

SHOP PACKET - EASW

REFERENCE	BW36D100	ODR. QTY	360	RS: 2 + 1(QC TEST)	ISSUED DATE	03/02/2022
ITEM CODE	BW010011	PACK SIZE	12/BOX	LOT NO.	B20301	
ITEM DESCRIPTION	Bactiguard Woundcare, 1000ml (Cap Closure)	CUSTOMER	Bactiguard AB (Lifecyn)	MFG. DATE	03/02/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 03/02/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 03/02/2022	EXP. DATE	28/01/2024	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	07333330201568	UDI-DI NO. (2nd Packaging) - Carton	17333330201565	INT. ORDER	IO/CYN/060505/01	
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)07333330201568 (17)28012024	(11)03022022 (10)B20301	UDI-PI NO. (2nd Packaging) - Carton	(01)17333330201565 (17)28012024	(11)03022022 (10)B20301	

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPOC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	2.00 PM 25-02-22	363PCS	363PCS	Nil	Hnayy 1049	Wah 5.40PM 23/02/22
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :	11:30 AM 10-02-22	364	364	Nil	Nisya 980	Roshni 789 10/02/2022
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	2:00 PM 23-02-22	363	363	Nil	Hnayy (1049)	Roshni 5.40PM 23/02/2022
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	2.00 PM 23-02-22	364	364	Nil	Hnayy 1049	Roshni 5.40 pm 24/2/22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	7.45 PM 24-02-22	363	363	Nil	Tanaya (740)	Roshni 8.00pm 24/2/22
CAP SEALING (Applicable for 1000mL)						
TIME START : DATE : TIME COMPLETE : DATE :				NA		
BOX PACKING & PRINTING (Applicable for 1000ml only)						
TIME START : DATE : TIME COMPLETE : DATE :				NA		
MANUAL UDI LABELLING (Applicable for 1000 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :	8.00PM 24-02-22	363	363	Nil	Hanong (1049) Ransana 790	Roshni 8.30PM 24/2/22
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	8.00PM 24-02-22	363	363	Nil	Ransana 790	Roshni 24/2/2022 8.35pm
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	9.30 AM 05-03-22	30 ctn	30 ctn	Nil	Vilster (1023) Rabin (1088) FACLI (1054) Hera (1053)	Nurin 25/2/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	9.30 AM 05-03-22	30 ctn	30 ctn	Nil	Vilster (1113) Rabin (1088) FACLI (1054) Hera (1053)	Nurin 25/2/2022

QUANTITY PRODUCED	363 btl
QUANTITY FOR QC / RETAIN SAMPLE	223 + 1 btl
SHIPMENT QUANTITY PCS / CTNS	360 btl
FINAL SHIPMENT DATE	
COMPLETE/ PARTIAL	COMPLETE PARTIAL

Checked by (PR), Signature : Name : Nuria Date : 26/2/2022	Approved by (QA), Signature : Name : Alhamza Orman Date : 13/2/2022	Released by (QC), Signature : Name : MARTINI Designation : IFCO SUP Date : 26/2/22 Stamp :
Remarks:		



Doc. No : PR-SP007, Rev : 07

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

Item Description	Bucti-guard Wundcare 100ml (Bottle cap closure)
Reference	BW 360100
Lot No.	B20301

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 type="checkbox"/>	<input type="checkbox"/>				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 type="checkbox"/> i) Starwheel ii) Nozzle iii) Stopper Insertor iv) Cap Dispenser v) Cap Pusher	<input type="checkbox"/> 			N/A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Conjour 23/02/22</i>	<i>Wah 23/02/22</i>	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"/>	<i>Conjour 23/02/22</i>	<i>Wah 23/02/22</i>	N/A	Production

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

Item Description	Bactigard Woundcare 1000 ml (Bottle cap closure)		
Reference / Lot No.	BW360100	/	B20301
Order Qty	360		
Volume Specification	1030	±	20
			ml

