

SHOP PACKET - EASW 12/2/22

REFERENCE	BW34E700	ODR. QTY (PCS)	600 550 B	RS(2) QC(2)	ISSUED DATE	09/02/2022
ITEM CODE	BW010002	PACK SIZE	50/Box	LOT NO.	B20966	
ITEM DESCRIPTION	Bactiguard Woundcare, 250ml (Spray Mist)	CUSTOMER	Bactiguard AB	MFG. DATE	09/02/2022	
		ODR. NO	B046	EXP. DATE	2024-02	
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN	INT. ORDER	IO/BD/270122/01	
	DATE : 09/02/2022		DATE : 09/02/2022			
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
STOCK SOLUTION PREPARATION						
TIME START : 8:10 PM						
DATE : 10-02-22	554	554	Nil	Kyanden (893)	wah	Tank 1000L/76
TIME COMPLETE : 7:45 AM						
DATE : 11-02-22					11.02.22	03HB100222035
UDI PRINTING (Label/Box/Carton)						
TIME START :						
DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE :						
DATE :						
SOLUTION FILLING & CAPPING						
TIME START : 2:30 PM						
DATE : 12-02-22	554	564	Nil	Vilci (1094)	Rashni	
TIME COMPLETE : 3:30 PM					3:30 PM	12/2/22
DATE : 12-02-22						NA
LABELLING						
TIME START :						
DATE : 12-02-22						NA
TIME COMPLETE :						
DATE : 12-02-22						
PRINTING LOT NUMBER						
TIME START : 2:30 PM						
DATE : 12-02-22	554	554	Nil	Netra (1103)	Rohy	NA
TIME COMPLETE : 3:30 PM					3:30 PM	12/2/22
DATE : 12-02-22						
CAP SEALING (Applicable for 100mL)						
TIME START : 3:20 PM						
DATE : 12-02-22	554	554	Nil	KALI (1708)	Rashni	NA
TIME COMPLETE : 4:45 PM				Tullamal (079)	4:45 PM	12/2/22
DATE : 12-02-22						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START :						
DATE :				NA		
TIME COMPLETE :						
DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START :						
DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE :						
DATE :						
FINAL CONTROL						
TIME START : 3:20 PM						
DATE : 12-02-22	554	554	Nil	Kali (1708)	Rashni	NA
TIME COMPLETE : 4:50 PM					4:50 PM	12/2/22
DATE : 12-02-22						
CARTON PACK						
TIME START : 10:30 AM						
DATE : 14-02-22	11	11	Nil	FACI (1054)	Nurin	hjr
TIME COMPLETE : 11:00 AM	ctn	ctn			14/2/2022	14/02/2022
DATE : 14-02-22						
UDI LABELLING						
TIME START :						
DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE :						
DATE :						


QUANTITY PRODUCED :	554 Yls
QUANTITY FOR QC / RETAIN SAMPLE :	20512 BH
SHIPMENT QUANTITY PCS / CTNS :	550 Yls / 11 ctn
FINAL SHIPMENT DATE :	
COMPLETE / PARTIAL :	COMPLETE

Checked by (PR), Signature : 	Approved by (QA), Signature : 	Released by (QC), Signature : 
Name : RATNASEGARAN Date : 14/2/22	Name : ROHANIZA Date : 14/2/2022	Name : NURIN Designation : QC DEPT Date : 14/2/22 Stamp : 
Remarks :		

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

Item Description	Bactiguard (unwashed 250ml C spray mist)
Reference	BW34E700
Lot No.	B20966

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 12/02/2022	<i>WCH</i> 12.02.22	NP	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 <ul style="list-style-type: none"> i) Starwheel <input checked="" type="checkbox"/> ii) Nozzle <input checked="" type="checkbox"/> iii) Stopper Insertor <input checked="" type="checkbox"/> iv) Cap Dispenser <input checked="" type="checkbox"/> v) Cap Pusher <input checked="" type="checkbox"/> 	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>[Signature]</i> 893 12/02/2022	<i>WCH</i> 12.02.22	NP	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> 12/02/22	<i>WCH</i> 12.02.22	NP	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> 12/02/22	<i>WCH</i>	NP	Production

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	Bactiguard woundcare, 950ml (Spray mist)		
Reference / Lot No.	BWS4E700 / Bgo B20966		
Order Qty	550		
Volume Specification	255	±	5 ml


By 12/2/22

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	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	260 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/1	260 ml	✓	✓	✓	✓	<input checked="" 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"/>


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"/>


QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bactiguard
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		Page: 2(3)

