

| SHOP PACKET - EASW | | | | | | |
|---|--|---|---|-------------------------|-------------|------------------|
| REFERENCE | HW35D100 | ODR. QTY (PCS) | 1824 <i>2136</i> | RS: 2 + <i>JQC TEST</i> | ISSUED DATE | 15/01/2022 |
| ITEM CODE | H0100001 | PACK SIZE | 24/BOX | LOT NO. | | A21507 |
| ITEM DESCRIPTION | Hydrocyn Aqua, 500ml (Bottle Cap Closure) | CUSTOMER | VMD (MALAYSIA) | MFG. DATE | | 15/01/2022 |
| PREPARED BY | NAME : NUR SHAHIRA <i>S.H.</i> DATE : 15/01/2022 | ODR. NO | A103 | EXP. DATE | | 2024-01 |
| VERIFIED BY | | VERIFIED BY | NAME : RATNASEGARAN <i>N.R.</i> DATE : 15/01/2022 | INT. ORDER | | IO/VMD/130122/01 |
| 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 : | <i>8:00 PM</i> <i>20-01-22</i> | 2140 | 2140 | Nil | Roshni | <i>8:15 AM</i> <i>21/01/22</i> TANK 1000L/TB 08HB200122013 |
| UDI PRINTING (Label/Box/Carton) | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |
| TIME START : DATE : TIME COMPLETE : DATE : | <i>8:15 AM</i> <i>21-01-22</i> | | | | | |
| SOLUTION FILLING & CAPPING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | <i>3:10 PM</i> <i>21-01-22</i> | 2140 | 2140 | Nil | Roshni (1061) | <i>10:00 AM</i> <i>22/01/22</i> |
| LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | <i>3:10 PM</i> <i>21-01-22</i> | 2140 | 2140 | 13 | Huwani's (998) | <i>10:40 AM</i> <i>22/01/22</i> |
| PRINTING LOT NUMBER | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | <i>3:10 PM</i> <i>21-01-22</i> | 2140 | 2140 | Nil | Huwani's (998) | <i>10:00 AM</i> <i>22/01/22</i> |
| CAP SEALING (Applicable for 100mL) | | | | NA | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | | | |
| BOX PACKING & PRINTING (Applicable for 100ml only) | | | | NA | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | | | |
| 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 : DATE : TIME COMPLETE : DATE : | <i>3:10 pm</i> <i>21-01-22</i> | 2140 | 2240 | Nil | Huwani's (998) | <i>1:00 PM</i> <i>22/01/22</i> |
| CARTON PACK | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | <i>4:00 PM</i> <i>22-01-22</i> | 89 ctn | 89 ctn | Nil | FAGI (1054) HERDI (1053) Rabin (1088) | JINSA 24/01/22 |
| UDI LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |

QUANTITY PRODUCED : *2140 btl*

QUANTITY FOR QC RETAIN SAMPLE : *QC(3) + RS(5) btl*

SHIPMENT QUANTITY PCS / CTNS : *2126 btl*

FINAL SHIPMENT DATE :

COMPLETE/PARTIAL : *COMPLETE* *PARTIAL*

| | | |
|---|---|---|
| Checked by (PR), Signature : <i>R. Hafizah</i> Name : <i>Hafizah</i> Date : <i>25/1/2022</i> | Approved by (QA), Signature : <i>Rohamita</i> Name : <i>Rohamita</i> Date : <i>26/1/2022</i> | Released by (QC), Signature : <i>Martini</i> Name : <i>Martini</i> Designation : <i>QC VEPT</i> Date : <i>25/1/2022</i> Stamp : <i>25/1/2022</i> |
| Remarks: | | |

RELEASED
BACTIGUARD (S.E.A) SDN BHD
QUALITY CONTROL

VIGILENZ®

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

Doc. No QC-IC002
Rev. 00

| | | | |
|-------------------------|--|--|--|
| Item Description | <i>Hydrogen Peroxide 500 ml (Bottle cap closing)</i> | | |
| Reference | <i>Hw 85Drcd</i> | | |
| Lot No. | <i>A21504</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>Klymenko 21/01/22</i> | <i>Poly 21/01/22</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 | | | | | | |
| i) | Starwheel | <input checked="" type="checkbox"/> | <input type="checkbox"/> | | | | |
| ii) | Nozzle | <input checked="" type="checkbox"/> | <input type="checkbox"/> | | | | |
| iii) | Stopper Inserter | <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>✓ Klymenko 21/01/22</i> | <i>Poly 21/01/22</i> | <i>ND</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>✓ Klymenko 21/01/22</i> | <i>Poly 21/01/22</i> | <i>ND</i> | Production |

