

SHOP PACKET - EASW

| REFERENCE | HW35D100 | ODR. QTY | 912 | RS: 2 + 1(QC TEST) | ISSUED DATE | 07/01/2022 |
|---|--|---|--|--------------------|---|---|
| ITEM CODE | H0100001 | PACK SIZE | 24/BOX | LOT NO. | A20721 | |
| ITEM DESCRIPTION | Hydrocyn Aqua, 500ml (Bottle Cap Closure) | CUSTOMER | VMD (MALAYSIA) | | MFG. DATE | 07/01/2022 |
| PREPARED BY | NAME : NUR SHAHIRA DATE : 07/01/2022 | ODR. NO | A033 | | EXP. DATE | 2024-01 |
| | | VERIFIED BY | NAME : RATNASEGARAN DATE : 07/01/2022 | | INT. ORDER | IO/VMD/060122/01 |
| 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 : DATE : TIME COMPLETE : DATE : | 5:20 PM 10-01-22 8:20 AM 11-01-22 | 915 | 915 | Nil | Nyanday (893) | wah 1037 Tank 1000L/16 11-01-22 03HB100122008 |
| UDI PRINTING (Label/Box/Carton) | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | | N/A | UDI NOT REQUIRED FOR THIS LOT |
| SOLUTION FILLING & CAPPING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 1:55 PM 13-01-22 3:15 PM 13-01-22 | 915 | 909 | 6 | FASII (1054) | wah 1037 3:15 PM 13-01-22 ~6 Blue Cap replace with new Label 13-01-22 |
| LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 1:55PM 13-01-22 3:15PM 13-01-22 | 915 | 901 | 14 | FARAH (1051) | wah 3:15PM 13-01-22 ~14 Label reject replace with new label |
| PRINTING LOT NUMBER | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 1:55 PM 13-01-22 3:15PM 13-01-22 | 915 | 915 | Nil | FARAH (1051) | wah 3:15PM 13-01-22 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 | NA |
| 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 : | 1:55PM 13-01-22 3:15PM 13-01-22 | 915 | 915 | Nil | FARAH (1051) | wah 3:30 PM 13-01-22 NA |
| CARTON PACK | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 2:30 PM 15-01-22 4:30 PM 15-01-22 | 38 ctn | 38 ctn | Nil | HERDI(1053) MANJU(846) khim (648) | JINWA 15/1/22 15/01/22 |
| UDI LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | | N/A | UDI NOT REQUIRED FOR THIS LOT |

QUANTITY PRODUCED : 915 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 3 btl
 SHIPMENT QUANTITY PCS / CTNS : 912 btl / 38 ctn
 FINAL SHIPMENT DATE :
 COMPLETE/ PARTIAL : COMPLETE PARTIAL

| | | |
|---|-----------------------------------|--|
| Checked by (PR), Signature : | Approved by (QA), Signature : | Released by (QC), Signature : |
| Name : NUR SHAHIRA Date : 07/01/2022 | Name : FARAH Date : 07/01/2022 | Name : MARTINI Designation : QC DEPT Date : 07/01/2022 Stamp : 07/01/2022 |
| Remarks: | | |

Doc. No : PR-SP007, Rev : 07

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

| | | | |
|------------------|---|---------|----------|
| Item Description | Hydrogen Aqua 500 mL (Bottle cap closure) | | |
| Reference | H/W 350100 | Doc. No | QC-LC002 |
| Lot No. | A 20721 | Rev. | 00 |

| | | | |
|------------------|---|---------|----------|
| Item Description | Hydrogen Aqua 500 mL (Bottle cap closure) | | |
| Reference | H/W 350100 | Doc. No | QC-LC002 |
| Lot No. | A 20721 | Rev. | 00 |

| 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"/> | K. Nandha 13/01/22 | Wah 13.01.22 | 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"/> | Wah 13.01.22 | Wah 13.01.22 | 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"/> | T. Jayas 13/01/22 | Wah 13.01.22 | 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"/> | T. Jayas 13/01/22 | Wah 13.01.22 | 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 | Hydrocyn Aqua, 500 ml (Bottle cap closure) | | |
| Reference / Lot No. | MW35D100 | 1 | A 20721 |
| Order Qty | 912 | | |
| 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 | 520 mL | ✓ | ✓ | ✓ | ✓ | PASS |
| 1/300 | 520 mL | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/300 | 520 mL | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/305 | 520 mL | ✓ | ✓ | ✓ | ✓ | FAIL |
| | | | | | | |
| | | | N/A | | | |
| | | | | | | |

