

SHOP PACKET - HYDROCYN AQUA GEL

| | | | | | | |
|-------------|-------------------------------|-------------|----------------|--------------------|-------------|-----------------|
| REF : | HW40F900 | ODR. QTY : | 940- 900 | RS 3 + 7 (QC TEST) | ISSUED DATE | 15-Jan-22 |
| ITEM CODE : | H0100016 | PACK SIZE : | 20/BOX | | LOT NO | A21519 |
| ITEM : | Hydrocyn Aqua Wound Gel (15g) | CUSTOMER | VMD (MALAYSIA) | | MFG. DATE | 15-Jan-22 |
| | | ORD. NO | A115 | | EXP DATE: | 2040-01-2023-07 |

| PROCESS | START QTY TUBE | OUTPUT TUBE | REJECT TUBE | OPERATOR | IQC APPROVAL | RESULTS |
|--|----------------|-------------|-------------|----------------|------------------|-------------------------------------|
| HYDROCYN AQUA GEL PREPARATION | | | | | | |
| TIME START : 7:4 pm | 910 | 910 | NIL | Wah | Wah | 2/2 |
| DATE : 24-01-22 | | | | | | |
| TIME COMPLETE : 7:12 pm | | | | | | |
| DATE : 24-01-22 | | | | | | |
| CHECK : pH / VISCOSITY / FAC | | | | | | |
| PR:HR001 QC-HR003 | | | | | | |
| LABELLING GEL TUBE | | | | | | |
| TIME START : 1:00 pm | 910 | 910 | NIL | Thilaima (079) | Thilaima 4:50 pm | 5/5 |
| DATE : 25-01-2022 | | | | | | |
| TIME COMPLETE : 4:50 pm | | | | | | |
| DATE : 25-01-2022 | | | | | | |
| GEL FILLING | | | | | | |
| TIME START : 2:00 pm | 910 | 910 | NIL | 8:ti (1099) | 8:ti 4:50 pm | 5/5 |
| DATE : 25-01-2022 | | | | | | |
| TIME COMPLETE : 4:50 pm | | | | | | |
| DATE : 25-01-2022 | | | | | | |
| SEALING AND CUTTING GEL TUBE | | | | | | |
| TIME START : 2:00 pm | 910 | 910 | NIL | ERA (932) | ERA 4:50 pm | 5/5 |
| DATE : 25-01-2022 | | | | | | |
| TIME COMPLETE : 4:50 pm | | | | | | |
| DATE : 25-01-2022 | | | | | | |
| LOT NUMBER AND EXPIRY DATE PRINTING | | | | | | |
| TIME START : 7:00 pm | 903 | 903 | NIL | Herdi (1053) | Herdi 8:20 pm | 5/6 |
| DATE : 26-01-2022 | | | | | | |
| TIME COMPLETE : 8:30 pm | | | | | | |
| DATE : 26-01-2022 | | | | | | |
| BOX PACKING & FINAL CONTROL | | | | | | |
| TIME START : 5:00 pm | 903 | 898 | 5 | Omer (884) | Omer 8:30 pm | - 5 Box reject replace with new box |
| DATE : 26-01-2022 | | | | | | |
| TIME COMPLETE : 8:30 pm | | | | | | |
| DATE : 26-01-2022 | | | | | | |
| CARTON PACKING | | | | | | |
| TIME START : 9:50 am | 45 box | 45 box | NIL | HERDI (1053) | HERDI 27/01/2022 | 27/01/2022 |
| DATE : 27-01-2022 | | | | | | |
| TIME COMPLETE : 10:10 am | | | | | | |
| DATE : 27-01-2022 | | | | | | |

| | |
|--------------------------------|--------------------------|
| QUANTITY PRODUCED | 908 PCS |
| QUANTITY FOR QC/RETAIN SAMPLE | 32577 PCS |
| SHIPMENT QUANTITY PCS / CTNS : | 900 PCS / 45 box / 40ctn |
| FINAL SHIPMENT DATE | |
| COMPLETE/PARTIAL : | COMPLETE |

| | | | |
|------------------|-------------|-------------------|-------------|
| Checked by (PR): | Signature : | Approved by (QC): | Signature : |
| Name : | Date : | Name : | Date : |