Title:

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

Document Type:
FORMIssue Date:
15/11/2021Page:
1(3)

| | | | |
|----------------------|--|------------------------|--|
| | | | |
| Reference / Lot No. | Hydrogen Peroxide, 500 ml (Bottle Open Closure) HW 66000 / A2150F 1824 | Doc Id: QC-IP002-09 | |
| Order Qty | | | |
| Volume Specification | 515 ± 5 ml | | |

| Item Description | Hydrogen Peroxide, 500 ml (Bottle Open Closure) HW 66000 / A2150F 1824 |
|----------------------|--|
| 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 |
|----------------------|-----------------------|---|---|----------------------------|---------------------|------------------|
| | | | | | | |
| 10/10 | 500 ml | ✓ | ✓ | ✓ | ✓ | PASS |
| 1/300 | 500 ml | - | ✓ | ✓ | ✓ | FAIL |
| 1/200 | 500 ml | - | ✓ | ✓ | ✓ | FAIL |
| 1/300 | 500 ml | - | ✓ | ✓ | ✓ | FAIL |
| 1/300 | 500 ml | - | ✓ | ✓ | ✓ | FAIL |
| 1/800 | 500 ml | - | ✓ | ✓ | ✓ | FAIL |
| 1/317 | 500 ml | - | ✓ | ✓ | ✓ | FAIL |

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 |
|----------------------|---|--|--|--|------------------|
| | | | | | |
| 10/10 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/200 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/300 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/300 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/300 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/300 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/317 | ✓ | ✓ | ✓ | ✓ | 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 | |

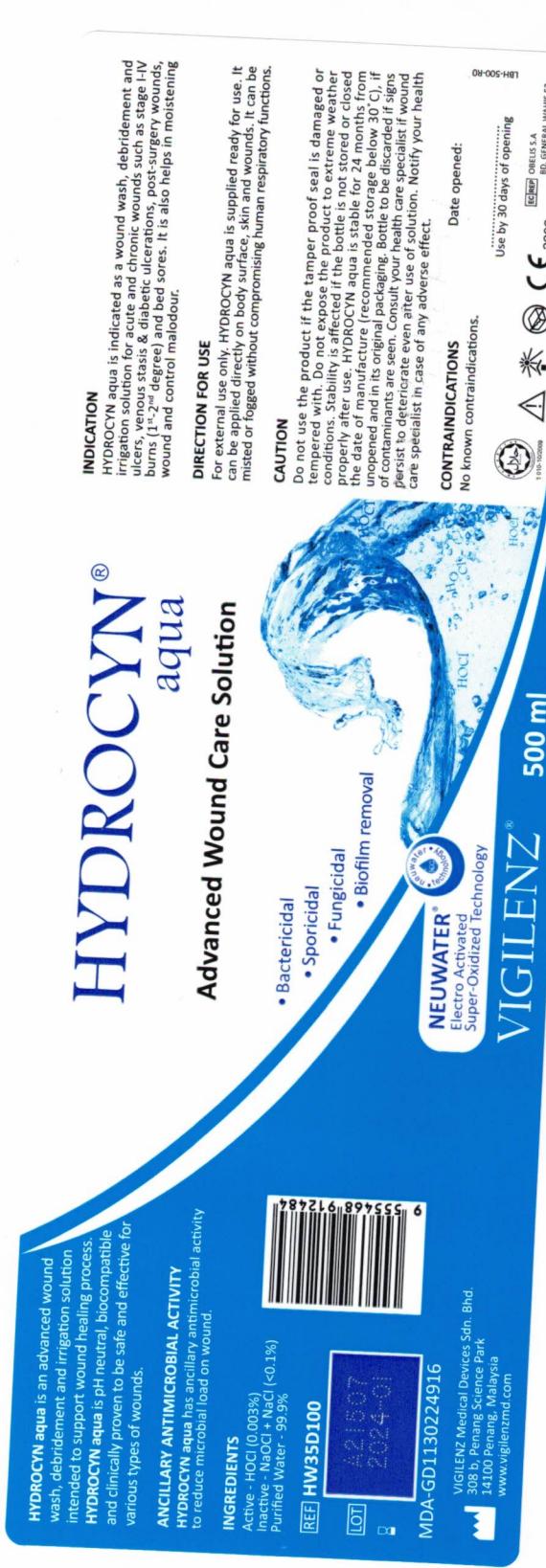
| Item Description | Reference / Lot No. | Order Qty | Volume Specification | \pm <i>N/P</i> | ml |
|------------------|---------------------|-----------|----------------------|------------------|----|
| | | | | | |