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 |
|----------------------|---|--|--|---|------------------|
| 10/10 | ✓ | ✓ | ✓ | ✓ | PASS |
| 1/300 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/300 | ✓ | ✓ | ✓ | ✓ | FAIL |
| 1/305 | ✓ | ✓ | ✓ | ✓ | FAIL |
| | | | | | |
| | | | N/A | | |
| | | | | | |

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

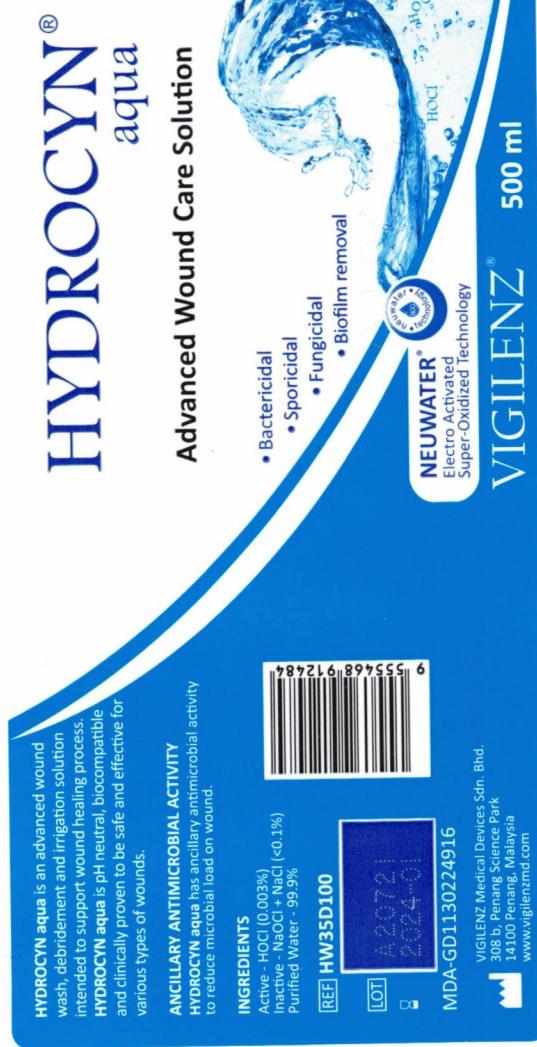
Document type:
FORM

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
2(3)

C. Attachment (First Printed Label)



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 tempered 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 is 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 persists to deteriorate even after use of solution. Notify your health care specialist in case of any adverse effect.

CONTRAINdicATIONS

No Known contraindications.

Date opened:

Use by 30 days of opening



✓
WCM

Disposition of the Lot : PASS FAIL

PASS FAIL

Inspected by : Lush

Name : Lush Lush

Date : 13.01.2022

| | |
|---|---------------------------|
| Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW) | Baciguard |
| Document type: FORM | Issue Date: 15/11/2021 |

D. Attachment (Last Printed Label)



Inspected by : Luch
 Name : Luch Luch
 Date : 13.01.2022

Disposition of the Lot : PASS FAIL

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

ITEM DESCRIPTION : Hydrogen Peroxide, 500 mL

REFERENCE : HWI 35 D 100

LOT NO. : A20721

QTY. PRODUCED (pcs) :

RETAIN SAMPLE QTY. (pcs) :

| | |
|----------|----------|
| Doc. No. | QC-FC004 |
| Rev. | 09 |

| |
|-----|
| 915 |
| 2 |

| No. | Inspection Criteria | Sampling Details | 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 |
| 2 | Free from contamination, deformed or damaged on packaging. | S ₃ , 0.15 | 80 | 0 | 1 | 80 | 0 |
| 3 | Proper sealing and no leaking. | S ₃ , 0.15 | 80 | 0 | 1 | 80 | 0 |
| 4 | Free from contamination / particle / foreign materials on product solution. | S ₃ , 0.15 | 80 | 0 | 1 | 80 | 0 |
| 5 | Correct volume filled (against reference sample). | S ₃ , 0.15 | 80 | 0 | 1 | 80 | 0 |

Remarks : N/A

Inspected By : Ewah
 Name : Ewah Wewah
 Date : 13.01.2022

Approved By : Rajesh
 Name : RAJESH
 Date : 13/01/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No:
Rev.