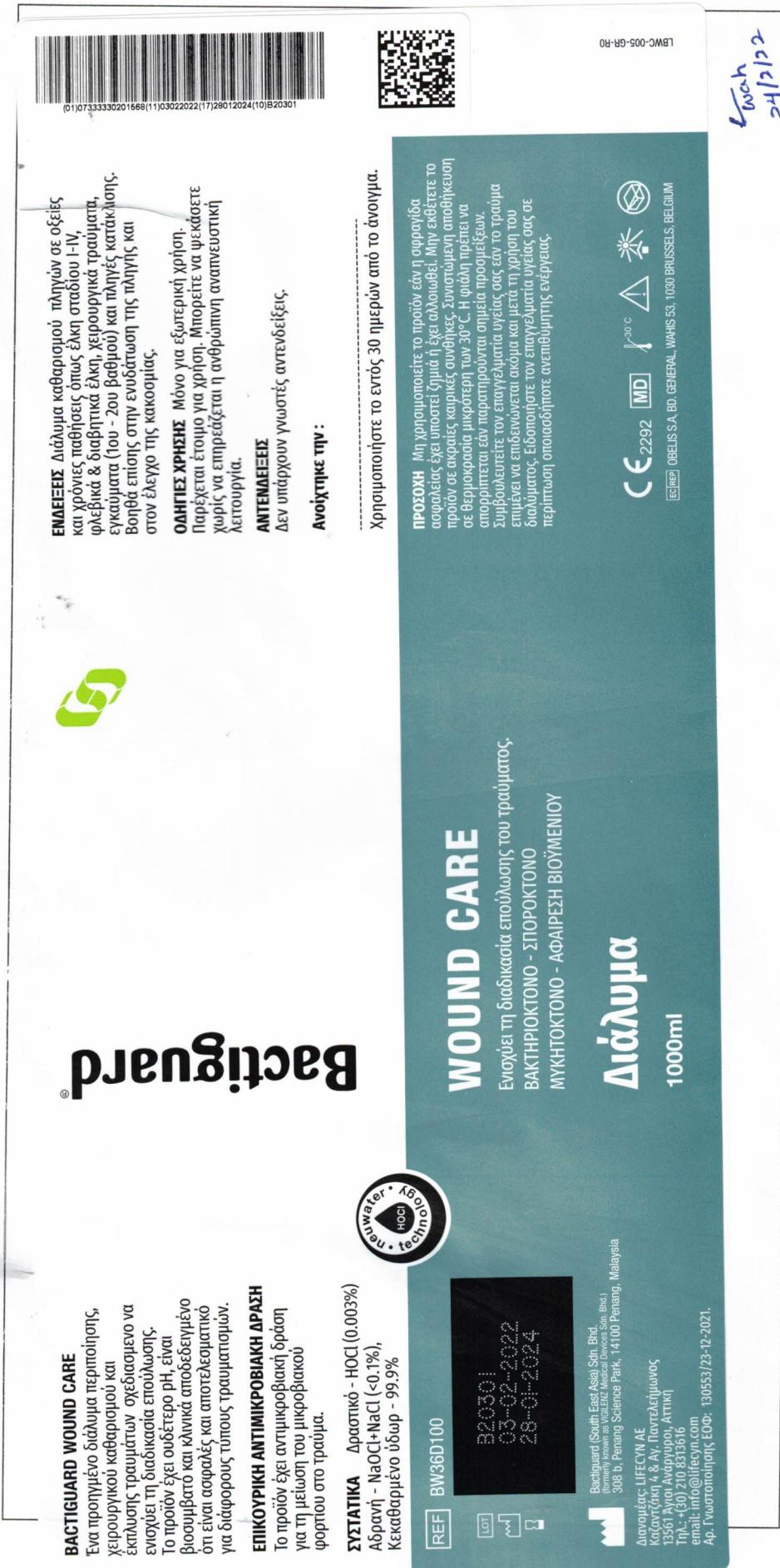
A. Filling Process

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

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

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C. Attachment (First Printed Label)



Disposition of the Lot :

PASS FAIL

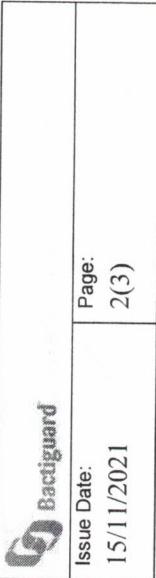
Inspected by : Wah

Name

: Wah Wah

Date

: 24/12/22



LBCMC-005-GR-RO

Title:

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

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FORM

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15/11/2021

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D. Attachment (Last Printed Label)**BACTIGUARD WOUND CARE**

Ενα προηγμένο διάλυμα περιποίησης, ρευστούργικου καθαρισμού και εγείρουργικού τραυματών σχεδιασμένο να ενισχύει τη διαδικασία επούλωσης. Το προϊόν έχει ουδέτερο pH, είναι βιοσυμβατό και κλινικά αποδεδεγμένο για ενιαία ασφαλέζ, και αποτελεσματικό για διάφορους τύπους τραυματομάνων.

ΕΠΙΚΟΥΡΙΚΗ ΑΝΤΙΜΙΚΡΟΒΙΑΚΗ ΔΡΑΣΗ

Το προϊόν έχει αντιμικροβιακή δράση για τη μείωση του μικροβιακού φρούτου στο τραύμα.

