

NO LABEL

SHOP PACKET - EASW

REFERENCE	BW3CE700	ODR. QTY (PCS)	3,375	RS(2) QC(5)	ISSUED DATE	28/01/2022
ITEM CODE	BW010001	PACK SIZE	50/Box		LOT NO.	A22828
ITEM DESCRIPTION	Bactiguard Woundcare 100ml (Bottle Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
		ODR. NO	A191		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 28/01/2022		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 : 7:00 PM DATE : 27-01-22 TIME COMPLETE : 8:15 AM DATE : 28-01-22	3382	3382	Nil	Kyanden (893)	Wah	Tank 1000L / TT 03HB270122020
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : 1:30 PM DATE : 29-01-22 TIME COMPLETE : 7:30 PM DATE : 29-01-22	3382	3382	Nil	Nisyah (980) Hawa (998) Mimi (1091)	Wah 29-01-22	N/A
LABELLING						
TIME START : 2:00 PM DATE : TIME COMPLETE : DATE :				NA		
PRINTING LOT NUMBER						
TIME START : 3:00 PM DATE : 29-01-22 TIME COMPLETE : 8:25 PM DATE : 29-01-22	3382	3382	Nil	Hawa (998) Rozzi (890)	Wah 29-01-22	N/A
CAP SEALING (Applicable for 100mL)						
TIME START : 3:30 PM DATE : 29-01-22 TIME COMPLETE : 8:30 PM DATE : 29-01-22	3382	3382	Nil	Nisyah (980) Netra (1103)	Wah 29-01-22	N/A
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :				NA		
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 : 3:30 PM DATE : 29-01-22 TIME COMPLETE : 8:30 PM DATE : 29-01-22	3382	3382	Nil	Nisyah (980) Netra (1103)	Wah 8:50 AM 31-01-22	N/A
CARTON PACK						
TIME START : 3:00 PM DATE : 03-02-22 TIME COMPLETE : 7:05 PM DATE : 03-02-22	68 ctn	68 ctn	Nil	Rabin (1098) Madiha (999) Netra (1103)	Nunn 3/2/22	lyn 04/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 3382 LK

QUANTITY FOR QC / RETAIN SAMPLE : 2 + 5 pes

SHIPMENT QUANTITY PCS / CTNS : 3375 LK / 68 ctns

FINAL SHIPMENT DATE :

COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : 4/2/22	Approved by (QA), Signature : <i>[Signature]</i> Name : <i>[Name]</i> Date : 4/2/2022	Released by (QC), Signature : <i>[Signature]</i> Name : MARTINI 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	Backward barcode 100 ml (bottle spray mist)
Reference	BW 3CE 700
Lot No.	A 22828

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>Hyawelan</i> 29/01/22	<i>Wich</i> 29.01.2022	NA	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>Wich</i> 29/01/2022	<i>Wich</i> 29.01.22	NA	Technician
	i) Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
	ii) Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
	iii) Stopper Insertor	<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>Wich</i> 29/01/22	<i>Wich</i> 29.01.22	NA	Production
4	All finished goods, materials and rejected items related to previous lot are cleaned and removed from working area	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Wich</i> 29/01/22	<i>Wich</i> 29.01.22	NA	Production

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:

1(3)


Item Description	Bactiguard Groundcare 100ml (Bottle spray mist)		
Reference / Lot No.	BW3CE700 / A22828		
Order Qty	3375		
Volume Specification	105	±	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	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<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"/>
		N/A			<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)		
Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/11/2021
		Page: 1(3)


Item Description	Bactiguard woundcare 100 ml (bottle spray mist)		
Reference / Lot No.	BW 3CE700	/	A22828
Order Qty	3375		
Volume Specification	105	±	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
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	110 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/372		NA				<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"/>
		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"/>
					<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		Issue Date: 15/11/2021	
		Doc Id: QC-IP002-09	

C. Attachment (First Printed Label)

LOT: R22828
EXP: 2024-01




✓
 29.01.22


Disposition of the Lot :

☒ PASS
 ☐ FAIL

Inspected by : Wach
 Name : uxh wach
 Date : 29.01.22

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

D. Attachment (Last Printed Label)



29.01.2022

Inspected by : Weth
 Name : Weth Weth
 Date : 29-01-2022

Disposition of the Lot : ☒ PASS ☐ FAIL

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

ITEM DESCRIPTION : Bactiguard Woundcare 100 mL

REFERENCE : BW3CE700

LOT NO. : A22828

QTY. PRODUCED (pcs) : 3382

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.	<u>S₃, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>PASS</u>
2	Free from contamination, deformed or damaged on packaging.	<u>S₃, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>PASS</u>
3	Proper sealing and no leaking.	<u>S₃, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>PASS</u>
4	Free from contamination / particle / foreign materials on product solution.	<u>S₃, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>PASS</u>
5	Correct volume filled (against reference sample).	<u>S₃, 0.15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>PASS</u>

Remarks : N/A

Inspected By : <u>Woh</u>	Approved By : <u>[Signature]</u>
Name : <u>Woh Woch</u>	Name : <u>MARTINI</u>
Date : <u>31.01.2022</u>	Date : <u>3/02/2022</u>

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. 06

Rev.

DATE : 28/01/2022

REF : BW3CE700

LOT NO. : A22828

SHOP PACKET QTY (pcs) : 3375

CUSTOMER : BACTIGUARD AB

LO NO. : IOBD/270122/01

RS

7

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		CONSUMPTION	RECEIVED BY
						REQUIRED	ISSUED		
1	P0100288	100ML HDPE BOTTLE	(NATURAL COLOUR WITH VIGILENZ LOGO)	H075210601	pcs	3382	3382	3382	Kanyana
2	P0100287	JQ-24A-PP	24/410 MIST SPRAYER, RUBBED, 316 SPRING, HALF CAP. PP, TUBE-90mm	H018200701	pcs	3382	3382	3382	Kanyana
3		STOCK SOLUTION		134827102020	ltr	355	355	355	Kanyana

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100265	Secure Capsal (For 100ml /250ml Hydrocyn) - Size: 47 x 0.04 x 55 mm (1C+P)	H019200601	3383	Kanyana
2					
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	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H	H164200501	68	medu
2	P0100681	100ml nesting short and Long-	H079200402	68	medu
3		#N/A			

(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)		119	
2		#N/A			

ISSUED BY (MM) :
Signature :
Name : LOVIN
Date : 28/01/2022

VERIFIED BY (PR) :
Signature :
Name :
Date : 4/2/2022

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

Description	Bactiguard Wandcare 100ml (Bottle spray mist)	Reference No.	BW38E700	Date of Inspection	31/01/2022
		Lot No.	A22828	Sample Size	561 x 100ml

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	pass
7.22	QC-78	875	QC-67	110	QC-80	

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : ND

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

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

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

