


SHOP PACKET - EASW

| | | | | | | |
|---|---|---|--|-------------|-------------|-----------------|
| REFERENCE | BW36D100 | ODR. QTY (PCS) | 180 | RS(2) QC(1) | ISSUED DATE | 29/01/2022 |
| ITEM CODE | BW010011 | PACK SIZE | 12/Box | | LOT NO. | A22901 |
| ITEM DESCRIPTION | Bactiguard Woundcare 1000ml (Cap Closure) | CUSTOMER | BACTIGUARD AB | | MFG. DATE | 29/01/2022 |
| | | ODR. NO | A200 | | 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 | IPQC APPROVAL | REMARKS |
|---|--------------|---------------|--------|----------------------------|----------------------|-------------------------------|
| STOCK SOLUTION PREPARATION | | | | | | |
| TIME START: 8:50 AM | | | | | | |
| DATE: 23-01-22 | 183 | 183 | NIL | Huang (1049) | Wah 23/2/22 | Tank 1000L/TG 03HB210222052 |
| TIME COMPLETE: 9:30 | | | | | | |
| DATE: 23-01-22 | | | | | | |
| UDI PRINTING (Label/Box/Carton) | | | | | | |
| TIME START: | | | | | | |
| DATE: | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |
| TIME COMPLETE: | | | | | | |
| DATE: | | | | | | |
| SOLUTION FILLING & CAPPING | | | | | | |
| TIME START: 9:40 AM | | | | | | |
| DATE: 23-01-22 | 183 | 183 | NIL | Huang (1049) | Wah 23/2/22 | N/A |
| TIME COMPLETE: 12:00 PM | | | | | | |
| DATE: 23-01-22 | | | | | | |
| LABELLING | | | | | | |
| TIME START: | | | | | | |
| DATE: | | | | N/A | | |
| TIME COMPLETE: | | | | | | |
| DATE: | | | | | | |
| PRINTING LOT NUMBER | | | | | | |
| TIME START: 11:15 AM | | | | | | |
| DATE: 23-01-22 | 183 | 183 | NIL | Ambiga (1029) FARAH (1051) | Wah 11:40 AM 25/2/22 | N/A |
| TIME COMPLETE: 11:40 AM | | | | | | |
| DATE: 23-01-22 | | | | | | |
| CAP SEALING (Applicable for 100mL) | | | | | | |
| TIME START: | | | | | | |
| DATE: | | | | N/A | | |
| TIME COMPLETE: | | | | | | |
| DATE: | | | | | | |
| BOX PACKING & PRINTING (Applicable for 100ml only) | | | | | | |
| TIME START: | | | | | | |
| DATE: | | | | N/A | | |
| TIME COMPLETE: | | | | | | |
| DATE: | | | | | | |
| MANUAL UDI LABELLING (Applicable for 100 mL & Bags only) | | | | | | |
| TIME START: | | | | | | |
| DATE: | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |
| TIME COMPLETE: | | | | | | |
| DATE: | | | | | | |
| FINAL CONTROL | | | | | | |
| TIME START: 11:15 AM | | | | | | |
| DATE: 23-01-22 | 183 | 183 | NIL | Ambiga (1029) FARAH (1051) | Wah 11:47 AM 25/2/22 | N/A |
| TIME COMPLETE: 11:40 AM | | | | | | |
| DATE: 23-01-22 | | | | | | |
| CARTON PACK | | | | | | |
| TIME START: 12:10 PM | | | | | | |
| DATE: 23-01-22 | 15 Ctn | 15 Ctn | NIL | Rabin (1088) FARLI (1053) | Nurin 25/2/22 | 25/02/2022 |
| TIME COMPLETE: 1:00 PM | | | | | | |
| DATE: 23-01-22 | | | | | | |
| UDI LABELLING | | | | | | |
| TIME START: | | | | | | |
| DATE: | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |
| TIME COMPLETE: | | | | | | |
| DATE: | | | | | | |


