

| SHOP PACKET - EASW | | | | | | |
|---|---|-------------|---|--------------------|-------------|------------------|
| REFERENCE | BW4CG800 | ODR. QTY | 42 | RS: 2 + 1(QC TEST) | ISSUED DATE | 31/01/2022 |
| ITEM CODE | BW010005 | PACK SIZE | | | LOT NO. | A231S00 |
| ITEM DESCRIPTION | Bactiguard Woundcare , Gel Spray (BOV) 100g | CUSTOMER | VMD (MALAYSIA) | | MFG. DATE | 31/01/2022 |
| | | ODR. NO | A207 | | EXP. DATE | 2023-07 |
| PREPARED BY | NAME : NUR SHAHIRA DATE : 31/01/2022 | VERIFIED BY | NAME : RATNASEGARAN DATE : 31/01/2022 | | INT. ORDER | IO/VMD/280121/01 |
| 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 : | 10:39 am 18-02-22 45 10:47 am 18-02-22 | 45 | NIL | ERA (932) | UWH | 2/2 |
| UDI PRINTING (Label/Box/Carton) | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | | | |
| SOLUTION FILLING & CAPPING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 4:45 pm 19-02-22 45 5:00 pm 19-02-22 | 45 | NIL | FARAH (1051) | Roshni 5:00 pm 19/02/22 | NA |
| LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 09:21 am 25-02-22 45 09:23 am 25-02-22 | 45 | NIL | FARAH (1051) Ambigen (1129) | Roshni 4:23 am 25/2/22 | NA |
| PRINTING LOT NUMBER | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 09:21 am 25-02-22 45 09:23 am 25-02-22 | 45 | NIL | FARAH (1051) Ambigen (1129) | Roshni 9:23 am 25/2/22 | NA |
| CAP SEALING (Applicable for 100mL) | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | NA | | | |
| BOX PACKING & PRINTING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | NA | | | |
| MANUAL UDI LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |
| FINAL CONTROL | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 09:21 am 25-02-22 45 09:23 am 25-02-22 | 45 | NIL | FARAH (1051) Ambigen (1129) | Roshni 9:50 am 25/2/22 | NA |
| CARTON PACK | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | 10:00 pm 25-02-22 1 12:10 pm 25-02-22 | 1 ctn | NIL | Herdi (1054) | Nurin 25/2/22 | 1 ctn 25/02/2022 |
| UDI LABELLING | | | | | | |
| TIME START : DATE : TIME COMPLETE : DATE : | | | | N/A | | UDI NOT REQUIRED FOR THIS LOT |

| | |
|-----------------------------------|----------------|
| QUANTITY PRODUCED : | 45 LHS |
| QUANTITY FOR QC / RETAIN SAMPLE : | 2 RS / 1 BH |
| SHIPMENT QUANTITY PCS / CTNS : | 42 LHS / 1 ctn |
| FINAL SHIPMENT DATE : | |
| COMPLETE/ PARTIAL : | COMPLETE |

| | | |
|--|--|--|
| Checked by (PR), Signature : Name : RATNASEGARAN Date : 25/2/22 | Approved by (QA), Signature : Name : Rohanaa Ghuman Date : 1/3/2022 | Released by (QC), Signature : Name : AARTINI Designation : IPAC SUP Date : 26/2/22 Stamp :  |
| Remarks: TESTING PURPOSE (HARCHANA) | | |

HYDROCYN[®] aqua[®] GEL - RECORDS OF PREPARATION

PR-HR001

04

18/02/23
::

| | Equipment ID | |
|---------------------------------------|--------------|-------------|
| | QC-S6 | 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 |
| PPV Salt (g) | 3.0 ± 0.1 | 20.0 ± 0.1 |

[illegible]

| VIGILENZ® | | QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® | | Doc. No | QC-IP006 |
|-----------------|--|--|--|---------|----------|
| GEL SPRAY (BOV) | | | | Rev. | 00 |

| | |
|---------------------|-------------------|
| Reference / Lot No. | BW40800 / P231500 |
| Order Qty. | 42 |