HYDROCYN aqua® GEL - RECORDS OF PREPARATION

| | |
|----------|----------|
| Doc. No. | PR-HR001 |
| Rev. | 04 |

Date : 24/1/2022

| | Equipment ID | |
|---------------------------------------|--------------|-------------|
| | QC-56 | HSM-01 |
| Purified Water (L) | 3.0 ± 3.1 | 20.0 ± 20.1 |
| Lithium Magnesium Sodium Silicate (g) | 120 ± 1 | 800 ± 1 |
| Sodium Hypochlorite (ml) | 30.0 ± 0.05 | 200.0 ± 0.5 |
| PDV Salt (g) | 3.0 ± 0.1 | 20.0 ± 0.1 |

[illegible]

| | | |
|--|-------------------------------|----------------------------------|
| Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL | | Bactiguard |
| Document type: FORM | Doc Id: QC-IP004-01 | Issue Date: 15/11/2021 |
| | | Page: 1(3) |


| | |
|----------------------------|----------|
| Reference / Lot No. | HW40F900 |
| Order Qty. | 900 |

A. Before Filling

| Batch No. | Container No. | pH (9.00 – 10.50) | FAC (100 – 200 ppm) | Viscosity (8,000 – 10,000 cps) | Gel is clear and free from contamination | Test disposition (PASS / FAIL) |
|------------|---------------|----------------------|------------------------|-----------------------------------|---|-----------------------------------|
| GB24012203 | G3 | 9.25 | comply | 9726 | ✓ | pass |
| GB24012204 | G4 | 9.25 | comply | 9726 | ✓ | pass |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

B. Tube Labelling

| Sampling / Frequency | Printed label is clear and legible | Reference no. corresponds to Shop Packet and approved artwork | Correct positioning of labelling | Test disposition (PASS / FAIL) |
|-------------------------|------------------------------------|--|----------------------------------|-----------------------------------|
| 5/5 | ✓ | ✓ | ✓ | pass |
| 1/5 | ✓ | ✓ | ✓ | pass |
| 2/5 | ✓ | ✓ | ✓ | pass |
| 3/5 | ✓ | ✓ | ✓ | pass |
| 4/5 | ✓ | ✓ | ✓ | pass |
| 5/5 | ✓ | ✓ | ✓ | pass |

| | | | |
|---|------------------------|---|---------------|
| Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL | |  Bactiguard | |
| Document type: FORM | Doc Id: QC-IP004-01 | Issue Date: 15/11/2021 | Page: 2(3) |

C. Filling Process

| Sampling / Frequency | Weight of Sample | | | | | | Leak Test | Test disposition (PASS / FAIL) |
|----------------------|---|-------|-------|-------|-------|---------|-----------|--------------------------------|
| | Specification: 15g (16.5 – 17.8g) / 30g (31.6 – 33.3g) / 50g (51.9 – 53.4g) / 100g (102.8 – 104.7g) | | | | | Average | | |
| 5/5 | 17.05 | 16.64 | 17.07 | 16.60 | 17.14 | 16.90 | ✓ | pass |
| 1/5 | 17.60 | 17.21 | 17.25 | 17.46 | 17.31 | 17.36 | ✓ | pass |
| 2/5 | 17.24 | 17.36 | 17.26 | 17.43 | 17.60 | 17.38 | ✓ | pass |
| 3/5 | 17.08 | 17.52 | 17.25 | 17.16 | 17.62 | 17.33 | ✓ | pass |
| 4/5 | 17.21 | 17.48 | 17.34 | 17.05 | 17.16 | 17.25 | ✓ | pass |
| 5/5 | 17.53 | 17.42 | 17.36 | 17.17 | 17.26 | 17.34 | ✓ | pass |