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

C. Attachment (First Printed Label)



Disposition of the Lot : PASS FAIL

PASS

FAIL

Inspected by : Boyle

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Page

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Title:

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

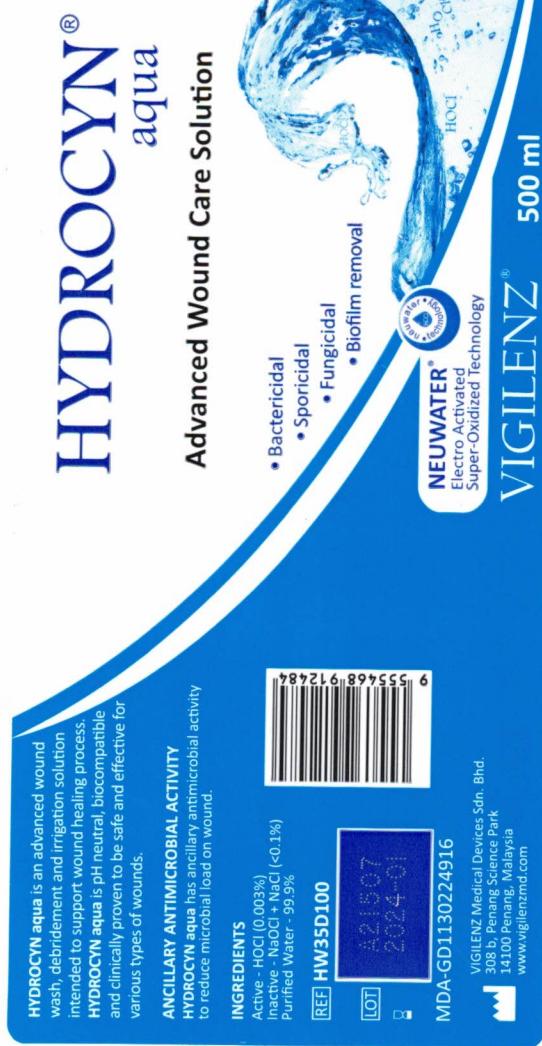
Document type:
FORM

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
3(3)

D. Attachment (Last Printed Label)



HYDROCYN aqua is an advanced wound wash, debridement and irrigation solution intended to support wound healing process. **HYDROCYN aqua** is pH neutral, biocompatible and clinically proven to be safe and effective for various types of wounds.

ANCILLARY ANTIMICROBIAL ACTIVITY

HYDROCYN aqua has ancillary antimicrobial activity to reduce microbial load on wound.

INGREDIENTS

Active - HOCl (0.003%)
Inactive - NaOCl + NaCl (<0.1%)
Purified Water - 99.9%

REF: HW35D100

LOT:

A21507

2024-01

MDA-GD1130224916

VIGILENZ Medical Devices Sdn. Bhd.
308b, Penang Science Park
14100 Penang, Malaysia
www.vigilenzmd.com

INDICATION
HYDROCYN aqua is indicated as a wound wash, debridement and irrigation solution for acute and chronic wounds such as stage I/IV ulcers, venous stasis & diabetic ulcerations, post-surgery wounds, burns (1st-2nd degree) and bed sores. It is also helps in moistening wound and control malodour.

DIRECTION FOR USE

For external use only. **HYDROCYN aqua** is supplied ready for use. It can be applied directly on body surface, skin and wounds, it can be misted or fogged without compromising human respiratory functions.

CAUTION

Do not use the product if the tamper proof seal is damaged or tampered with. Do not expose the product to extreme weather conditions. Stability is affected if the bottle is not stored or closed properly after use. **HYDROCYN aqua** stable for 24 months from the date of manufacture (recommended storage below 30°C). If unopened and in its original packaging. Bottle to be discarded if signs of contaminants are seen. Consult your health care specialist if wound persist to deteriorate even after use of solution. Notify your health care specialist in case of any adverse effect.

CONTRAINDICATIONS

No known contraindications.

