

SHOP PACKET - EASW

SHIP PACKET - EASW						
REFERENCE	BW36D100	ODR. QTY (PCS)	500	RS(2) QC(1)	ISSUED DATE	28/01/2022
ITEM CODE	BW010011	PACK SIZE	12/Box		LOT NO.	A22834
ITEM DESCRIPTION	Bactiguard Woundcare 1000ml (Cap Closure)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
		ODR. NO	A197		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN		INT. ORDER	IO/BD/270122/01
	DATE : 28/01/2022		DATE : 28/01/2022			
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
STOCK SOLUTION PREPARATION						
TIME START : 7:00 PM	503	50	Nil	Kyandari (893)	Wah 1037	Tank 500L/T1 03HB2701220022
DATE : 27-01-22						
TIME COMPLETE : 10:30 AM						
DATE : 28-01-22						
UDI PRINTING (Label/Box/Carton)						
TIME START :				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :						
TIME COMPLETE :						
DATE :						
SOLUTION FILLING & CAPPING						
TIME START : 11:30 AM	503	503	Nil	Hanny (1049)	Roshni 4:45 PM 29/01/22	ND
DATE : 29-01-22						
TIME COMPLETE : 4:45 PM						
DATE : 29-01-22						
LABELLING						
TIME START :				N/A		N/A
DATE :						
TIME COMPLETE :						
DATE :						
PRINTING LOT NUMBER						
TIME START : 8:50 PM	503	503	Nil	Herdi (1053) Netra (1103)	Roshni 9:40 PM 31/01/2022	ND
DATE : 31-01-22						
TIME COMPLETE : 9:40 PM						
DATE : 31-01-22						
CAP SEALING (Applicable for 100mL)						
TIME START :				N/A		ND
DATE :						
TIME COMPLETE :						
DATE :						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START :				N/A		ND
DATE :						
TIME COMPLETE :						
DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START :				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :						
TIME COMPLETE :						
DATE :						
FINAL CONTROL						
TIME START : 8:50 AM	503	503	Nil	Herdi (1053) Netra (1103)	Roshni 9:45 AM 31/1/22	ND
DATE : 31-01-22						
TIME COMPLETE : 9:40 AM						
DATE : 31-01-22						
CARTON PACK						
TIME START : 7:15 PM	42	42	Nil	PASLI (1084) Thi Ha (894)	Nunn 31/1/22	NA
DATE : 31-01-22						
TIME COMPLETE : 8:40						
DATE : 31-01-22						
UDI LABELLING						
TIME START :				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :						
TIME COMPLETE :						
DATE :						


QUANTITY PRODUCED :	503 Yks
QUANTITY FOR QC / RETAIN SAMPLE :	211 btl
SHIPMENT QUANTITY PCS / CTNS :	500 Yks / 42 ctu
FINAL SHIPMENT DATE :	
COMPLETE / PARTIAL :	COMPLETE

Checked by (PR), Signature :  Name : RATNASEGARAN Date : 4/2/22	Approved by (QA), Signature :  Name : RATNASEGARAN Date : 7/2/2022	Released by (QC), Signature :  Name : R. RATNASEGARAN Designation : QC DEPT Date : 4/2/2022 Stamp : 
Remarks: TO PRODUCE WITHOUT LABEL		

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

Item Description	Bactiguard Wundcare 1000mL (Cap closure)
Reference	Hw 363100
Lot No.	A 22834

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"/>	Kyandun 24/01/22	Wah 1037 29.01.22	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 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"/>	N A	N A	N A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Kyandun 29/01/22	Wah 29.01.22	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"/>	Kyandun 29/01/22	Wah 29.01.22	N A	Production

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


Item Description	Bactiguard woundcare 100mL Cap closure		
Reference / Lot No.	HW 363100	/	A22834
Order Qty	500		
Volume Specification	1030	±	20 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	1030 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/200	1030ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/193	1030ml	-	✓	✓	✓	<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"/>
					<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)



Lot: A22634
Date: 2024-01

✓
Rev: 21/01/2022

Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL	Inspected by : <u>Wah</u>
			Name : <u>Wah Wah</u>
			Date : <u>31.01.2022</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)

N/A

Disposition of the Lot : ☐ PASS ☐ FAIL

Inspected by : N/A
Name : N/A
Date : N/A

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

ITEM DESCRIPTION : Baciguard wandclean 1000 ml

REFERENCE : BW 260100

LOT NO. : A23834

QTY. PRODUCED (pcs) : 503

RETAIN SAMPLE QTY. (pcs) : 2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	S ₂ , 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S ₂ , 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	8	0	pass
5	Correct volume filled (against reference sample).	S ₃ , 0.15	80	0	1	80	0	pass

Remarks : N/A

Inspected By : Poly
 Name : ROSHNI
 Date : 31/01/2022

Approved By : [Signature]
 Name : MARTINI
 Date : 3/2/2022

VIGILENZ®

Doc. No.

Rev.

RAW MATERIAL LOADING FORM (RMLF)

DATE : 28/01/2022

REF : BW36D100

LOT NO. : A22834

SHOP PACKET QTY (pcs) : 500

CUSTOMER : BACTIGUARD AB

LO NO. : 10/BD/270122/01

RS

RECEIVED BY

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		CONSUMPTION	RECEIVED BY
						REQUIRED	ISSUED		
1	P0100799	1000ml HDPE Plastic Container	0	H01C211201	pcs	503	503	503	Kaujawa
2	P0100814	White Cap for 250ml/500ml/1000ml HDPE Plastic Container - Bactiguard Wouncare	0	H168210701	pcs	503	503	503	Kaujawa
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078220101	pcs	503	503	503	Kaujawa
4		STOCK SOLUTION		03HB270122023	ltr	519	519	519	Kaujawa

(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	P0100582	DSN-H-011(A) - VIG-001-CTN,Printed Carton for Hydrocyn 1000ml,Size: 380 x 290 x 220mm(E), Mat: T180M/T180 BA FLUTE	H103211101	42	MADHANA
2	P0100583	DSN-H-011(B) - VIG-904-ASY,NL: 377 x 145mm (2pcs) & NS: 282 x 145mm(3pcs) for Carton E, Mat: T150/T150 B Flute	H041200401	42	MADHANA
3	P0100584	DSN-H-011(C) - VIG-904-ASY, Layer Pad for Carton E, Size: 377 x 282mm, Mat: T150/T150 B Flute	H042210601	42	MADHANA

(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)		N/A	
2		#N/A			


ISSUED BY (MM) :

Signature : 

Name : FIRDAUS

Date : 28/01/2022

VERIFIED BY (PR) :

Signature : 

Name : R. RATNASEKARAN

Date : 26/2/22

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

Description	Backguard Woundcare 1000ml (Cap Closure)	Reference No.	BW360100	Date of Inspection	31/01/2022
		Lot No.	A22834	Sample Size	16H x 1000ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)						Test Disposition (PASS / FAIL)
pH		ORP (mV)		FAC (ppm)		
Spec:	Result	Instrument	Result	Instrument	Result	
Spec: 6.50 - 8.00			Spec: ≥ 850		Spec: 95 - 140	
Result	7.26	QC-78	Result	858	QC-67	116
			Instrument		Instrument	
						QC-80
						pass

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : N/P

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Praj
 Name : POSHNI
 Date : 31/01/2022

Approved By : [Signature]
 Name : M. K. TH. I.
 Date : 31/01/2022

