

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.	A22827	
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	UDI-PI NO. (2nd Packaging) - Carton	INT. ORDER	IO/BD/270122/01	
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	N/A					
PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	9:10 AM 08-02-22	4504	4504	NIL	Roshni (893)	Rank 10004/16 03HB08022023
UDI PRINTING (Label/Box/Carton)				N/A	—	UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :	—	—	—	—	—	—
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	11:40 AM 10-02-22	4504	4504	NIL	FARAH (1051) NETRA(1108)	Wah 7:30pm 10.2.22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	—	—	—	N/A	—	—
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	11:10 AM 10-02-22	4504	4504	NIL	FARAH (1051) NETRA(1103)	Wah 7:30PM 10.2.22
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 :	11:10 AM 10-02-22	4504	4504	NIL	FARAH (1051) NETRA(1103)	Wah 7:45 pm 10.2.22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	9:45 am 11-02-22	90 ctn	90 ctn	NIL	FASLI(1054) RABIN (1088)	Jinda 11/02/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	—	—	—	N/A	—	UDI NOT REQUIRED FOR THIS LOT

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

Checked by (PR), Signature : <i>Nur</i> Name : RMT NURSHIRAH Date : 11/1/22	Approved by (QA), Signature : <i>Jamz</i> Name : Rohaniza Osman Date : 11/1/2022	Released by (QC), Signature : <i>Martini</i> Name : MARTINI Designation : QC DEPT Date : 11/1/2022 Stamp : <i>11/1/2022</i>
Remarks: TO PRODUCE WITHOUT LABEL		



Doc. No : PR-SI007, Rev : 0

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CHECKLIST FOR LINE CLEARANCE OF
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Item Description	<i>Bottling round one 25ml (cap closing)</i>
Reference	<i>Bwg4 E100</i>
Lot No.	<i>A23827</i>

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>Zayn 10/02/22</i>	<i>Poly 10/01/22</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>Zayn 10/02/22</i>	<i>Zayn 10/02/22</i>	<i>NP</i>	Technician
	i) Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
	ii) Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
	iii) Stopper Inserter	<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>Canuwe 10/02/22</i>	<i>Zayn 10/02/22</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>Canuwe 10/02/22</i>	<i>Poly 10/02/22</i>	<i>NP</i>	Production

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

Item Description	Baliguard Wound care 150ml (cap closure)
Reference / Lot No.	BW34E100 / A30807
Order Qty	1500
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	✓	✓	✓	✓	✓	□
1/800	260 ml	✓	✓	✓	✓	✓	□
1/200	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/300	260 ml	✓	✓	✓	✓	✓	□
1/200	260 ml	✓	✓	✓	✓	✓	□

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

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

Item Description	<i>Bectiguard woundcare 250ml (exp closure)</i>
Reference / Lot No.	<i>Buct4E180</i>
Order Qty	<i>4500</i>
Volume Specification	<i>255 ± 5 ml</i>

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	Issue Date: 15/11/2021	Page: 1(3)
Document type: FORM	Doc Id: QC-IP002-09			

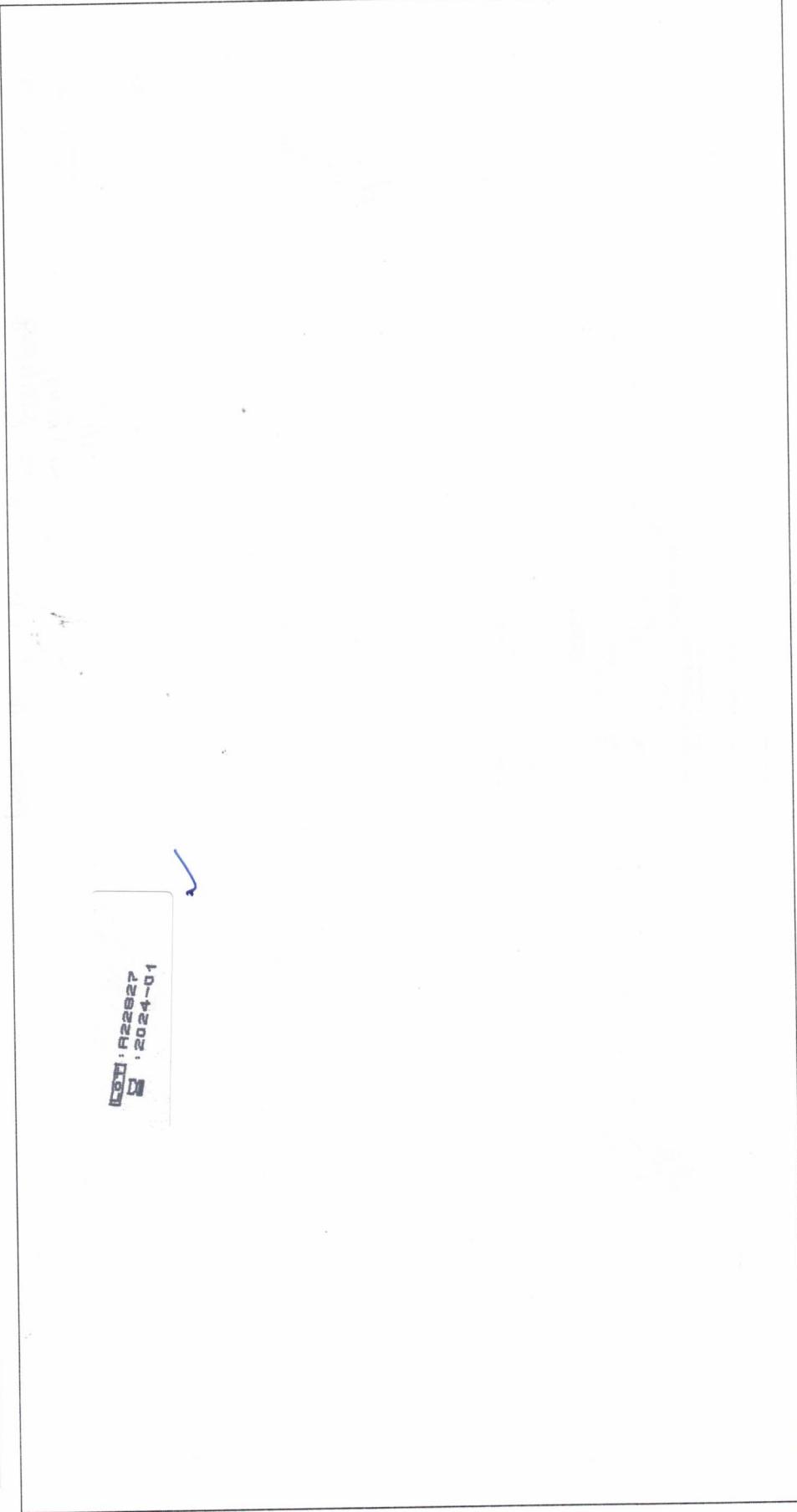
Item Description	Baitguard woundcare 250ml (cap closure)
Reference / Lot No.	Buzy E100 / A 22897
Order Qty	4500
Volume Specification	255 ± 5 ml