| | |
|-----------|------------|
| DATE : | 08/01/2022 |
| REF : | HW35D100 |
| LOT NO. : | A20721 |

| | | | |
|-----------------------|---|-----------------|----|
| SHOP PACKET QTY (pes) | : | 912 | RS |
| CUSTOMER | : | VMD (MALAYSIA) | |
| LO NO. | : | IOVMD/060122/01 | |

| 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 | pcs | 915 | | 915 | <u>Loyawo</u> |
| 2 | P0100200 | Blue Cap for 500ml HDPE Plastic Container | 0 | H020210601 | pcs | 915 | | 915 | <u>1Gangsa</u> |
| 3 | P0100357 | DROPPER STOPPER (500ML & 250ML BOTTLE) | | H078211101 | pcs | 915 | | 915 | <u>1Gangsa</u> |
| 4 | N/A | STOCK SOLUTION | N/A | 02HB/10012008 | ltr | 475 | | 475 | <u>Loyawo</u> |

(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 | P0100633 | LBH-500-R0 - Hydrocyn Aqua 500ml Label , Size : 71mm X 210mm, Material : White PP + Gloss Lamination | L18J211102 | 916 | <u>1Gangsa</u> | 1 | P0100679 | 500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF) | H165211103 | 38 | <u>Murah</u> |
| 2 | | #N/A | | | | 2 | P0100680 | 500ml nesting short and long- | H065211103 | 38 | <u>Murah</u> |
| 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 | | | | | |
| 2 | | | | | | 2 | | | | | |
| 3 | | | | | | 3 | | | | | |

(4) SPECIAL REQUIREMENT

| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pes) | RECEIVED BY |
|----|-------------|--------------------|---------|--------------------|-------------|
| 1 | | | | | |
| 2 | | | | | |

ISSUED BY (MM) :

Signature : LOVINName : Ramly MuzramDate : 08/01/2022

VERIFIED BY (PR) :

Signature : AbdName : Ramly MuzramDate : 09/01/2022

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**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. | HW35 D/00 | Date of Inspection | 14/01/2022 |
| Lot No. | A00721 | Sample Size | 1000 ml | | |

Release Criteria:

| Analysis of Electro Activated Super-Oxidized Water (EASW) | | | | | |
|---|----------|-----------|-------------------------------------|--------|------------|
| pH | ORP (mV) | FAC (ppm) | Test Disposition (PASS / FAIL) | | |
| Spec: | Spec: | Spec: | Instrument | Result | Instrument |
| 7.0 | 81.78 | 859 | Q1.67 | 112 | Q1-80 |
| | | | | | Pass |

RO water and product bioburden meeting the acceptance criteria.

Remarks : 10/1

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Raji
Name : Raji
Date : 14/01/2022

Approved By : Martin
Name : Martin
Date : 14/01/2022



| Rework Instruction No. : R1-PM12-22013 | | | | | | |
|---|--|--|--|--------------------|-----|--------------------------|
| Reference Code | HW35D100 | Lot No. | A20721 | Lot Quantity (pcs) | 915 | Quantity Affected (pcs) |
| 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 checked="" type="checkbox"/> Not Required | Trainer : N/A | | | |
| Rework Operator | Farah | | | | | |
| Required Tools | N/A | | | | | |
| Rework Step | | Verified by (PR) | Inspection Details | | | Verified by (QAQC) |
| 1) Segregate the affected bottles | | <i>Kayana</i> 13/01/2022 | All the bottles were verified | | | <i>Lix</i> 13/01/2022 |
| 2) Remove the damage labels (Misalignment printing) | | <i>Kayana</i> 13/01/2022 | All the labels were removed from the bottles | | | <i>Lix</i> 13/01/2022 |
| 3) Replace with new labels | | <i>Kayana</i> 13/01/2022 | New labels were replaced | | | <i>Lix</i> 13/01/2022 |
| 4) Re-print again the Expiry date and Lot number at correct position | | <i>Kayana</i> 13/01/2022 | Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position | | | <i>Lix</i> 13/01/2022 |
| 5) Proceed to Final Control Process | | <i>Kayana</i> 13/01/2022 | Verified in Final Control process and complies with all the specifications | | | <i>Lix</i> 13/01/2022 |
| Rework Disposition : | | | | | | |
| <p>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.</p> | | | | | | |
| Prepared By : Name : MR.RATNA Date: 13/01/2022 | Acknowledge By : <i>Amir</i> Name : MARTINI BINTI GHAZALI Date: 13/01/2022 | | Approved By : <i>Parash</i> Name : MR.JEEVANEND Date : 14/01/2022 | | | |

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

