

NO LABEL

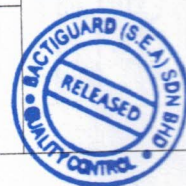
SHOP PACKET - EASW

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.	A22829
ITEM DESCRIPTION	Bactiguard Woundcare 100ml (Bottle Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
		ODR. NO	A192		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 28/01/2022		INT. ORDER	10/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 : 9.00 AM						
DATE : 29-01-22	3382	3382	Nil	Ryandan (893)	Roshni 12.00pm 29/01/22	Tank 500L/15 03HB 290122023
TIME COMPLETE : 12.00 PM						
DATE : 29-01-22						
UDI PRINTING (Label/Box/Carton)						
TIME START :				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :						
TIME COMPLETE :						
DATE :						
SOLUTION FILLING & CAPPING						
TIME START : 7.50 PM						
DATE : 29-01-22	3382	3382	Nil	Fasli (1053)	Roshni 31/01/22	NA
TIME COMPLETE : 5.05 PM						
DATE : 31-01-22						
LABELLING						
TIME START :				N/A		
DATE :						
TIME COMPLETE :						
DATE :						
PRINTING LOT NUMBER						
TIME START : 10.00 AM						
DATE : 31-01-22	3382	3382	Nil	Herdi (1053) Netra (1103)	Roshni 5.5pm 31/01/22	NA
TIME COMPLETE : 5.05 PM						
DATE : 31-01-22						
CAP SEALING (Applicable for 100mL)						
TIME START : 9.00 AM						
DATE : 31-01-22	3382	3382	Nil	Fasli (1054) Rubi (1088)	Roshni 31/01/22	NA
TIME COMPLETE : 7.00 PM						
DATE : 31-01-22						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START :				N/A		
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 : 4.00 AM						
DATE : 31-01-22	3382	3282	Nil	Herdi (1053) Netra (1103)	Roshni 5.20pm 31/01/22	NA
TIME COMPLETE : 5.05 PM						
DATE : 31-01-22						
CARTON PACK						
TIME START : 9.00 AM						
DATE : 04-02-22	68	68	X/11	Fasli 1054 Herdi 1053	Jmda 04/02/22	04/02/2022
TIME COMPLETE : 11.30 AM						
DATE : 04-02-22						
UDI LABELLING						
TIME START :				N/A		UDI NOT REQUIRED FOR THIS LOT
DATE :						
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED :	3382 btl's
QUANTITY FOR QC / RETAIN SAMPLE :	2 RS + 5 btl
SHIPMENT QUANTITY PCS / CTNS :	3375 btl's / 68 ctns
FINAL SHIPMENT DATE :	
COMPLETE / PARTIAL :	COMPLETE

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: <i>[Name]</i> Date: 04/02/2022
Remarks: TO PRODUCE WITHOUT LABEL		



VIGILENZ®

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

Doc. No

QC-LC002

Rev.

00

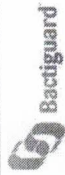
Item Description	Raciguard wandlere Hydran Part, 180cm (spray mist)	
Reference	H108CF700	
Lot No.	A02829	

29/1/22

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>K. Soudan</i> 29/01/22	<i>P. B. B.</i> 29/01/2022	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>K. Soudan</i> 29/01/2022	<i>P. B. B.</i> 29/01/2022	ND	Technician
	ii) Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
	iii) Stopper Insertor	<input 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>K. Soudan</i> 29/01/22	<i>P. B. B.</i> 29/01/2022	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"/>	<i>K. Soudan</i> 29/01/22	<i>P. B. B.</i> 29/01/2022	ND	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 wound care 100ml (Bottle spray mist)		
Reference / Lot No.	BW2CE700 / A22829		
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	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 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"/>
					<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: 1(3)


Item Description	Bactiguard woundcare 100ml (Bottle spray mist)		
Reference / Lot No.	HW3CE400 / A22829		
Order Qty	3375		
Volume Specification	105	±	5 ml

A. Filling Process

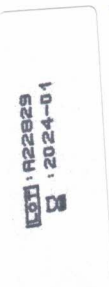
Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition	
						PASS	FAIL
1/200	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/200	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/200	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/200	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/372	105 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
			NA			<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"/>

Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Battiguard	
Document type: FORM		Doc Id: QC-IP002-09	Issue Date: 15/11/2021
		Page: 2(3)	

C. Attachment (First Printed Label)




✓


24/1/22

Disposition of the Lot : ☒ PASS ☐ FAIL

Inspected by : Poly
Name : PUSHNE
Date : 31/01/2022

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)



LOT: R22823
EXP: 2024-01

✓ *Pass* 21/01/2022

Disposition of the Lot : ☒ PASS ☐ FAIL

Inspected by : *Phay* Name : *Phay* Date : *21/01/2022*

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

ITEM DESCRIPTION : HyBactiguard woundcare 100ml Bag 3/1/22

REFERENCE : BW3CE700 QTY. PRODUCED (pcs) : 3375

LOT NO. : A32829 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/P

Inspected By :	<u>Raj</u>	Approved By :	<u>[Signature]</u>
Name :	<u>ROSHNI</u>	Name :	<u>MARTIN</u>
Date :	<u>31/01/2022</u>	Date :	<u>3/02/2022</u>

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE : 28/01/2022
REF : BW3CE700
LOT NO. : A22829

SHOP PACKET QTY (pcs) : 3375
CUSTOMER : ~~DR. MALAKSIA~~ BASIGUND AB
LO NO. : 10/BD/27012201

RS
RECEIVED BY

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2 (NATURAL COLOUR WITH VIGILENZ LOGO)	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100288	100ML HDPE BOTTLE		H075210601	pcs	3382	3382	1. Kanjara
2	P0100287	JQ-24A-PP	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP- PP, TUBE:90mm	H018200701	pcs	3382	3382	1. Kanjara
3		STOCK SOLUTION		08.H.B 29/01/2023	ltr	355	355	1. Kanjara

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100265	Secure Capsel (For 100ml /250ml Hydrocort) - Size: 47 x 0.04 x 55 mm (1C+P)	H019200601	3383	1. Kanjara
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 Hydrocort Aqua Carton-440L X 220W X 156H	H164200501	68	1. Kanjara
2	P0100681	100ml nesting short and Long-	H079200402	68	1. Kanjara
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)		249	
2		#N/A			

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

VERIFIED BY (PR) :
Signature :
Name :
Date : 4/2/20

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

Description	Bactiguard woundcare 100ml (bottle spray mist)	Reference No.	BW3CE 700	Date of Inspection	31/01/2022
		Lot No.	A22829	Sample Size	56+1 x 100ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)						Test Disposition (PASS / FAIL)
pH		ORP (mV)		FAC (ppm)		
Spec:	Instrument	Result	Instrument	Result	Instrument	
Spec: 6.50 - 8.00		Spec: ≥ 850		Spec: 95-140		
7.30	QC-78	855	QC-67	109	QC-80	
						PASS

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : N/D

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

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

Approved By : [Signature]
 Name : KARTINI
 Date : 31/2/2022

