

SHOP 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.	A22835
ITEM DESCRIPTION	Bactiguard Woundcare 1000ml (Cap Closure)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
		ODR. NO	A198		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN		INT. ORDER	10/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:						
DATE:	29-01-22	503	503	NIL	Myarden	Tarik 1000L/77
TIME COMPLETE:	9:00 Am				893	03HB290122024
DATE:	30-01-22					
UDI PRINTING (Label/Box/Carton)						
TIME START:						
DATE:				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE:						
DATE:						
SOLUTION FILLING & CAPPING						
TIME START:	9:55 Am	503	503	NIL	Anaury	Wah
DATE:	31-01-22				1049	5:55 pm
TIME COMPLETE:	5:55 pm					N/A
DATE:	31-01-22					31-01-22
LABELLING						
TIME START:						
DATE:				N/A		
TIME COMPLETE:						
DATE:						
PRINTING LOT NUMBER						
TIME START:	07:15 pm	503	503	NIL	Tashq	Wah
DATE:	31-01-22				1089	8:18 pm
TIME COMPLETE:	08:18 pm				HERDI (1083)	N/A
DATE:	31-01-22					31-01-22
CAP SEALING (Applicable for 100mL)						
TIME START:						
DATE:				N/A		
TIME COMPLETE:						
DATE:						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START:						
DATE:				N/A		
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:	07:15 pm	503	503	NIL	Tashq	Wah
DATE:	31-01-22				1089	8:25 pm
TIME COMPLETE:	08:18 pm				HERDI (1083)	N/A
DATE:	31-01-22					31-01-22
CARTON PACK						
TIME START:	07:15 pm	503	503	NIL	Tashq	Nurin
DATE:	31-01-22	42 ctn	42 ctn		1089	10/2/22
TIME COMPLETE:	08:18 pm				HERDI (1083)	10/02/2022
DATE:	31-01-22					
UDI LABELLING						
TIME START:						
DATE:				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED :	503 btl
QUANTITY FOR QC / RETAIN SAMPLE :	2 + 1 btl
SHIPMENT QUANTITY PCS / CTNS :	500 btl / 42 ctn
FINAL SHIPMENT DATE :	
COMPLETE/ PARTIAL :	COMPLETE

Checked by (PR),
Signature:

Name: RATNASEGARAN
Date: 10/2/22

Approved by (QA),
Signature:

Name: ROHMANIA GIPMAN
Date: 10/2/2022

Released by (QC),

Signature:
Name: KARTINI
Designation: QC DEPT
Date: 10/2/22
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	Batch guard surround core 1000ml (Cap cleaning)
Reference	BW26 0100
Lot No.	A22835

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"/>	Kyau Chan 31/01/22	Peg 31/01/22	ND	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"/>	NA	NA	ND	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Kyau Chan 31/01/22	Peg 31/01/22	ND	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"/>	Kyau Chan 31/01/22	Peg 31/01/22	ND	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	Bactiguard wound care 100cm (Cap closure)		
Reference / Lot No.	Bw 262100 / P22825		
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	1030ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	1030 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/193	1030 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"/>
		NA				<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"/>
		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"/>

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C. Attachment (First Printed Label)




LOT: A22835
EXP: 2024-01

31.10.13
 4002

Disposition of the Lot :

☒ PASS
 ☐ FAIL

Inspected by : Wah
 Name : Wah Wah
 Date : 31-01-22

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: 3(3)

D. Attachment (Last Printed Label)

_____ *NP* _____

Disposition of the Lot : ☐ PASS ☐ FAIL

Inspected by : *u/a*
 Name : *u/a*
 Date : *u/a*

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

ITEM DESCRIPTION : Bactiguard woundcare 1000 mL

REFERENCE : BW363100

LOT NO. : A22835

QTY. PRODUCED (pcs) : 503

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 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/A

Inspected By : Woh
 Name : Woh woh
 Date : 31.01.2022

Approved By : [Signature]
 Name : MARTINI
 Date : 10/02/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

DATE : 28/01/2022

REF : BW36DI00

LOT NO. : A22835

SHOP PACKET QTY (pcs) : 500

CUSTOMER : BACTIGUARD AB

LO NO. : IO/BD/270122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100799	1000ml HDPE Plastic Container	0	H01C211201	pcs	503	503	1. <i>Canjaya</i>
2	P0100814	White Cap for 250ml/500ml/1000ml HDPE Plastic Container - Bactiguard Wouncare	0	H168210701	pcs	503	503	1. <i>Canjaya</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078220101	pcs	503	503	1. <i>Canjaya</i>
4		STOCK SOLUTION		<i>03/10/2024</i>	ltr	518	518	1. <i>Canjaya</i>

(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100382	DSN-H-011(A) - VIG-001-CTN, Printed Carton for Hydrocort 1000ml Size: 380 x 290 x 220mm(E), Mat: T1 80/M/T1 80 BA FLUTE	H103211101	42	<i>m. Del</i>
2	P0100583	DSN-H-011(B) - VIG-904-ASY, NL: 377 x 145mm (2pcs) & NS: 282 x 145mm (3pcs) for Carton E, Mat: T1 50/T1 50 B Flute	H041200401	42	<i>m. Del</i>
3	P0100584	DSN-H-011(C) - VIG-904-ASY, Layer Pad for Carton E, Size: 377 x 282mm, Mat: T1 50/T1 50 B Flute	H042210601	42	<i>m. Del</i>

(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)		<i>N/A</i>	
2		#N/A			

ISSUED BY (MM) :

Signature : *FRDAUS*

Name : FRDAUS

Date : 28/01/2022

VERIFIED BY (PR) :

Signature : *Canjaya*

Name : *Canjaya*

Date : *30/1/2022*

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

Description	Backguard wound care 1000ml (cap closure)	Reference No.	BW 365100	Date of Inspection	03/02/2022
		Lot No.	A00835	Sample Size	1641 x 1000ml

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: 7, 850		Spec: 95 - 140		
Result	Instrument	Result	Instrument	Result	Instrument	Pass
7.27	QC-78	857	QC-67	120	QC-80	

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : 4/A

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : [Signature]
Name : Restin
Date : 3/2/2022

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