C. Attachment (First Printed Label)


LOT: B20966



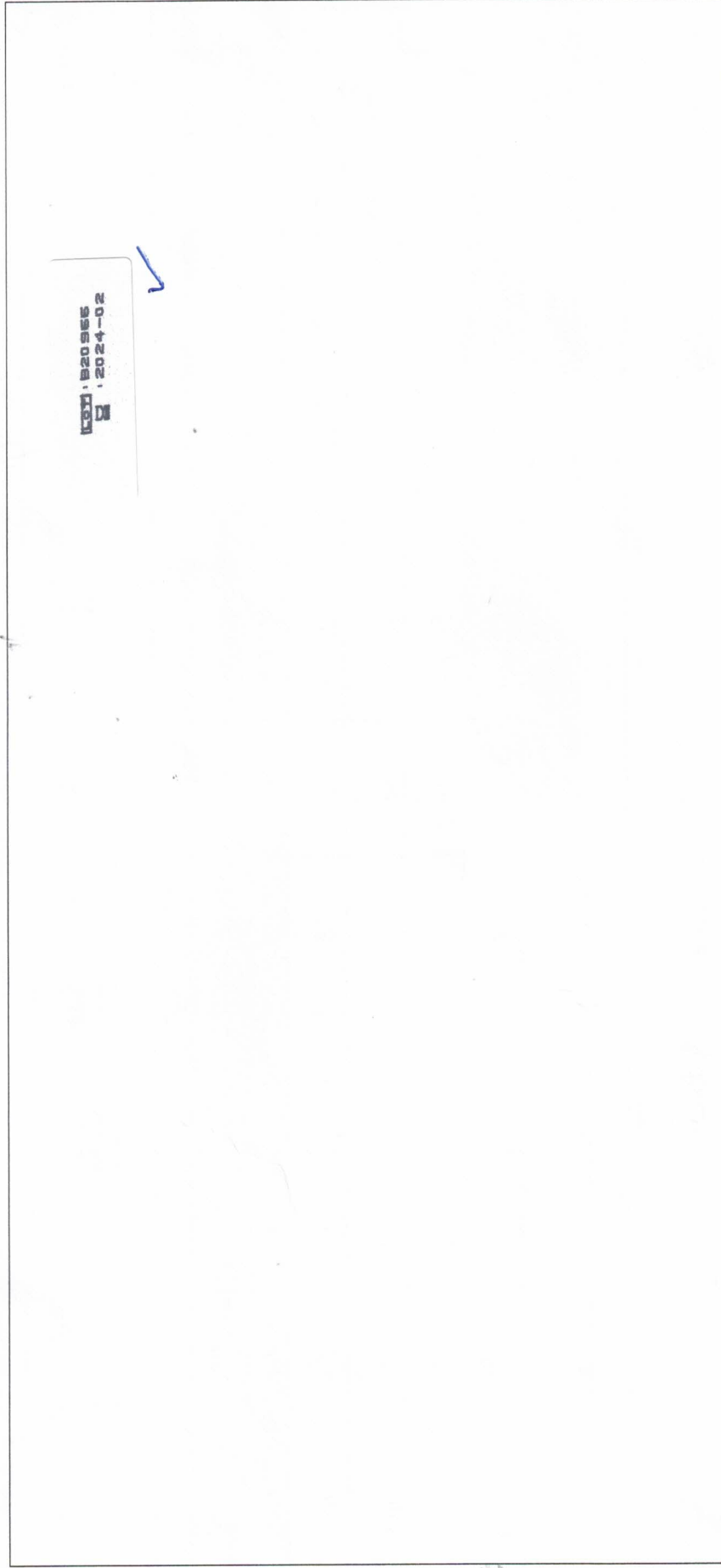
EXP: 2024-02



Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL
	Inspected by : <u>Poly</u>	
	Name : <u>ROSHNI</u>	
	Date : <u>12/2/2022</u>	

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)



Disposition of the Lot :
 ☒ PASS
 ☐ FAIL

Inspected by : Poly
 Name : Reshmi
 Date : 12/3/22

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

ITEM DESCRIPTION : Bactiguard wound care (250ml)

REFERENCE : BW34E700

QTY. PRODUCED (pcs) : 550

LOT NO. : B20966

RETAIN SAMPLE QTY. (pcs) : 2

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

Remarks : N/A

Inspected By : Poly
 Name : ROHINI
 Date : 12/12/2022

Approved By : [Signature]
 Name : KARTINI
 Date : 12/12/2022

RAW MATERIAL LOADING FORM (RMLF)

DATE : 10/02/2022

REF : BW34E700

LOT NO. : B20966

Rev. : 550

RS : BACTIGUARD AB

10/BD/270122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100578	271-24410(VG)	250ml HDPE Round Container (Natural Color)	H012210602	pcs	554	554	1. Cayana
2	P0100563	JQ-24A-PP (11cm)	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP. PP, TUBE: 110mm	H091200402	pcs	554	554	1. Cayana
3		STOCK SOLUTION	N/A	03HB100220035	ltr	143	143	1. Cayana

(2) PRODUCT PACKAGING					(3) OVER WRAPPING AND CARTON PACK		
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	NO	SYSTEM CODE
1	P0100265	Secure Capsel (For 100ml /250ml Hydrocort) - Size: 47 x 0.04 x 55 mm (LC+P)	H019200601	555	1. Cayana	1	P0100560
2						2	P0100567
3		#N/A				3	P0100568
4		#N/A				(4) SPECIAL REQUIREMENT	
5		#N/A				NO	SYSTEM CODE
6		#N/A				1	P0100324
7		#N/A				2	

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100560	Printed Carton (Hydrocort 250ml, Spray Mist) - Size: 330 x 330 x 365mm, Material: AB Flute DW 175N/M/M/175G	H060211103	11	malu
2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS:312 x 90mm(4pcs each), Mat:T150/T150 B Flute	H069210601	22	malu
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute	H070210601	11	malu
(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)		NA	
2		#N/A			

ISSUED BY (MM) :

Signature : LOVIN

Name : 10/02/2022

VERIFIED BY (PR) :

Signature : 1. Cayana

Name : 1. Cayana

Date : 10/02/2022

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

Description	Reference No.	Date of Inspection
Bactiguard wound care 250ml (Spray mist)	B234E700	14/02/2022
	Lot No. B20966	Sample Size 26H x 250 ml

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
7.23	QC-78	863	QC-67	113	QC-80
					pass

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Peggy
 Name : ROSHNE
 Date : 14/02/2022

Approved By : [Signature]
 Name : AARTINI
 Date : 14/02/2022

