REFERENCE	BW35D100		ODR. QTY (PCS)	ET - EASW 11/0			Michael Charles
ITEM CODE	BW010007		PACK SIZE	24/Box	RS(2) QC(1) +1	ISSUED DATE	29/01/2022
					12	LOT NO.	A22907
ITEM DESCRIPTION	Bactiguard Woundcare 500r	nl (Cap Closure)	CUSTOMER	Bactiguard AB		MFG. DATE	29/01/2022
	NAME AND CHAIRDA	1	ODR. NO	A206		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 29/01/2022	- VE	VERIFIED BY	NAME: RATNASEO DATE: 29/01/2022	GARAN	INT. ORDER	IO/BD/270122/01
UDI-DI NO.				UDI-DI NO.	- CI-		
(1st Packaging) - Bottle/Box/Bag		N/A		(2nd Packaging) -		N/A	
UDI-PI NO.				Carton UDI-PI NO.			
(1st Packaging) -		N/A		(2nd Packaging) -		N/A	
Bottle/Box/Bag	9			Carton			
PROC	CESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPA							and would
TIME START : DATE :	8:00 Pm 23-02-22			01'1	Kyandon (893)	Roshni 8-15 am	TANK 10001/77
TIME COMPLETE:	8:15 Am	2568+3	2571	Nil	(993)	8.15 am	03482302220
DATE:	24-92-22				(010)	04/2/20	Tank 5001 1 TS
UDI PRINTING (Label/Box/ TIME START:	(Carton)					//	03HB23022205
DATE:					NVA		UDI NOT REQUIRED
TIME COMPLETE:					N/A		FOR THIS LOT
DATE:		F					
SOLUTION FILLING & CA TIME START:						D4'	
DATE:	200 pm	07711		Nil	Dewi (1126)	Rosum	
TIME COMPLETE:	5:00 pm	2574	2574	7011	Dewi (1126)	7 5.00 019	AA
DATE:	26-02-22					20/0 2/22	
LABELLING TIME START :						,	
DATE:			*				
TIME COMPLETE:				V	N/a -	-	
DATE : PRINTING LOT NUMBER					·		
TIME START :	2:25:00					0.1	
DATE:	25-02-22	2574	05741	N;)	Fareth	Roslini	. 0
TIME COMPLETE :	5:00 PM	- 7 7 7	25754	,		1 5.00 pm	AM
DATE :	26-02-22				(1051)	26/02/28	
CAP SEALING (Applicable f	or 100mL)			7.			
TIME START :							
DATE:		-		NA			
TIME COMPLETE : * DATE :							
BOX PACKING & PRINTIN	G						
(Applicable for 100ml only)							
TIME START : DATE :				N/	9		
TIME COMPLETE :		-					
DATE:							
MANUAL UDI LABELLING Applicable for 100 mL & Bay						*	
TIME START :	go utily)						
DATE:					N/A		UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE : DATE :							
FINAL CONTROL							
ΓΙΜΕ START :	2:25 PM					Roshin	
DATE:	25-02-22	2574	2574	~;')	E 1	5.00pm	NA
TIME COMPLETE : DATE :	5:00 pm	2 -) '	2.71	, ,	Faverly	26/02/22	
CARTON PACK	26-02-27			-	(105)		
ΓΙΜΕ START :	8Lau pm	104	107	Hel	Rasin(1988)	Nurin	tand
DATE:	16-02-22	•	efn	1111	Vister (1023) Earli (1054)		iag~
TIME COMPLETE : DATE :	28-03-22	em	0100		Hudi (1053)	28/2/2022	28/02/22
DILABELLING		×			,		2010212
TIME START :							
DATE : TIME COMPLETE :					N/A		FOR THIS LOT
DATE:							TOR THIS EQT
QUANTITY PRODUCED	12571141	9	Checked by (PR	Appre	oved by (QA),	Released by (QC),
QUANTITY FOR QC /	11 24 1 - 1 41		Signature:	Signat	ture :	4	Sund
RETAIN SAMPLE	: 425 + 2 bt		Not	G	and a	Signature :	Notice .
UIDMENT OUT A PROPERTY	000	0 1	Name HA	Dert ADA	11118	P	LATINI
HIPMENT QUANTITY CS / CTNS	: 2568 lans / (Ach	Name: MACAC Date: 04		J Rohamba O	Kman ote	100 sup
			28/2	la Date:	1/3/2022	Stamp:	
INAL SHIPMENT DATE	:	_	Remarks:			/	EN SON de
						6	(o).
OMPLETE/ PARTIAL	: COMPLETE	PARTIAL	×			GUARD	13/15
						10	(8/ 15)
						13	18/

ECKLIST FOR LINE CLEARANCE OF Doc. No QC-LC002	CTIVATED SUPER-OXIDIZED WATER (EASW) Rev. 00
VIGII FN7®	ELECTRO ACTIVAT

Item Description	Bactiound	woundcare	600m)	BOHP L	(Joense)
Reference	5	13 W35 DIOD			1
Lot No.		Opec A	to		