LBI-500-010
Date opened:
Use by 30 days of opening
EU OBES L.A.
CE 2292
1010-02008
00 GENERAL WAHS 13
3000 BRUSSELS, BELGIUM

Disposition of the Lot : PASS FAIL

FAIL

Inspected by : *Pog*
Name : *Poh Sin*
Date : *21/01/22*

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

| | | | |
|--------------------|------------------------------|----------|----------|
| ITEM DESCRIPTION : | <i>Hydrogen Aquae, 500ml</i> | Doc. No. | QC-FC004 |
| Rev. | 09 | Rev. | 09 |

ITEM DESCRIPTION :

Hydrogen Aquae, 500ml

REFERENCE :

HWW35 D100

LOT NO. :

A21507

QTY. PRODUCED (pcs) :

2140

RETAIN SAMPLE QTY. (pcs) :

0

| No. | Inspection Criteria | Sampling Details | Sample Size | AQL | | Results | Status |
|-----|---|------------------|-------------|----------|----------|-----------|----------|
| | | | | Accept | Reject | | |
| 1 | Legible and clean printing of label. | <i>5s, 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>5s, 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>5s, 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>5s, 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>5s, 0.15</i> | <i>80</i> | <i>0</i> | <i>1</i> | <i>80</i> | <i>0</i> |

Remarks :

No

Inspected By : *Praj*
Name : *Roshni*
Date : *22/01/2022*

Approved By : *M. Martin*
Name : *M. Martin*
Date : *22/01/2022*

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.

Rev.

| | |
|-----------|------------|
| DATE : | 20/01/2022 |
| REF : | HW35D100 |
| LOT NO. : | A21507 |

| | | |
|-----------------------|---|------------------|
| SHOP PACKET QTY (pes) | : | 2136 |
| CUSTOMER | : | VMD (MALAYSIA) |
| LO NO. | : | IO/VMD/130122/01 |

| NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | DESCRIPTION 2 | LOT NO. | UOM | REQUIRED | QUANTITY (pes) | | RECEIVED BY |
|-----|-------------|--|--|----------------------|-----|----------|----------------|-------------|-------------------|
| | | | | | | | ISSUED | CONSUMPTION | |
| 1 | P0100242 | 500ml HDPE Plastic Container (New Version) | (c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap) | H010211101 | pes | 2140 | 2140 | 2140 | <i>✓ Cengkuat</i> |
| 2 | P0100290 | Blue Cap for 500ml HDPE Plastic Container | 0 | H020210601 | pes | 2140 | 2140 | 2140 | <i>✓ Cengkuat</i> |
| 3 | P0100357 | DROPPER STOPPER | (500ML & 250ML BOTTLE) | H078211101 | pes | 2140 | 2140 | 2140 | <i>✓ Cengkuat</i> |
| 4 | N/A | STOCK SOLUTION | N/A | <i>03H0200122016</i> | ltr | 1113 | 1113 | 1113 | <i>✓ Cengkuat</i> |

(2) PRODUCT PACKAGING

| NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pes) | RECEIVED BY | (3) OVER WRAPPING AND CARTON PACK | | |
|-----|-------------|---|------------|--------------------|-------------------|-----------------------------------|-------------|---|
| | | | | | | NO. | SYSTEM CODE | ITEM DESCRIPTION 1 |
| 1 | P0100633 | LBH-500-RO - Hydrocyan Aqua 500ml Label Size : 71mm X 210mm , Material: White PP + Gloss Lamination | L18J211201 | 2141 | <i>✓ Cengkuat</i> | 1 | P0100679 | 500ml Hydrocyan Aqua carton -469L X 315W X 219H (BAF) |
| 2 | | #N/A | | | | 2 | P0100680 | 500ml nesting short and long- |
| 3 | | #N/A | | | | 3 | | #N/A |
| 4 | | #N/A | | | | | | |

(3) OVER WRAPPING AND CARTON PACK

| NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pes) | RECEIVED BY | (4) SPECIAL REQUIREMENT | | | |
|-----|-------------|--------------------|---------|--------------------|-------------|-------------------------|-------------|---|------------|
| | | | | | | NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. |
| 5 | | #N/A | | | | 1 | P0100324 | "SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers) | <i>N/A</i> |
| 6 | | #N/A | | | | 2 | | #N/A | |
| 7 | | #N/A | | | | | | | |

ISSUED BY (MM) :

Signature :

Name :

Date :

VERIFIED BY (PR) :