ΣΥΓΧΑΤΙΚΑ Δραστικό - HOCl (0.003%)

Αδρανή - NaOCl+NaCl (<0.1%),
Κεκαθαριμένο υεδύρ - 99.9%

REF: BW36D100



320301
03-02-2022
28-01-2024

LOT: 320301
EXPIRY DATE: 28-01-2024

Bactiguard (South East Asia) Sdn. Bhd.
Formerly known as Waterless International Sdn. Bhd.
308 B, Penang Science Park, 14100 Penang, Malaysia

Διορυγές: LIFECON AE
Κασαρίδης 4 & Ay, Παντελεήμονας
1551 Άγιο Ανδρινό, Αττική
Τηλ.: +30 210 8313616
email: info@lifecon.com
Αρ. Γνωστοποίησης ΕΟΦ: 130553/23-12-2021.

**WOUND CARE**

Ενισχύει τη διαδικασία επούλωσης του τραύματος.
ΒΑΚΤΗΡΙΟΚΤΟΝΟ - ΣΠΟΡΟΚΤΟΝΟ
ΜΥΚΗΤΟΚΤΟΝΟ - ΑΦΑΙΡΕΣΗ ΒΙΟΥΜΕΝΙΟΥ

Διάλυμα

1000ml



LBWC-005-GR-R0



Bactiguard

ΕΝΑΛΛΕΛΕΙΣ Διάλυμα καθαρισμού πληγών σε οξείς και χρόνιες πληγέσεις διπλώς έλλειμη σταδιού I-II, φλεγμικά & δαστητικά έλλειμη, χειρουργικά τραύματα, εγκεφαλίστα (Ιου - 2ου βαθμού) και πληγές καταλληλότητας. Βοηθά επίσης στην ευδαπάνωση της πληγής και στον έλλειγο πηγαδούνα.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ Μόνο για εξωτερική χρήση. Παρέχεται έπουμο για χρήση. Μπορείτε να ψεκάσετε χώρις να επηρεάζεται η ανθρώπινη αναπνευστική λειτουργία.

ΑΝΤΕΜΑΘΕΣΗΣ

Δεν υπάρχουν γνωστές αντανακλάσεις.

Χρησιμοποιήστε το εντός 30 ημερών από το άνοιγμα.

ΠΡΟΣΟΧΗ Μη χρησιμοποιούστε το προϊόν εάν η σφραγίδα ορισμένων έγγειων υποστοί ή γημαί ή έχει αλοιφαθεί. Μην εκδίδετε το προϊόν σε απορρεικές ανιψήσεις συνήθως συνιστώνται από θερμοπλαστικό πλαστικό πουλόβερ. Η φιλιά πρέπει να απορριμμέται εάν παρατηρούνται σημεία προστρεβέλων. Συμβολουλεύετε τον επαγγελματία υγείας, σας, εάν το τραύμα διαλογίστηκε. Ειδοποιήστε τον επαγγελματία υγείας σας σε περίπτωση οποιοδήποτε ανεπιθύμητης ενέργειας.



ECEREP OBELIS S.A. BD. GENERAL, WAHRS 53, 1030 BRUSSELS, BELGIUM

Inspected by : Σταύρος Ρωσήνης
Name : _____
Date : 24/11/2021

Disposition of the Lot : PASS FAIL

VIGILENZ®

FINAL CONTROL TEST REPORT -
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

ITEM DESCRIPTION : *Bottleguard roundneck 1000ml*REFERENCE : *BW 36 DIV 0*LOT NO. : *B20301*

QTY. PRODUCED (pcs) :

RETAIN SAMPLE QTY. (pcs) :

ITEM DESCRIPTION : <i>Bottleguard roundneck 1000ml</i>	QTY. PRODUCED (pcs) : <i>363</i>
LOT NO. : <i>B20301</i>	RETAIN SAMPLE QTY. (pcs) : <i>2</i>

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	<i>S5, 0.1S</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>
2	Free from contamination, deformed or damaged on packaging.	<i>S5, 0.1S</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>
3	Proper sealing and no leaking.	<i>S5, 0.1S</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>
4	Free from contamination / particle / foreign materials on product solution.	<i>S5, 0.1S</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>
5	Correct volume filled (against reference sample).	<i>S5, 0.1S</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>

Remarks : *N/P*

Inspected By : *Rajesh*
 Name : *Rajesh*
 Date : *24/1/2013*

Approved By : *Shankar*
 Name : *Shankar*
 Date : *24/1/2013*

RAW MATERIAL LOADING FORM (RMLF)

Rev.