Responsibility	Technician			Technician	37			Production	Production
Remarks	A/N	N/A						N/A	N/A
Verified by QC (Signature / Date)	woh 25/2/22	600h			V			294 35/1/33	11 /se fr) 13
Performed by (Signature / Date)	25/02/2022	25/02/2022	i		^{			1 Componer	25/02/22
No									
Yes				\		/		7	
Checklist	Flush machine HD-01 with approximately 20L of RODI water & 10L of EASWsolution before each production batch	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	Working area are cleaned and free from any dirt / dust and foreign particles	All finished goods, materials and rejected items related to previous lot are cleared and removed from working area
No.		2 2 9				.=	>	3 V	A A ref

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

Item Description	Bacifyward woundcard gooms (Bottle cap Closure)	ndcoro s	(00 m)	(BOH)	cap closure)
Reference / Lot No.	Bussoier / Assgot	1 Assgot			,
Order Qty	2568	. /			
Volume Specification	315	+1	5	m	1

A. Filling Process

position	FAIL							
Test Disposition	PASS	Ď	\(\)		Ц	Д	Image: Control of the	Ď
No Leaking	Observed	2	7	1	\	7	7	7
Proper Cap	Sealing/Stopper	> = =====	7 8 200 1	TANKS /	2	1	7	7
Functionality of Sprayer or Dispenser	(applicable to bottle only)	>	7	7	1	1	2	1
No contamination of	foreign material / dirt	5	`		V	A second	·	à
Volume Inspected (ml)		(wass)	Saomi	530m1	530ml	52011	520ml	920m)
Sampling /	Frequency	01/01	1/300	1/500	1/380	008/,	cope!	1/300

B. Labelling, Lot No, Manufacturing Date and Expiry Date Process

position	FAIL					
Test Disposition	PASS					
Correct UDI number printing on labelling	Manufacturing Date,	\				
Correct Position of Labelling on	Packaging					
Reference No, Lot No, Manufacturing Date and Expiry Date are	corresponding to Shop		S	N		
Label printing is clear and legible (inclusive of special printing when	applicable)					
Sampling /	rrequency					1

actiguard	ate: Page:	2021
5	Issue Date:	15/11/202
TIVATED SUPER-OXIDIZED WATER (EASW	Doc Id:	QC-IP002-09
ritie: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPEI	Document type:	FORM

Item Description	Bariguind wound and soo mi (BOTHE CAP Closine)
Reference / Lot No.	BWS50100/Asigot
Order Qty	3568
Volume Specification	5/8 ± 5/8

A. Filling Process

_								
position	FAIL							
Test Disposition	PASS			Q				
No Leaking	Observed	2	1	7		New	WALE.	
Proper Cap	Sealing/Stopper	7	7	7			100.55	
Functionality of Sprayer or Dispenser	(applicable to bottle only)	1	7	>	3	N. M.		
No contamination of	Ioreign material / dirt	7	\	\ \ ?				
Volume Inspected (ml)		520ml	(wats	Szemi				
Sampling /	Frequency	1/200	1/5000	191/				

B. Labelling, Lot No, Manufacturing Date and Expiry Date Process

position	FAIL				
Test Disposition	PASS				
Correct UDI number printing on labelling	Manufacturing Date,	1			
Correct Position of Labelling on	Packaging				
Reference No, Lot No, Manufacturing Date and Expiry Date are	corresponding to Shop		AIR		
Label printing is clear and legible (inclusive of special printing when	applicable)				
Sampling /	Lieduency				

	/ Page:	7(2)	
Bactiguard Bactiguard	<u></u> ,	15/11/2021	
Title: ACTIVATED SUPER-OXIDIZED WATER (EASW)	-	Document type:	FORM

C. Attachment (First Printed Label)

	44°5.5
2T: R22907	37
Loth H2	

Inspected by: Weh

Name : Weth Woth

FAIL

PASS

Disposition of the Lot:

Date : 25.2.2

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

D. Attachment (Last Printed Label)

9		
4		
*		
	6	

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N.O		
W 4		
E W		
Towash For		
Bra		
	· · · · · · · · · · · · · · · · · · ·	

Inspected by:

FAIL

Disposition of the Lot:

Name Date

ROSHNI

e : 16/310

Doc. No. QC-FC004	Rev. 09	
FINAL CONTROL TEST REPORT -	ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	
® ~ 1 V I I I V I V	VIGILEINZ	

ITEM DESCRIPTION

: Backguard wounders 500 m)

BUSSDIOU

REFERENCE

QTY. PRODUCED (pcs)

HSC

tobeely

RETAIN SAMPLE QTY. (pcs) :

LOT NO.

