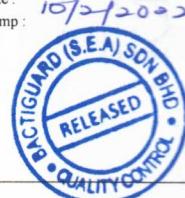


SHOP PACKET - EASW						
REFERENCE	BW35D100	ODR. QTY (PCS)	3288	RS(4) QC(2)	ISSUED DATE	29/01/2022
ITEM CODE	H0100007 BW010007	PACK SIZE	24/Box		LOT NO.	A22904
ITEM DESCRIPTION	Bactiguard Woundcare Hydrogen Aqua, 500ml (Cap Closure)	CUSTOMER	Bactiguard AB		MFG. DATE	29/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 29/01/2022	ODR. NO	A203		EXP. DATE	2024-01
		VERIFIED BY	NAME : RATNASEGARAN DATE : 29/01/2022		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 : 9:45 AM DATE : 07-02-22 TIME COMPLETE : 5:40 PM DATE : 07-02-22	3294 4011	3294	Nil	Kyandan (893)	wan 5:40pm 07/01/22	TANK 1000L/T7 08HB070222030 TANK 500L/T5 03HB210122027
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : 9:30 AM DATE : 07-02-22 TIME COMPLETE : 3:00 PM DATE : 07-02-22	3294	3294	Nil	Rashmi (1051)	Rashmi 3:00pm 07/01/22	ND
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
PRINTING LOT NUMBER						
TIME START : 9:40 AM DATE : 07-02-22 TIME COMPLETE : 4:20 PM DATE : 07-02-22	3294	3294	Nil	Nedra (1103) Huang (1049)	Rashmi 4:20pm 07/01/2022	NA
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
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 : 9:30 AM DATE : 07-02-22 TIME COMPLETE : 4:20 PM DATE : 07-02-22	3294	3294	Nil	Nedra (1103)	Rashmi 4:20 PM 07/01/22	ND
CARTON PACK						
TIME START : 10:00 AM DATE : 10-02-22 TIME COMPLETE : 3:40 PM DATE : 10-02-22	137 etn	137 etn	Nil	FASLI (1054) RABIN (1088)	Jinda 10/01/2022	Kyra 10/01/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 3294 btl  
 QUANTITY FOR QC / RETAIN SAMPLE : 425 + 2611  
 SHIPMENT QUANTITY PCS / CTNS : 3288 btl  
 FINAL SHIPMENT DATE :  
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : 	Approved by (QA), Signature : 	Released by (QC), Signature : 
Name : RAZMIKA Date : 10/2/2022	Name : Rohamiza Othman Date : 10/2/2022	Name : KARINI Designation : QC DEPT Date : 10/2/2022
Remarks:		
		

## VIGILENZ®

## ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No	QC-LC002
Rev.	00

Item Description	<i>Baingard wound care foam (cap closure)</i>		
Reference	<i>B035 D100</i>		
Lot No.	<i>A22qy</i>		

No.	Checklist	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Performed by (Signature / Date) <i>K. V. Andan 07/02/22</i>	Verified by QC (Signature / Date) <i>Umesh 9/02/22</i>	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. V. Andan 07/02/22</i>	<i>Umesh 9/02/22</i>	<i>N/A</i>	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>K. V. Andan 07/02/22</i>	<i>Umesh 9/02/22</i>	<i>N/A</i>	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>K. V. Andan 07/02/22</i>	<i>Umesh 9/02/22</i>	<i>N/A</i>	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. V. Andan 07/02/22</i>	<i>Umesh 9/02/22</i>	<i>N/A</i>	Production

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

Item Description	Bactiguard	Woundcare	500ml	(cap closure)
Reference / Lot No.	BW 35 Doc		/	A 22904
Order Qty	4008			
Volume Specification	515	±	5	ml

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)
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Item Description	Bactiguard Woundcare 500 ml (Cap closure)
Reference / Lot No.	BCU 35 D100 / A22904
Order Qty	4008 3288
Volume Specification	515 ± 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	Test Disposition	
					PASS	FAIL
1/300	515 ml	✓	✓	✓	□	□
1/300	515 ml	—	✓	✓	☒	□
1/300	515 ml	—	✓	✓	□	□
1/300	515 ml	—	✓	✓	□	□
1/300 284	515 ml	—	✓	✓	□	□
400	515 ml	N.D.	N.D.	N.D.	□	□
400	515 ml	N.D.	N.D.	N.D.	□	□

