

SHOP PACKET - EASW

H2

REFERENCE	BW35D100	ODR. QTY (PCS)	4,000 4008	R5(2) QC(1)	ISSUED DATE	29/01/2022
ITEM CODE	BW010007	PACK SIZE	24/Box	M1/22	LOT NO.	A22905
ITEM DESCRIPTION	Bactiguard Woundcare 500ml (Cap Closure)	CUSTOMER	BACTIGUARD AB		MFG. DATE	29/01/2022
		ODR. NO	A204		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 29/01/2022	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	IPOC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	11:40AM 12-02-22	4017	4017	NIL	Roshni (893) 12/02/22	TANK 1000L/T 03HB120222037 TANK 1000L/T6 03HB100222035
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :	12-02-22			N/A	—	UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	10:30AM 14-02-22	4017	4013 4013	4	NETRA (1103) FARAH (1051) 14/02/22	Roshni 5:11 pm 14/02/22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 14-02-22			ND	—	BOTTLE dented replace NEW BOTTLE 14/02/22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 14-02-22	4017	4017	NIL	NETRA (1103) Mukhairineg (909)	Roshni 7:57 pm 14/02/22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :	12-02-22			NA	—	—
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :	12-02-22			NA	—	—
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :	12-02-22			N/A	—	UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	11:00AM 14-02-22	4017	4017	NIL	NETRA (1103)	Roshni 8:15 pm 14/02/2022
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	9:00 AM 15-02-22	167	167 ctn	NIL	NETRA (1089) SNEVA (1044)	Linde 18/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	12-02-22			N/A	—	UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED	4017 btl	
QUANTITY FOR QC / RETAIN SAMPLE	6 RST + 3 btl	
SHIPMENT QUANTITY PCS / CTNS	4008 Mls / 167ctn	
FINAL SHIPMENT DATE	15/2/22	
COMPLETE/ PARTIAL	COMPLETE PARTIAL	

Checked by (PR), Signature : <i>Ack</i>	Approved by (QA), Signature : <i>Jin</i>	Released by (QC), Signature : <i>Shahid</i>
Name : RATNASEGARAN Date : 15/2/22	Name : RONALDA CHIN Date : 15/2/2022	Signature : <i>RTN</i> Name : QC DEPT Designation : QC DEPT Date : 15/2/2022 Stamp : <i>QC DEPT</i>
Remarks:		

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

Doc. No	QC-LC002
Rev.	00

Item Description	<i>Bacnigued wundang 500ml (cay closure)</i>
Reference	<i>Bw35D100</i>
Lot No.	<i>A22905</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>Wah 293</i> 14/02/2022	<i>Wah</i> 14.2.22	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>Wah 293</i> 14/02/2022	<i>Wah</i> 14.2.22	N A	Technician
i)	Starwheel	<input 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>Lobu</i> 14/02/22	<i>Wah</i> 14.2.22	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>Lobu</i> 14/02/22	<i>Wah</i> 14.2.22	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	Bactericidal wound dressing (topical)
Reference / Lot No.	BW35D100 / A21905
Order Qty	4008
Volume Specification	515 ± 5 ml

A. Filling Process			Test Disposition		
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
10/10	520ml	✓	✓	✓	✓
1/300	520ml	-	✓	✓	✓
1/300	520ml	-	✓	✓	✓
1/300	520ml	-	✓	✓	✓
1/300	515ml	-	✓	✓	✓
1/300	520ml	-	✓	✓	✓
1/300	515ml	-	✓	✓	✓
1/300	515ml	-	✓	✓	✓

Title:

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

Document type:

FORM

Bactiguard	Issue Date: 15/11/2021	Page: 1(3)
Doc Id: QC-IP002-09		

Item Description	Bactiguard <i>Unidose</i> 500 mL (Cap closure)	
Reference / Lot No.	BWJ35900	1 A22905
Order Qty	4008	
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	No Leaking Observed		Test Disposition	
					PASS	FAIL	PASS	FAIL
1/300	520 mL	✓	✓	✓	✓	□	□	□
1/300	620 mL	—	✓	✓	✓	□	□	□
1/300	520 mL	—	✓	✓	✓	□	□	□
1/300	520 mL	—	✓	✓	✓	□	□	□
1/300	520 mL	—	✓	✓	✓	□	□	□
1/300	520 mL	—	✓	✓	✓	□	□	□
1/300	520 mL	—	✓	✓	✓	□	□	□
1/300	520 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, Expiry Date)	Test Disposition	
					PASS	FAIL
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□
—	—	—	—	—	□	□

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

Item Description	<i>Bactiguard woundcare 500 ml (cup closure)</i>
Reference / Lot No.	<i>B005900 / A 22905</i>
Order Qty	<i>4008</i>
Volume Specification	<i>515</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)