| | |
|-----------------------------------|------------------|
| QUANTITY PRODUCED : | 183 btl |
| QUANTITY FOR QC / RETAIN SAMPLE : | 2 + 1 btl |
| SHIPMENT QUANTITY PCS / CTNS : | 180 btl |
| FINAL SHIPMENT DATE : | |
| COMPLETE/ PARTIAL : | COMPLETE PARTIAL |

| | | |
|--|--|--|
| Checked by (PR), Signature: <i>P. Ratnasegaran</i> Name: Ratnasegaran Date: 26/2/2022 | Approved by (QA), Signature: <i>P. Ratnasegaran</i> Name: Ratnasegaran Date: 1/3/2022 | Released by (QC), Signature: <i>P. Ratnasegaran</i> Name: Ratnasegaran Designation: IPQC Sup Date: 26/2/22 Stamp:  |
| Remarks: | | |

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

| | |
|------------------|--|
| Item Description | Bactiguard woundcare 1000ml (Bottle cap closure) |
| Reference | BW363100 |
| Lot No. | A22901 |

| 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 i) Starwheel ii) Nozzle iii) Stopper Insertor iv) Cap Dispenser v) Cap Pusher | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <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>Wahid</i> 23/02/22 | <i>Wahid</i> 23/02/22 | 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>Wahid</i> 23/02/22 | <i>Wahid</i> 23/02/22 | N/A | Production |

| | | | |
|--|-------------------------------|--|----------------------|
| 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) |


| | | | |
|----------------------|---|---|-------|
| Item Description | Bactiguard Woundcare 1000 mL (Bottle cap closure) | | |
| Reference / Lot No. | BW363100 / A22901 | | |
| Order Qty | 180 | | |
| Volume Specification | 1030 | ± | 20 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 |
| 10/10 | 1050 mL | ✓ | ✓ | ✓ | ✓ | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 1/143 | 1050 mL | ✓ | ✓ | ✓ | ✓ | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | N/A | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> | <input type="checkbox"/> |

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 |
| | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | N/A | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | | | <input type="checkbox"/> | <input type="checkbox"/> |

| | | |
|--|-------------------------------|----------------------------------|
|  | | Page: 2(3) |
| Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW) | | Issue Date: 15/11/2021 |
| Document type: FORM | Doc Id: QC-IP002-09 | |

C. Attachment (First Printed Label)


 1222501
 2024-01
 Wch 25.2.22

Disposition of the Lot :
 ☒ PASS
 ☐ FAIL

Inspected by : Wch
 Name : Wch Wch
 Date : 25.2.22

| | | | | | | |
|------------------|--|---|----------|----------|------|----|
| VIGILENZ® | FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW) | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Doc. No.</td> <td style="width: 50%;">QC-FC004</td> </tr> <tr> <td>Rev.</td> <td>09</td> </tr> </table> | Doc. No. | QC-FC004 | Rev. | 09 |
| Doc. No. | QC-FC004 | | | | | |
| Rev. | 09 | | | | | |

ITEM DESCRIPTION : Bactiguard woundcare 1000mL

REFERENCE : BW363100

QTY. PRODUCED (pcs) : 183

LOT NO. : A22901

RETAIN SAMPLE QTY. (pcs) : 2

| No. | Inspection Criteria | Sampling Details | Sample Size | AQL | | Results | | Status (PASS/FAIL) |
|-----|---|------------------|-------------|--------|--------|---------|--------|-----------------------|
| | | | | Accept | Reject | Accept | Reject | |
| 1 | Legible and clean printing of label. | $S_3, 0.15$ | 80 | 0 | 1 | 80 | 0 | pass |
| 2 | Free from contamination, deformed or damaged on packaging. | $S_3, 0.15$ | 80 | 0 | 1 | 80 | 0 | pass |
| 3 | Proper sealing and no leaking. | $S_3, 0.15$ | 80 | 0 | 1 | 80 | 0 | pass |
| 4 | Free from contamination / particle / foreign materials on product solution. | $S_3, 0.15$ | 80 | 0 | 1 | 80 | 0 | pass |
| 5 | Correct volume filled (against reference sample). | $S_3, 0.15$ | 80 | 0 | 1 | 80 | 0 | pass |