## 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
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□

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)

<b>Item Description</b>	<i>Bacteriogard Woundcare 500ml (copper closure)</i>		
<b>Reference / Lot No.</b>	<i>BW 350100</i>	<i>/</i>	<i>A22904</i>
<b>Order Qty</b>	<i>+1008-</i>	<i>3288</i>	<i>total 422</i>
<b>Volume Specification</b>	<i>5.5</i>	<i>±</i>	<i>5</i>
			<i>ml</i>

#### 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)	Bactiguard
Document type: FORM	Doc Id: QC-IP002-09 Issue Date: 15/11/2021 Page: 2(3)

C. Attachment (First Printed Label)

Lot : R22904  
Expiry : 2024-01

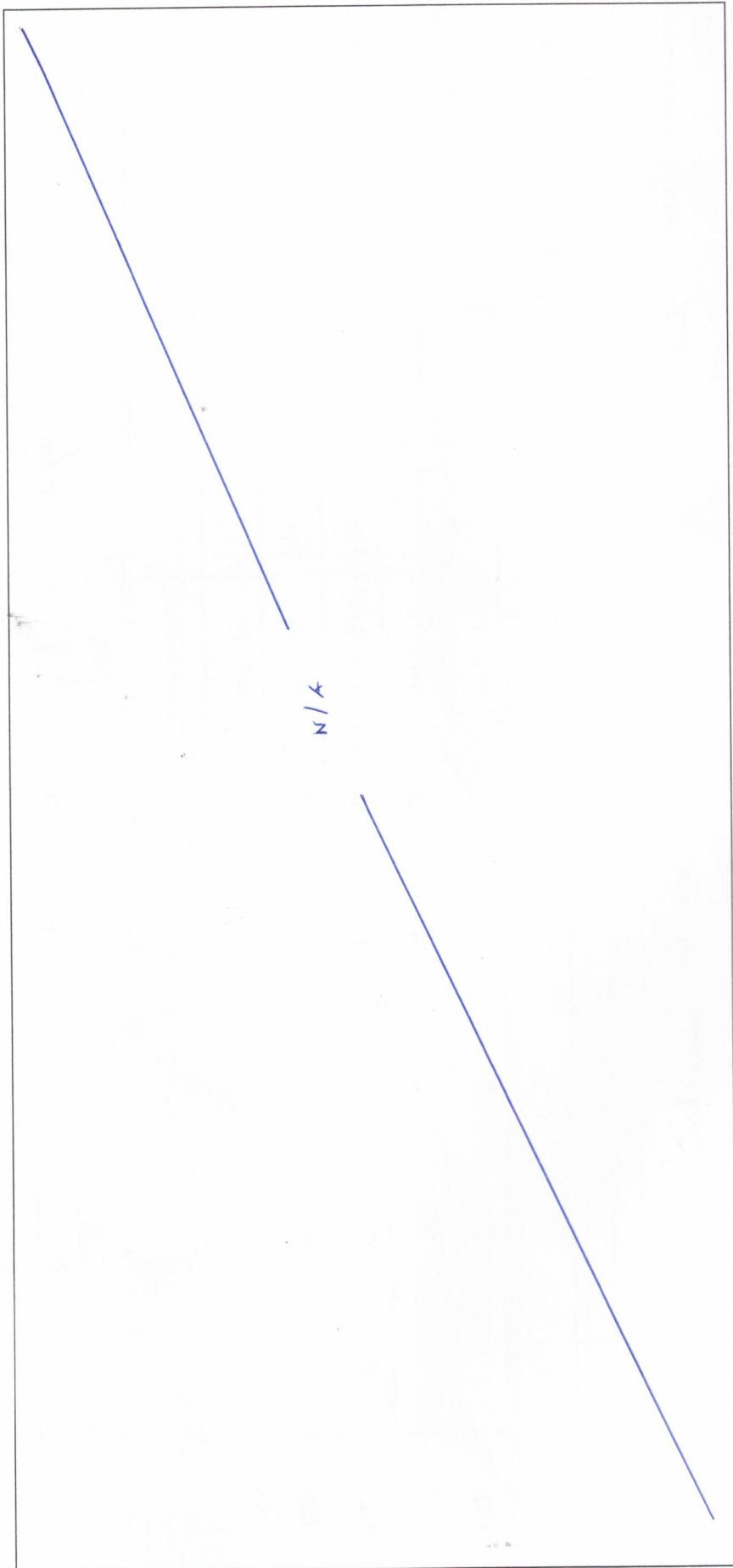
✓  
q.2.12

Disposition of the Lot :  PASS  FAIL

Inspected by : Woh  
Name : Woh Woh  
Date : q.2.22

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

**D. Attachment (Last Printed Label)**



Disposition of the Lot :  PASS  FAIL

Inspected by : N/A  
 Name : N/A  
 Date : N/A

VIGILENZ®

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

Doc. No.	QC-FC004
Rev.	09

ITEM DESCRIPTION :

*Balgund woundcare 500ml*

REFERENCE :

*BW35.D100*

LOT NO. :

*A02904*

QTY. PRODUCED (pcs) :

*5288*

RETAIN SAMPLE QTY. (pcs) :

*1*

No.	Inspection Criteria	Sampling Details	AQL		Results		Status (PASS/FAIL)
			Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	<i>5g, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>
2	Free from contamination, deformed or damaged on packaging.	<i>5g, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>
3	Proper sealing and no leaking.	<i>5g, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>
4	Free from contamination / particle / foreign materials on product solution.	<i>5g, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>
5	Correct volume filled (against reference sample).	<i>5g, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>

Remarks :

*N/A*

Inspected By

Approved By

Name	<i>R. Polmne</i>