Document type:

FORM

C. Attachment (First Printed Label)

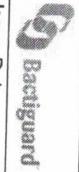
Lot : R22905
Date : 2024-01

WJM

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
2(3)



Disposition of the Lot :

PASS FAIL

Inspected by : WJM

Name

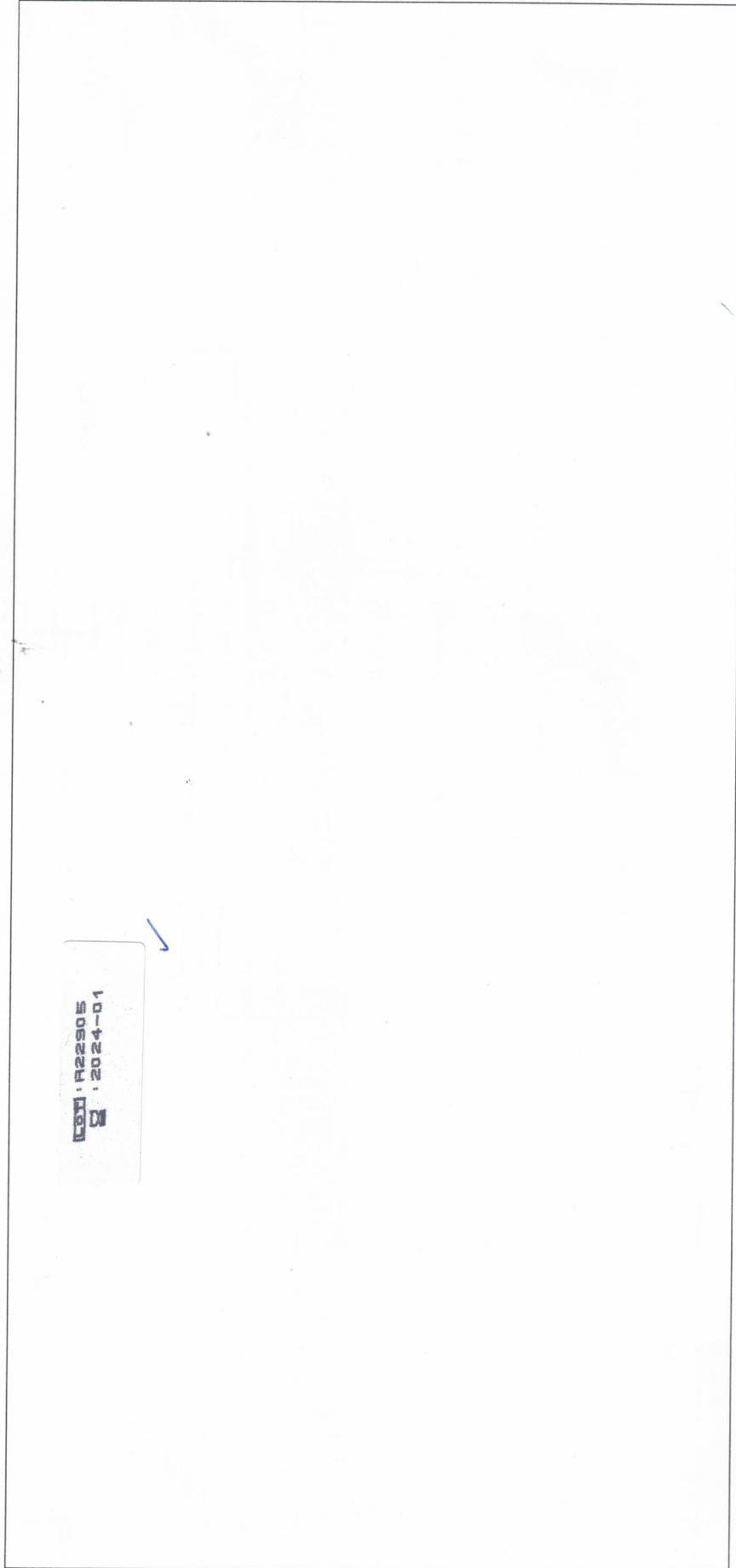
: WJM

Date

: 14.2.22

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

D. Attachment (Last Printed Label)



Disposition of the Lot : PASS FAIL

Inspected by : Raj
 Name : Roshni
 Date : 14/03/2023

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

ITEM DESCRIPTION	: <i>Bactericidal wound care foam</i>	Doc. No.	QC-FC004
REFERENCE	: <i>BW 36000</i>	Rev.	09