D. Sealing and Cutting

| Sampling / Frequency | Sealing is intact | No sharp edge and not slanted after sealing and cutting | Lot no. and expiry date on tube is correct as in Shop Packet and legible | Seal Width Specification: (15g : 4-6mm) (30g/ 50g/ 100g : 6-8mm) | Leak Test | Test disposition (PASS / FAIL) |
|----------------------|-------------------|---|--|--|-----------|--------------------------------|
| 5/5 | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 1/5 | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 2/5 | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 3/5 | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 4/5 | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 5/5 | ✓ | ✓ | ✓ | ✓ | ✓ | pass |

| | | | |
|---|------------------------|---|---------------|
| Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL | |  Bactiguard | |
| Document type: FORM | Doc Id: QC-IP004-01 | Issue Date: 15/11/2021 | Page: 3(3) |

E. Printing on Primary Packaging

| Sampling / Frequency | Print information must be clear / legible and conforms to specifications as stated in approved artwork | Lot no. and expiry date are corresponding to Shop Packet and approved artwork | Correct position of printing | Test disposition (PASS / FAIL) |
|----------------------|--|---|------------------------------|--------------------------------|
| 5/c | ✓ | ✓ | ✓ | pass |
| 1/b | ✓ | ✓ | ✓ | pass |
| 2/s | ✓ | ✓ | ✓ | pass |
| 3/c | ✓ | ✓ | ✓ | pass |
| 4/b | ✓ | ✓ | ✓ | pass |
| 5/s | ✓ | ✓ | ✓ | pass |

F. Primary Packaging

| Sampling / Frequency | Product is properly pack in primary packaging | Ref. no., lot no. and expiry date on primary box is correct and legible | Special requirement printing is clear and legible | Presence of secure stickers on both opening sides of the primary box | Presence of hologram sticker on the primary box | Test disposition (PASS / FAIL) |
|----------------------|---|---|---|--|---|--------------------------------|
| 5/c | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 1/s | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 2/s | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 3/c | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 4/b | ✓ | ✓ | ✓ | ✓ | ✓ | pass |
| 5/s | ✓ | ✓ | ✓ | ✓ | ✓ | pass |

G. Conclusion

Overall in – process inspection: (PASS / FAIL)

Inspected By : Raj
 Name : POSTHANE
 Date : 26/01/2022

| | | | | |
|-----------|--|--|----------|----------|
| VIGILENZ® | FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL | | Doc. No. | QC-FC006 |
| | | | Rev. | 03 |

REF : H1040F900 QTY PRODUCED (pcs) : 910

LOT NO : A 21519 RETAIN SAMPLE QTY (pcs) : 3

| No | Inspection Criteria | Sampling Details | Sample Size | AQL | | Results | | Status (PASS/FAIL) |
|----|--|------------------|-------------|--------|--------|---------|--------|-----------------------|
| | | | | Accept | Reject | Accept | Reject | |
| 1 | Legible and correct printing of label. | S3,0.15 | 80 | 0 | 1 | 80 | 0 | pass |
| 2 | Availability of Hologram and Secure Sticker. | S3,0.15 | 80 | 0 | 1 | 80 | 0 | pass |
| 3 | Free from contamination, deformed or damaged on packaging. | S3,0.15 | 80 | 0 | 1 | 80 | 0 | pass |
| 4 | Proper sealing and no leakage. | S3,0.15 | 80 | 0 | 1 | 80 | 0 | pass |
| 5 | Correct quantity in secondary box packaging. | S3,0.15 | 80 | 0 | 1 | 80 | 0 | pass |

Remarks : N/A

Inspected By : Peggy
 Name : PEGGY
 Date : 26/01/2022

Approved By : [Signature]
 Name : MARTINI
 Date : 27/01/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

19/01/2022
HW40F900
A21519

SHOP PACKET QTY (pcs) : 900
CUSTOMER : VMD (MALAYSIA)
LO NO. : IOVMD/130122/01

RS 10

REF :
LOT NO. :

| NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | DESCRIPTION 2 | LOT NO. | UOM | QUANTITY (pcs) | | RECEIVED BY |
|-----|-------------|---|--|----------------------------|-----|----------------|--------|-------------|
| | | | | | | REQUIRED | ISSUED | |
| 1 | P0100225 | 15ml Long Nozzle Tube with white color screw on cap | Diameter 22 x 80mm, White Colour Tube with Long Nozzle 5 layers, Open End, Glass Finishing | H022210902 | pcs | 910 | 910 | Kanjana |
| 2 | C0100026 | RHEOLOGICAL ADDITIVE (SUPPLEMENT MP) | - | H080210801 | gms | 800 | 800 | Kanjana |
| 3 | C0100048 | Sodium Hypochloride, 10% Available Chlorine | 0 | C023210701 | ml | 200 | 200 | Kanjana |
| 4 | C0100024 | Pure Dry Vacuum Salt (25kg) | - | C021210601 | gms | 20 | 20 | Kanjana |
| 5 | N/A | STOCK SOLUTION | N/A | 64B24012203 64B24012204 | ltr | 20 | 20 | Kanjana |

(2) PRODUCT PACKAGING

| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | RECEIVED BY |
|----|-------------|---|--------------|--------------------|-------------|
| 1 | P0100397 | LBH-006-R4 - Hydrocyn Tube Label, Size: 65mm x 62mm, Material: Transparent PE | L220211202 | 911 | Kanjana |
| 2 | P0100316 | L63810 REV - ROUND HOLOGRAM LABEL, SIZE: 15.0mm X 15.0mm | L020211101 | 911 | Kanjana |
| 3 | P0100849 | Secure-Secure Round Sticker For Gel Tube (15mm) Size: 15mm (D), Material: Breakable PVC, Color: Black, Roll Form (1.5g only) | LB23210801/3 | 1821 | Kanjana |
| 4 | P0100399 | BX002, Inner Tube Box for Hydrocyn Gel - Size: 30mm(L) x 25mm(W) x 116mm(H), Material: 310gsm 1 Side Coated Art Card (4 colors), Rev: 3 | H076210801 | 911 | Kanjana |
| 5 | P0100318 | Outer Tube Box for Hydrocyn Gel - Size: 120 x 125 x 130mm, Material: 400gsm Grey Back | H077210801 | 45 | Kanjana |
| 6 | P0100208 | BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm | L190210802 | 45 | Kanjana |
| 7 | | #N/A | | | |

(3) OVER WRAPPING AND CARTON PACK

| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | RECEIVED BY |
|----|-------------|---|--------------|--------------------|-------------|
| 1 | P0100661 | Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LRI150/MLRI150 (BC FLUTE) | H114210801/2 | 4 | madheli |
| 2 | | #N/A | | | |
| 3 | | #N/A | | | |

(4) SPECIAL REQUIREMENT

| NO | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | 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) :

Signature :
Name : MOVIN
Date : 19/01/2022

VERIFIED BY (PR) :

Signature :
Name : RAJANISE CATHALAN
Date : 28/1/2022

| | | | | |
|-----------------------------|--|--|---------|----------|
| VIGILENZ[®] | PRODUCT RELEASE TEST REPORT – HYDROCYN aqua[®] GEL | | Doc No. | QC-PC008 |
| | | | Rev. | 02 |

| | | | | | |
|-------------|--------------------------------|---------------|----------|--------------------|-------------|
| Description | Hydrocyn Aqua, wound Gel (15g) | Reference No. | HW40F900 | Date of Inspection | 27/01/2022 |
| | | Lot No. | A21519 | Sample Size | 2 pcs x 15g |

Release Criteria:

| Packing Integrity | | | | Visual Inspection | Chemical Testing | | Test Disposition |
|---------------------------------------|----------------|---------------------|--|-------------------|---|-------------------|----------------------|
| Correct and legible printing of label | Proper sealing | Ability to dispense | Free from contamination/deformed/damaged | No leakage | Free from contamination / particles / foreign matters | pH (9.00 – 10.50) | FAC (100 – 200 ppm) |
| ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | 9.35 | comply |
| | | | | | | | PASS / FAIL |
| | | | | | | | pass |

✓ = Pass, X = Fail

Remarks: N/P

CONCLUSIONS: ☒ RELEASE ☐ ON-HOLD

Inspected By : Polly
 Name : ROSEANE
 Date : 27/01/2022

Approved By : [Signature]
 Name : M. M. T. INI
 Date : 27/01/2022