Signature : *J. May*Name : *Maryza*Date : *25/1/2022*

VIGILENZ®

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

| | | | |
|--|--|---------|----------|
| | | Doc No. | QC-PC007 |
| | | Rev. | 06 |

| | | | | | |
|-------------|---|---------------|---------|--------------------|------------------|
| Description | Hydrogen Aqua 500ml (Bottle Cap closure) | Reference No. | 4035100 | Date of Inspection | 22/01/2022 |
| | | Lot No. | A21507 | Sample Size | 1 bottle 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: 7850 | Spec: 95 - 140 | | |
| Result | Instrument | Result | Instrument | Result | Instrument |
| 7.10 | OC-78 | 852 | OC-67 | 118 | OC-80 |
| | | | | | Pass |

RO water and product bioburden meeting the acceptance criteria.

Remarks : Result for lot/ 4035100

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Raj
Name : Kochhar
Date : 22/01/2022

Approved By : M. J. Kumar
Name : M A R TIN
Date : 22/01/2022



VIGILENZ®

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

| | |
|---------|----------|
| Doc No. | QC-PC007 |
| Rev. | 06 |

| | | | | | |
|-------------|---|---------------|-------------|--------------------|------------|
| Description | Hydrogen Peroxide 500ml 6 bottle cap closure | Reference No. | HU35D160 | Date of Inspection | 25/01/2022 |
| Lot No. | A01507 | Sample Size | 16L x 500ml | | |

Release Criteria:

| Analysis of Electro Activated Super-Oxidized Water (EASW) | | | | | |
|---|------------|--------------|------------|--------|--------------------------------|
| pH | ORP (mV) | FAC (ppm) | | | Test Disposition (PASS / FAIL) |
| Spec: | Spec: >850 | Spec: 95-140 | | | |
| Result | Instrument | Result | Instrument | Result | Instrument |
| 7.07 | 8C-78 | 853 | Q1-67 | 119 | 80 |
| | | | | | Pass |

RO water and product bioburden meeting the acceptance criteria.

Remarks : *NP*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Poly Rosma*
 Name : *MARRIEN*
 Date : *25/01/2022*



| | |
|-------------|-------------------|
| Approved By | <i>Shanti</i> |
| Name | <i>MARRIEN</i> |
| Date | <i>25/01/2022</i> |

| Rework Instruction No. : R1-PM12-22021 | | | | | |
|--|--|--|---------------------------------------|--------------------|--------------------------|
| Reference Code | HW35D100 | Lot No. | A21507 | Lot Quantity (pcs) | 2140 |
| Quantity Affected (pcs) | 13 | | | | |
| Process / Operation | Labelling & Printing Lot No. | | | | |
| Type of Rework | Replace New label, Re-do the printing of the Lot number and Expiry date | | | | |
| Reason for Rework | Misalignment printing of Lot No and Expiry date on labels | | | | |
| Potential Adverse Effect (Filled by QA) | Scratch marks on bottles | | | | |
| Training / Trainer (Tick whichever applicable) | <input type="checkbox"/> Required | / | <input type="checkbox"/> Not Required | Trainer : N/A | |
| Rework Operator | <i>Hawani's, Era</i> | | | | |
| Required Tools | N/A | | | | |
| Rework Step | Verified by (PR) | Inspection Details | | | Verified by (QAQC) |
| 1) Segregate the affected bottles | <i>Ratna</i> 21/01/22 | All the bottles were verified | | | <i>Ratna</i> 21/01/22 |
| 2) Remove the damage labels (Misalignment printing) | <i>Ratna</i> 21/01/22 | All the labels were removed from the bottles | | | <i>Ratna</i> 21/01/22 |
| 3) Replace with new labels | <i>Ratna</i> 21/01/22 | New labels were replaced | | | <i>Ratna</i> 21/01/22 |
| 4) Re-print again the Expiry date and Lot number at correct position | <i>Ratna</i> 21/01/22 | Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position | | | <i>Ratna</i> 21/01/22 |
| 5) Proceed to Final Control Process | <i>Ratna</i> 21/01/22 | Verified in Final Control process and complies with all the specifications | | | <i>Ratna</i> 21/01/22 |
| Rework Disposition : | | | | | |
| Production had completed all the rework steps and proceed to Final Control process. QC had verified during all the rework steps and all complies with the specification. | | | | | |
| Prepared By : Name : MR.RATNA Date: 22/01/2022 | Acknowledge By : Name : MARTINI BINTI GHAZALI Date: 22/01/2022 | Approved By : Name : MR.JEEVANEND Date : 24/1/2022 | | | |

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