Remarks : N/A

Inspected By : Wach

Name : Wach Wach

Date : 25/02/2022

Approved By : [Signature]

Name : MAKTHI

Date : 26/2/2022

DATE : 03/02/2022

REF : HW36D100

LOT NO. : A22901

SHOP PACKET QTY (pcs) : 180

CUSTOMER : BACTIGUARD AB


LO NO. : IOBD/270122/01

| NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | DESCRIPTION 2 | LOT NO. | UOM | QUANTITY (pcs) | | RECEIVED BY |
|-----|-------------|---|------------------------|---------------------|-----|----------------|------------|-------------|
| | | | | | | REQUIRED | ISSUED | |
| 1 | P0100799 | 1000ml HDPE Plastic Container | 0 | H01C211201 | pcs | 183 | 183 | <i>183</i> |
| 2 | P0100814 | White Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woundcare | 0 | H020210901 | pcs | 183 | 183 | <i>183</i> |
| 3 | P0100357 | DROPPER STOPPER | (500ML & 250ML BOTTLE) | H078220101 | pcs | 183 | 183 | <i>183</i> |
| 4 | | STOCK SOLUTION | | <i>03HB21072052</i> | ltr | <i>188</i> | <i>188</i> | <i>188</i> |

| (2) PRODUCT PACKAGING | | | | | RECEIVED BY |
|-----------------------|-------------|--------------------|---------|--------------------|-------------|
| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | |
| 1 | | | | | |
| 2 | | #N/A | | | |
| 3 | | #N/A | | | |
| 4 | | #N/A | | | |
| 5 | | #N/A | | | |
| 6 | | #N/A | | | |
| 7 | | #N/A | | | |

| (3) OVER WRAPPING AND CARTON PACK | | | | | RECEIVED BY |
|-----------------------------------|-------------|---|------------|--------------------|-------------|
| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | |
| 1 | P0100582 | DSN-H-011(A) - VIG-001-CTN,Printed Carton for Hydrocyn 1000ml,Size: 380 x 290 x 220mm(E), Mat: TI 80/M/TI 80 BA FLUTE | H103220201 | 15 | <i>15</i> |
| 2 | P0100583 | DSN-H-011(B) - VIG-904-ASY,NL: 377 x 145mm (2pcs) & NS: 282 x 145mm(3pcs) for Carton E, Mat: TI 50/TI 50 B Flute | H041200501 | 15 | <i>15</i> |
| 3 | P0100584 | DSN-H-011(C) - VIG-904-ASY, Layer Pad for Carton E, Size: 377 x 282mm, Mat: TI 50/TI 50 B Flute | H042220201 | 15 | <i>15</i> |

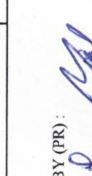
| (4) SPECIAL REQUIREMENT | | | | | RECEIVED BY |
|-------------------------|-------------|---|---------|--------------------|-------------|
| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | |
| 1 | P0100324 | "SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers) | | <i>NA</i> | |
| 2 | | #N/A | | | |

ISSUED BY (MM) : 

Signature : L. LOVIN

Name : L. LOVIN

Date : 03/02/2022

VERIFIED BY (PR) : 

Signature : P. M. M.

Name : P. M. M.

Date : 26/2/2022

| | | | | |
|-----------|--|--|---------|----------|
| VIGILENZ® | PRODUCT RELEASE TEST REPORT – ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW) | | Doc No. | QC-PC007 |
| | | | Rev. | 06 |

| | | | | | |
|-------------|---|---------------|----------|--------------------|--------------|
| Description | Baciguard wound care 1000ml (Bottle cap closure) | Reference No. | BW260100 | Date of Inspection | 25/02/2022 |
| | | Lot No. | A22901 | Sample Size | 1bH x 1000ml |

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 | pass |
| 7.21 | QC- 78 | 853 | QC- 67 | 113 | QC- 80 | |

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Raj
Name : PASHNE
Date : 25/02/2022

Approved By : [Signature]
Name : MARTINI
Date : 25/02/2022