2	I monode on a medical	Someline Dotoile	Comp. Circ.	AQL	L	Res	Results	Status	
		Sampling Details Sample Size	Sample Size	Accept	Reject	Accept	Reject	(PASS/FAIL)	AIL)
_	1 Legible and clean printing of label.	83,0.15	80	0	1	80	0	Spd	
2	2 Free from contamination, deformed or damaged on packaging.	85,015	80	0	,	Se	0	pass	33
3	3 Proper sealing and no leaking.	83, 0.15	08	0	1	98	0	Spad	\$3
4	Free from contamination / particle / foreign materials on product solution.	\$3, 0.15	80	0	1	80	0	nd	sppd.
5	Correct volume filled (against reference sample).	53, 0.15	80	0	1	80	0		Spod

Remarks:

MIN

Inspected By

Name

Date

6602/20/32 KOSHNI

Approved By :

Name Date

28/2/2002 MARTIUI

	RS		
Doc. No. Rev.	2568	BACTIGUARD AB	IO/BD/270122/01
(RMLF)	rY (pcs) :		
OING FORM	SHOP PACKET QTY (pcs)	CUSTOMER	LO NO.
RAW MATERIAL LOADING FORM (RMLF)	11/02/2022	BW35D100	A22907
VIGILENZ [®]			2
VIGIL	DATE :	REF :	LOT NO. :

Doc. No

,		The Comment of Post of Particular					QUANTITY (pcs)		10110
O	SYSTEM CODE	HEM DESCRIPTION I	DESCRIPTION 2	LOI NO.		REQUIRED	ISSUED	CONSUMPTION	RECE
-	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilerz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	11010226/01 pcs	pcs	2571	2571	2571	i Conjune
7	P0100814	e Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woun	o	H168211201	pcs	2571	2571	2571	, Compans
ю	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	2571	2571	1257/	, Canjara
4		STOCK SOLUTION		03HB330333653 PS06663838489	基	1336	7 821	1335	1 Compans

	100							
(3) OVER WRAPPING AND CARTON PACK	ITEM DESCRIPTION 1	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	500ml nesting short and long-	#W/A	MENT	ITEM DESCRIPTION 1	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	#N/A
ER WRAPPING A	SYSTEM CODE	P0100679	P0100680		(4) SPECIAL REQUIREMENT	SYSTEM CODE	P0100324	
(3) 0V	ON	1	2	6	(4) SPI	ON	1	7
	RECEIVED BY							
	QTY REQUIRED (pcs)						10	
	LOT NO.		17.6					
CKAGING	ITEM DESCRIPTION 1		#ΝΑ	#N/A	#N/A	#N/A	#N/A	#N/A
(2) PRODUCT PACKAGING	SYSTEM CODE				. 4			
2	ON	-	7	ю	4	v	9	7

	THE STREET WATER				
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECE
-	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H165211201	107	maly
2	P0100680	500ml nesting short and long-	H065220101	107	ned
		#N/A		4	maly
(4) SP	4) SPECIAL REQUIREMENT	MENT			
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECE
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour. Red (2 layers)	4	MA AM	
2		#N/A			

ISSUED BY (MM):

Signature: Name: Date:

VERIFIED BY (PR)

Signature:

VIGILENZ®

ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW) PRODUCT RELEASE TEST REPORT –

Doc No.	QC-PC007
Rev.	90

	Bactiguard woundcore	Reference No.	BW35 D160	Date of Inspection	01/02/2033
Description	500ml (Cap Closure)	Lot No.	N 23007	Sample Size	16H V 5000

Release Criteria:

	Test Disposition	(TASS/FAIL)		SIND
	(mdd)	0/10	Instrument	08 - 30
er (EASW)	FAC (ppm)	Spec: 95-140	Result	7/3
uper-Oxidized Wate	ORP (mV)		Instrument	19-20
Analysis of Electro Activated Super-Oxidized Water (EASW)		Spec: ≥ 85 <i>l</i>	Result	998
Analysis of	H	8.00	Instrument	8c. 78
	pH Spec: 6.50 - 8.00		Result	ee. £

RO water and product bioburden meeting the acceptance criteria.

Remarks: Jank 10001/17 03118 230222054

Disposition of the Lot:

RELEASE

ON-HOLD

Analyzed By

Name

Date

6601/6/10: POCHNI

Approved By : Name

01/03/2020 MARTINI

Date



VIGILENZ®

PRODUCT RELEASE TEST REPORT – ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

	Backguard Woordare Reference No.	Reference No.	B w 3 S D COO Date of Inspection	Date of Inspection	" allallan
Description	500 ml (cap closure)	Lot No.	Eneco	Sample Size	1/2/2000

Release Criteria:

	Test Disposition (PASS/FAIL)		ssad		
	(mdd)	0/1	Instrument	08-18	
er (EASW)	FAC (ppm)	Spec: 95- 140	Result	tol	
Analysis of Electro Activated Super-Oxidized Water (EASW)	ORP (mV)		Instrument	Q1-67	
		Spec: > 860	Result	859	
	pH Spec: 6.50 - 8.00	8.00	Instrument	&c-78	
		Result	2.76		

RO water and product bioburden meeting the acceptance criteria.

Remarks: Tank 5001/15 03HB 320333053

Disposition of the Lot:

| RELEASE

ON-HOLD

Analyzed By

Name

Date

POSMNE 01/03/1000

Approved By : "refune \nearrow "

Name : $\alpha \land R \vdash l \land u$ Date : $o(l \circ 3 / 2 \circ 3)$

CONTRACTOR OF THE PROPERTY OF