DATE :	09/02/2022
REF :	HW36D100
LOT NO. :	B20301

SHOP PACKET QTY (pes)	:	360
CUSTOMER	:	BACTIGUARD AB (LIFECYN)
LO NO.	:	10/CYN/060505/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100799	1000ml HDPE Plastic Container	0	H01C211201	pcs	363		363	<i>Carjane</i>
2	P0100814	White Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woundcare	0	H020210901	pcs	363		363	<i>Carjane</i>
3	P0100357	DROPPER STOPPER (500ML & 250ML BOTTLE)		H078220101	pcs	363		363	<i>Carjane</i>
4		STOCK SOLUTION		0244B210900052	ltr	373		373	<i>Carjane</i>

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100893	LBWC-005-GR-R0 (1000ML - Cap Closure- GREECE), VIGILENZ0145; 250MM X 110MM, IN ROL, GLOSS WHITE BOPP; 4C + EYEMARK	LG08220201	364	<i>Carjane</i>
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 (pes)	RECEIVED BY
1	P0100582	DSN-H-011(A) - VIG-001-CTN Printed Carton for Hydrogen 1000ml,Size: 380 x 290 x 220mm(E), Mat: T180/MAT180 BA FLUTE	H103220201	30	<i>Melly</i>
2	P0100583	DSN-H-011(B) - VIG-904-ASY-NL, 377 x 145mm (2/pes) & NS: 282 x 145mm(3/pes) for Carton E , Mat: T150/T150 B Flute	H041200501	30	<i>Melly</i>
3	P0100584	DSN-H-011(C) - VIG-904-ASY, Layer Pad for Carton E, Size: 377 x 282mm, Mat: T150/T150 B Flute	H042220201	30	<i>Melly</i>

(4) SPECIAL REQUIREMENT

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	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		#N/A	

ISSUED BY (MM) :

Signature : *LOVIN*
 Name : *LOVIN*
 Date : *09/02/2022*

VERIFIED BY (PR) :

Signature : *J. May J. M. Yaneza*
 Name : *J. May J. M. Yaneza*
 Date : *26/2/2022*

Title: OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD		 Bactiguard	Page: 1(2)
Document type: FORM		Doc ID: QC-O1001-04	Issue Date: 09/02/2022

SHIPMENT	<input type="checkbox"/>	TOTAL LOTS	: <u>1</u>
GAMMA	<input type="checkbox"/>	TOTAL CARTONS	: <u>30</u>
		SAMPLING DETAILS	: <u>I, AQL 1.5</u>

TOTAL CARTONS : 30 : 1.5
AMPLIING DETAILS : T.A.GI

RETURN DATE

AVAILABILITY OF RETAIN SAMPLES

Doc ID:
QC-O100

Document type:
FORM

_____ (Applicable for Gamma only) YES / NO : _____

INSPECTION CRITERIA	REMARKS		
	QUANTITY	CARTON CHECKED	CARTON / CARTON
PACKAGING INFORMATION NUMBER OF CARTON (UID Number, Product Code, Manufacturing Date, Expiry Date & Lot No.)	-	✓	✓
CORRECT UDI DISPLAY ON CARTON (UID Number, Product Code, Manufacturer's (Ref. No. & Lot No.). Should Correspond to Shop Package)	1-30	✓	✓
PRODUCT TYPE	REF. NO.	LOT NO.	QTY (BXS / PCS / BTLS) / CARTON
25/12/2022	BN36D100	B20301	12
	wound care.		
	(160ml)		

*Please print addition sheet if required

Inspected by : 
Name : Nuvia
Date : 25/12/2022

Page

Verified by
Name _____ Date _____

R. Malini 07/03/2022 01/03/2022

	Doc ID: QC-O1001-04	Issue Date: 09/02/2022	Page: 2(2)
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A. Attachment (Carton UDI label)

Bactiguard®

PRODUCT : Bactiguard Woundcare, 1000ml
QUANTITY : 12 PCS

Manufacturer:

Bactiguard (South East Asia) Sdn Bhd
(formerly known as VIGILENZ Medical Devices Sdn Bhd)
308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia.



REF BW36D100

LOT B20301

EXPIRY 28-01-2024



(91173333020156)(11)03022022(17)28012024(10)B20301

*Only print this sheet for products with UDI

Inspected by : Nurin
Name : 25/12/2022
Date :

Page: 3

Verified by
Name : K. Nalin
Date : 01/03/2022

VIGILENZ®

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

		Doc No.	QC-PC007
		Rev.	06

Description	Bottle word and number/ (Bottle cap closure)	Reference No.	Date of Inspection
		BW360100	> 5/6/2022

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)				Test Disposition (PASS / FAIL)
pH	ORP (mV)	FAC (ppm)	Spec:	
Spec: 6.00 - 8.00	Spec: > 850	Spec: 95 - 140		
Result	Instrument	Result	Instrument	
7.20	Qc-78	857	Qc-80	pH

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/P

Disposition of the Lct : RELEASE ON-HOLD

Analyzed By : Praj
Name : Prajwal
Date : 15/01/2022

Approved By : R. Jaiswal
Name : MARTINI
Date : 5/6/2022

