25-2-22

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: 3(3)

D. Attachment (Last Printed Label)

1001 . 122907
1001 . 2024-04

✓

Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL	Inspected by : <u>Ray</u>
			Name : <u>RESHMI</u>
			Date : <u>26/11/2022</u>

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

ITEM DESCRIPTION : Bactiguard woundcare 500 ml

REFERENCE : BW355D10-U QTY. PRODUCED (pcs) : 2574

LOT NO. : A22907 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.	S ₃ , 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S ₃ , 0.15	80	0	1	80	0	pass
3	Proper sealing and no leaking.	S ₃ , 0.15	80	0	1	80	0	pass
4	Free from contamination / particle / foreign materials on product solution.	S ₃ , 0.15	80	0	1	80	0	pass
5	Correct volume filled (against reference sample).	S ₃ , 0.15	80	0	1	80	0	pass

Remarks : N/P

Inspected By	:	<u>Ray</u>	Approved By	:	<u>E. August</u>
Name	:	<u>ROSHNE</u>	Name	:	<u>MARTINI</u>
Date	:	<u>26/02/2020</u>	Date	:	<u>28/2/2020</u>

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

DATE : 11/02/2022

REF : BW35D100

LOT NO. : A2907

SHOP PACKET QTY (pcs) :

CUSTOMER :

LO NO. :

Doc. No. : 2568

Rev. : RS

BACTIGUARD AB

10/BD/27012201


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)	14010226101	pcs	2571	2571	1 Canjane
2	P0100814	Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woun	0	H168211201	pcs	2571	2571	1 Canjane
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	2571	2571	1 Canjane
4		STOCK SOLUTION		03HB23022053 03HB23022054	ltr	1336	1336	1 Canjane

(2) PRODUCT PACKAGING					RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
1					
2		#N/A			
3		#N/A			
4		#N/A			
5		#N/A			
6		#N/A			
7		#N/A			

(3) OVER WRAPPING AND CARTON PACK					RECE
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H165211201	107	malu
2	P0100680	500ml nesting short and long-	H065220101	107	malu
3		#N/A		h	malu

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

ISSUED BY (MM) :

Signature : 

Name : LOVIN

Date : 11/02/2022

VERIFIED BY (PR) :

Signature : 

Name : PR

Date : 12/2/22

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

Description	Bactiguard woundcare 500ml (Cap Closure)	Reference No.	BW35D100	Date of Inspection	01/03/2022
		Lot No.	A22907	Sample Size	16H x 500ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH		ORP (mV)		FAC (ppm)	
Spec: 6.50 - 8.00		Spec: ≥ 850		Spec: 95-140	
Result	Instrument	Result	Instrument	Result	Instrument
7.22	QC-78	866	QC-67	112	QC-80
					PASS

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 10004/17 C341B230222054

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Ray
Name : PASHNI
Date : 01/03/2022

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



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

Description	Background Woundcare 500 ml (cap closure)	Reference No.	BW35D100	Date of Inspection	01/03/2022
		Lot No.	A22907	Sample Size	1 lot (x 500 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	
7.26	QC-78	859	QC-67	107	QC-80	PASS

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks: TANK 500L/TS 03HB23022053

Disposition of the Lot: ☒ RELEASE ☐ ON-HOLD

Analyzed By: [Signature]
Name: ROSHNI
Date: 01/03/2022

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