ITEM DESCRIPTION : *Bactericidal wound care foam*

REFERENCE : *BW 36000*

LOT NO. : *A3905*

OTY. PRODUCED (pcs) : *4017*

RETAIN SAMPLE QTY. (pcs) : *6 btl*

No.	Inspection Criteria	Sampling Details	Sample Size	AQL			Results	Status
				Accept	Reject	Accept		
1	Legible and clean printing of label.	<i>S1, 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>S2, 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>S4, 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>S5, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>

Remarks : *n/a*

Approved By : *M. A. R. T. N. I.*
 Name : *M. A. R. T. N. I.*
 Date : *15/02/2022*

Inspected By : *Raj*
 Name : *Roshni*
 Date : *14/02/2022*

RAW MATERIAL LOADING FORM (RMLF)

DATE :	09/02/2022	SHOP PACKET QTY (pcs) :	4008
REF :	BW35D100	CUSTOMER :	BACTIGUARD AB
LOT NO. :	A22905	LO NO. :	IO/BD/270122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilanz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	10102111202	pes	4011	4011	4011 + 6 1 Caja
2	P0100814	e Cap for 250ml/500ml HDPE Plastic Container - Backguard Wour	0	H168211201	pes	4011	4011	4011 + 6 1 Caja
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pes	4011	4011	4011 + 6 1 Caja
4		STOCK SOLUTION		0311010222035 03481010222035 0311010222036	ltr	2088	2088	2088

(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 Hydrocyan Aqua carton -469L X 315W X 219H (BAF)	H165211201	167	only
2		#N/A				2	P0100680	500ml nesting short and long-	H065220101	167	whole
3		#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	NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1						1	P0100679	500ml Hydrocyan Aqua carton -469L X 315W X 219H (BAF)	H165211201	167	only
2						2	P0100680	500ml nesting short and long-	H065220101	167	whole
3						3		#N/A			
4											
5											
6											
7											

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 Hydrocyan Aqua carton -469L X 315W X 219H (BAF)	H165211201	167	only
2						2	P0100680	500ml nesting short and long-	H065220101	167	whole
3						3		#N/A			
4											
5											
6											
7											

ISSUED BY (MM):


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

VERIFIED BY (PR):


 Signature : Lovin
 Name : Lovin
 Date : 19/2/2022

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

		Doc. No.	QC-FC004
		Rev.	09

ITEM DESCRIPTION : *Baligund woundcare foam*

REFERENCE :

BW 36000

LOT NO. :

A32905

QTY. PRODUCED (pes) :

4017

RETAIN SAMPLE QTY. (pes) :

6 btl

No.	Inspection Criteria	Sampling Details	Sample Size	AQL			Results	Status
				Accept	Reject	Accept		
1	Legible and clean printing of label.	<i>S1, 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>S2, 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>S4, 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>S5, 0'15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>

Remarks :

N/A

N/A

Inspected By

Raj

Name

Roshni

Date

14/02/2022

Approved By

M. A. R. T. N. I.

Name

15/02/2022

Date

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

Doc No.	QC-PC001
Rev.	06

Description	Batch/Unit (e.g. 500mL)	Reference No.	Date of Inspection
Lot No.	Lot No.	Sample Size	1001 X 500mL
Batch/Unit (e.g. 500mL) (Cap closure)	Batch/Unit (e.g. 500mL) (Cap closure)	BW35D100 A2295	14/01/2022

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)				Test Disposition (PASS / FAIL)
pH	ORP (mV)	FAC (ppm)	Spec: 95 - 140	
Result	Instrument	Result	Instrument	PASS
7.21	QC-78	851	QC-67	QC-80

- RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank No-6 03H810032035

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Raj
Name : Roshni
Date : 14/01/2022

Approved By : Ingram
Name : Mark Tinni
Date : 14/02/2022



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

Doc No.	QC-PC00,
Rev.	06

Description	Baciguard woundcare 500ml (exp closure)	Reference No.	BUSS50100	Date of Inspection	14/02/2022
Lot No.	A22905	Sample Size	1btl x 500ml		

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 - 110		
Result	Instrument	Result	Instrument	Result	Instrument
7.20	Qc-78	866	Qc-67	112	Qc-80 pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank No. 1 03HB100222026

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Poly
Name : Rosni
Date : 14/02/2022



Approved By : Ma RTINI
Name : _____
Date : 14/02/2022

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

Doc No.	QC-PC001
Rev.	06

Description	Bactericidal woundcare 500ml (cap closure)	Reference No.	DW352000	Date of Inspection	14/11/21
Lot No.	A33905	Sample Size	100 ml x 500 ml		

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
7.01	Qc-78	863	Qc-67	112	Qc-80
					Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Done NOV 7 03HB120322037

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rajiv
Name : Roshni
Date : 14/11/2021

Approved By : Rajiv
Name : KRTR/1
Date : 14/11/2022

