

SHOP PACKET - EASW

REFERENCE	BW34E700	ODR. QTY (PCS)	5,000 4500	RS(2) QC(2) 814/4	ISSUED DATE	28/01/2022
ITEM CODE	BW010002	PACK SIZE	50/Box		LOT NO.	A22831
ITEM DESCRIPTION	Bactiguard Woundcare 250ml (Spray Mist)	CUSTOMER	Bactiguard AB		MFG. DATE	28/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 28/01/2022		EXP. DATE	2024-01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton			INT. ORDER	IO/BD/270122/01
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 :	10:00 AM					
DATE :	04-02-22	450474	450474	Nil	Wah	Tank 1000L/T6
TIME COMPLETE :	5:45 PM				5:45PM	03HB04022209
DATE :	04-02-22				4.2.22	Tank 1000L/T7
UDI PRINTING (Label/Box/Carton)						03HB29012204
TIME START :						
DATE :						UDI NOT REQUIRED FOR THIS LOT
TIME COMPLETE :						
DATE :						
SOLUTION FILLING & CAPPING						
TIME START :	9:30AM					
DATE :	07-02-22	4508	4508	Nil	Wah	
TIME COMPLETE :	5:00 PM				5:00 PM	
DATE :	07-02-22				07/02/22	NA
LABELLING						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						
PRINTING LOT NUMBER						
TIME START :	3:30 PM					
DATE :	07-02-22	4508	4508	Nil	Roshni	
TIME COMPLETE :	4:20 PM				4:20PM	
DATE :	08-02-22				08/02/22	NA
CAP SEALING (Applicable for 100mL)						
TIME START :	1:30 PM					
DATE :	07-02-22	4508	4508	Nil	Viki	
TIME COMPLETE :	4:20 PM				Netsa (1103)	
DATE :	08-02-22				Roshni	
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						
FINAL CONTROL						
TIME START :	1:30 PM					
DATE :	07-02-22	4508	4508	Nil	Viki	
TIME COMPLETE :	4:20 PM				Netsa (1103)	
DATE :	08-02-22				Roshni	
CARTON PACK						
TIME START :	4:00PM					
DATE :	08-02-22	90	90	Nil	FASLI (1054)	
TIME COMPLETE :	4:30 PM	ctn	ctn		HERDI (1053)	Jinla
DATE :	09-02-22				RABIN (1088)	09/02/22
UDI LABELLING						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED : 4508 4508 10/2/22

QUANTITY FOR QC / RETAIN SAMPLE : 4257461

SHIPMENT QUANTITY PCS / CTNS : 4500 (Ms) / 96ctns

FINAL SHIPMENT DATE :

COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature: Name: MARTINI Date: 10/2/22	Approved by (QA), Signature: Name: Rohamiza Othman Date: 10/2/2022	Released by (QC), Signature: Name: MARTINI Designation: QC DEPT Date: 10/02/2022 Stamp:
Remarks: TO PRODUCE WITHOUT LABEL		
		

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ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No	QC-LC002
Rev.	00

Item Description	<i>Bactiguard Workware 250ml (Spray mist)</i>
Reference	<i>BW 34E F00</i>
Lot No.	<i>A 22831</i>

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>Kyaw Soe 07/02/22</i>	<i>Wah 7.2.22</i>	N/A	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>Kyaw Soe 07/02/22</i>	<i>Wah 7.2.22</i>	N/A	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>' Kyaw Soe 07/02/22</i>	<i>Wah 7.2.22</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>' Kyaw Soe 07/02/22</i>	<i>Wah 7.2.22</i>	N/A	Production

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

Item Description	<i>Bactiguard Woundcare 250ml (Spray mist)</i>		
Reference / Lot No.	<i>BW 34 E700 A22831</i>		
Order Qty	<i>4500</i>		
Volume Specification	<i>255</i>	<i>± 5</i>	<i>ml</i>

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	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓
1/300	260 ml	✓	✓	✓	✓	✓

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
					□	□
					□	□
					□	□
					□	□
					□	□
					□	□
					□	□
					□	□

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Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/11/2021	

Item Description	<i>Butiguent Woundcare 250 ml (spray mist)</i>
Reference / Lot No.	<i>BW 34E 700</i> / <i>A 22831</i>
Order Qty	<i>4500</i>
Volume Specification	<i>255</i> ± <i>5</i> ml

A. Filling Process

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

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

Item Description	<i>Bactiguard Woundcare 250ml (spray mist)</i>		
Reference / Lot No.	<i>BW34E700</i>		
Order Qty	<i>4500</i>		
Volume Specification	<i>255</i>	<i>±</i>	<i>5</i>
		<i>ml</i>	