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)		
Document type:	Doc Id:	Bactiguard	
FORM	QC-IP002-09	Issue Date:	Page: 15/11/2021 2(3)

C. Attachment (First Printed Label)



Disposition of the Lot : PASS FAIL
 Inspected by : Patty
 Name : Romni
 Date : 10/10/2021

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

D. Attachment (Last Printed Label)



Disposition of the Lot : PASS FAIL

Inspected by : Luth
 Name : Luth Wagh
 Date : 10.02.2022

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

REFERENCE : Blw34 E100
LOT NO. : A22827

ITEM DESCRIPTION : Bacteriostatic Water 250 ml
REFERENCE : Blw34 E100
LOT NO. : A22827

QTY. PRODUCED (pes) :

RETAIN SAMPLE QTY. (pes) :

504
2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results	Status
				Accept	Reject		
1	Legible and clean printing of label.	S3, 0.15	80	0	1	80	0
2	Free from contamination, deformed or damaged on packaging.	S3, 0.15	80	0	1	80	0
3	Proper sealing and no leaking.	S3, 0.15	80	0	1	80	0
4	Free from contamination / particle / foreign materials on product solution.	S3, 0.15	80	0	1	80	0
5	Correct volume filled (against reference sample).	S3, 0.15	80	0	1	80	0

Remarks : N/A

Inspected By : Luchi
Name : M. R. T. I. N. I
Date : 10.02.2022

Approved By : M. R. T. I. N. I
Name : M. R. T. I. N. I
Date : 10.02.2022

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RAW MATERIAL LOADING FORM (RMLF)

DATE	03/02/2022
REF	<i>Joh 3492</i>
LOT NO.	<i>BW34ET00-00</i>
	A22827

SHOP PACKET QTY (pcs)
CUSTOMER
I.O NO.

#: : BACTIGUARD AB
#: : 4500 IO(BD27012201

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)
2	P0100814	White Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Wound	0
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)
4		STOCK SOLUTION	

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1		#N/A			
2		#N/A			
3		#N/A			
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
1	P0100566	DSN-H-009(A) - VIG-003-CTN+HYDROCYN 250mL(Cap Closure). Size: 330x330x 305mm, Mat: T180/M7/T180 BA Flute	H060210601	90	<u>maQd</u>
2	P0100567	DSN-H-009(B) - VIG-901-ASY+HYDROCYN 250mL, NL & NS: 312 x 90mm(4pes each), Mat: T150/T150 B Flute	H069200101	180	<u>maQd</u>
3	P0100568	DSN-H-009(C) - VIG-901-ASY+HYDROCYN 250mL(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute	H070201201	90	<u>maQd</u>

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

ISSUED BY (MM) _____
Signature : _____
Name : _____
Date : _____

Signature : _____
Name : _____
Date : _____

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

Description	Bactiguard Woundcare 250ml (Cap Closure)	Reference No.	BW34 E100	Date of Inspection	11/2/2022
Lot No.	A220827	Sample Size	2671 x 250ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	FAC (ppm)	Test Disposition (PASS / FAIL)		
Spec:	Spec: > 850	Spec: 95 - 140			
Result	Instrument	Result	Instrument	Result	Instrument
7.18	Qc-93	872	Qc-95	114	Qc-80
					Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : RELEASE ON-HOLD



Approved By : JR
Name : MARIA
Date : 11/02/2022

Analyzed By : informed
Name : MARIA
Date : 11/02/2022