Date	<i>9/2/2022</i>

Name	<i>M. Kartini</i>
Date	<i>9/2/2022</i>

## RAW MATERIAL LOADING FORM (RMLF)

Doc. No.  
Rev.

06

DATE :	04/02/2022
REF :	BW75D100
LOT NO. :	A22904

SHOP PACKET QTY (pes) :  
 CUSTOMER :  
 LO NO. :  
 10/BD/270/22/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	10/02/11202	pes	3294	3294	3294	1 <i>Canjana</i>
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210601	pes	3294	3294	3294	1 <i>Canjana</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pes	3294	3294	3294	1 <i>Canjana</i>
4		STOCK SOLUTION		02H807032030	ltr	1712	1712	1712	1 <i>Canjana</i>

## (2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1						1	P0100679	500ml Hydrogen Aqua carton -469L X 315W X 219H (BAF)	H165210602	137	<i>m. Quir</i>
2						2	P0100680	500ml nesting short and long-	H065210701	137	<i>m. Quir</i>
3						3		#N/A			
4											
5											
6											
7											

## (3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1						1	P0100679	500ml Hydrogen Aqua carton -469L X 315W X 219H (BAF)	H165210602	137	<i>m. Quir</i>
2						2	P0100680	500ml nesting short and long-	H065210701	137	<i>m. Quir</i>
3						3		#N/A			
4											
5											
6											
7											

## (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			

ISSUED BY (MM) :

*LOVIN*  
 Signature :  
 Name :  
 Date : 04/02/2022

VERIFIED BY (PR) :

*VINUS SURENDRA*  
 Signature :  
 Name :  
 Date : 15/02/2022



VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Background <i>background</i> , 500 ml cap closure .	Reference No.	BW35D100	Date of Inspection	10/02/2022
Lot No.	A2 2904	Sample Size	1 x 500 ml		

*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	
7.17	QC-78	865	QC-67	106	QC-80	Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : TANK NO. 7. (03HB070202030 )

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : *3. Jumai*  
 Name : *MARTIN*  
 Date : *10/02/2022*

Approved By : *J. S.*  
 Name : *Ramachandran*  
 Date : *10/02/2022*