Manufacturing Date and Expiry Date Process

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C. Attachment (First Printed Label)



Inspected by : Wah
 Name : Wah Wah
 Date : 7.2.2022

Disposition of the Lot : PASS FAIL

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
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D. Attachment (Last Printed Label)

 <i>Prajjwal</i> <i>10/11/2021</i>

Disposition of the Lot : PASS FAIL

Inspected by : *Prajjwal*
 Name : *Prajjwal*
 Date : *10/11/2021*

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

ITEM DESCRIPTION	: <i>Bactiguard Waterbottle 250 ml</i>	Doc. No.	QC-FC004
REFERENCE	: <i>BLU 34 E 700</i>	Rev.	09

ITEM DESCRIPTION : *Bactiguard Waterbottle 250 ml*

REFERENCE : *BLU 34 E 700*

LOT NO. : *A22831*

QTY. PRODUCED (pcs) : *450 8*

RETAIN SAMPLE QTY. (pcs) : *4*

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Accept	Reject	Status (PASS/FAIL)
				Accept	Reject			
1	Legible and clean printing of label.	<i>S3, 0.15</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>S3, 0.15</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>S3, 0.15</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>S3, 0.15</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>S3, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>

Remarks :

N.D

Inspected By : *Robby*
 Name : *Roshni*
 Date : *8/2/2022*

Approved By : *M. A. R. T. M.*
 Name : *M. A. R. T. M.*
 Date : *8/2/2022*

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RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE :	03/02/2022
REF :	BW34E700
LOT NO. :	A22831

SHOP PACKET QTY (pes) : 5000 4500 RS

CUSTOMER : BACTIGUARD AB

LO NO. : IOBD/27/01/22/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100578	271-24410(VG)	250ml HDPE Round Container (Natural Color)		pes	5004 <u>4504</u>	5004 <u>4504</u>	4500	<u>Camelia</u>
2	P0100563	JQ-24A-PP (11cm)	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP, PP, TUBE:10mm	H091200402	pes	5004 <u>4504</u>	5004 <u>4504</u>	4500	<u>Camelia</u>
3		STOCK SOLUTION		03HB220122024 02BB 03HB240222029	ltr	1171	1171	1171	<u>Camelia</u>

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capsal (For 100ml /250ml HydrocyN) - Size: 47 x 0.04 x 55 mm (1C+P)	H019210901	5005 <u>4504</u>	<u>Camelia</u>
2					<u>Camelia</u>
3					<u>Camelia</u>
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	P0100560	Printed Carton (HydrocyN 250ml, Spray Mist) - Size: 330 x 330 x 365mm, Material: AB Flute DW 175/M/MM/175G	H06211101	100 <u>100</u>	<u>Camelia</u>
2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS:31.2 x 90mm(pcs each), Mat: TI50/TI50 B Flute	H069210601	200 <u>180</u>	<u>Camelia</u>
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 31.2 x 12mm, Mat: TI50/TI50 B Flute	H070211103	100 <u>90</u>	<u>Camelia</u>

(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)		100 <u>100</u>	
2		#N/A			

ISSUED BY (MM) :

Signature : Lovin
 Name : Lovin
 Date : 03/02/2022

VERIFIED BY (PR) : Det
 Signature : Parvaneh Gandomi
 Name : Parvaneh Gandomi
 Date : 16/2/22

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

Doc No.	QC-PC007
Rev.	06

Description	Bactericidal woundcare 350mL	Reference No.	BW34E700	Date of Inspection	08/06/2021
Lot No.	AEO 831	Sample Size	250 mL		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH Spec: 6.50 - 8.00	ORP (mV)		FAC (ppm) Spec: 95 - 140		
	Result	Instrument	Result	Instrument	Result
7.14	QC - 7.2	862	QC - 6.7	107	QC - 80 pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000 L / 77,03HB009010004

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rony
Name : Roshni
Date : 08/06/2021

Approved By : M. Arun
Name : M. Arun
Date : 8/2/2022



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

Doc No.	QC-PC007
Rev.	06

Description	Bactiguard Wondcase 350mL	Reference No.	BW34E700	Date of Inspection	08/02/2021
Lot No.	A92831	Sample Size	350mL		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	FAC (ppm)	Test Disposition (PASS / FAIL)		
Spec: 6.50 - 8.00	Spec: ≥ 850	Spec: 95 - 140			
Result	Instrument	Result	Instrument	Result	Instrument
7.15	Q.C. - TS	867	Q.C. - ET	107	Q.C. - 80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000L/T6, OSHB04002209

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Ray
 Name : Destin
 Date : 08/02/2022

Approved By : M. Ammar
 Name : M. Ammar
 Date : 08/02/2022