A. Before Filling

| Batch No. | Container No. | pH (9.00 – 10.50) Instrument No.: QC-78 Calibration due date: 12/03/2022 | FAC (100 – 200 ppm) Instrument No.: 480044 Calibration due date: N/A | Viscosity (8,000 – 10,000 cps) Instrument No.: QC-96 Calibration due date: 01/07/2022 | Gel is Clear and Free from Contamination | Test Disposition (PASS / FAIL) |
|------------|---------------|---|---|--|--|-----------------------------------|
| | | | | | | |
| 61B1802201 | 611 | 9.84 | comply | 9.84 | ✓ | pass |
| 61B1802202 | 612 | 9.84 | comply | 9.84 | ✓ | pass |
| | | | | | | |
| | | | | | | |

B. Gassing Process

| Sampling / Frequency | Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa) | | | | | Test Disposition (PASS / FAIL) |
|----------------------|---|---------|---------|---------|---------|-----------------------------------|
| | Instrument No.: QC- 130 | | | | | |
| | Calibration due date: 16/12/2023 | | | | | |
| | 1 | 2 | 3 | 4 | 5 | |
| 5/5 | 0.9 mpa | 0.9 mpa | 0.8 mpa | 0.8 mpa | 0.8 mpa | pass |
| 1/5 | 0.8 mpa | 0.8 mpa | 0.9 mpa | 0.8 mpa | 0.8 mpa | pass |
| 2/5 | 0.8 mpa | 0.8 mpa | 0.9 mpa | 0.8 mpa | 0.8 mpa | pass |
| 3/5 | 0.8 mpa | 0.8 mpa | 0.9 mpa | 0.8 mpa | 0.8 mpa | pass |
| 4/5 | 0.7 mpa | 0.8 mpa | 0.7 mpa | 0.8 mpa | 0.9 mpa | pass |
| 5/5 | 0.8 mpa | 0.9 mpa | 0.8 mpa | 0.8 mpa | 0.8 mpa | pass |

| | | | | |
|-----------|--|--|---------|----------|
| VIGILENZ® | QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® | | Doc. No | QC-IP006 |
| | GEL SPRAY (BOV) | | Rev. | 00 |

C. Crimping Process

| C. Crimping Process | | | | | | | | | | | | Test Disposition (PASS / FAIL) |
|----------------------|--|-------|-------|-------|-------|--|--------|--------|--------|--------|------|-----------------------------------|
| Sampling / Frequency | Crimp width and depth (mm) – 50g / 100g | | | | | | | | | | | |
| | Depth Specifications: ≥ 5.1 mm | | | | | Width Specifications: ≥ 27.1 mm | | | | | | |
| | Instrument No.: QC-128 Calibration due date: NA | | | | | Instrument No.: QC-129 Calibration due date: NA | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 | | |
| 5/5 | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 27.6mm | 27.8mm | 27.8mm | 27.6mm | 27.5mm | pass | |
| 1/5 | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 27.7mm | 27.8mm | 27.8mm | 27.6mm | 27.8mm | pass | |
| 2/5 | 5.1mm | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 27.7mm | 27.9mm | 27.6mm | 27.7mm | 27.9mm | pass | |
| 3/5 | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 27.6mm | 27.8mm | 27.6mm | 27.5mm | 27.9mm | pass | |
| 4/5 | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 5.2mm | 27.6mm | 27.8mm | 27.8mm | 27.5mm | 27.7mm | pass | |
| 5/5 | 5.2mm | 5.2mm | 5.2mm | 5.1mm | 5.2mm | 27.6mm | 27.8mm | 27.8mm | 27.5mm | 27.7mm | pass | |

D. Filling Process

Weight Specifications:
50g : 76.0g – 83.0g
100g: 139.0 – 154.0g

| Sampling / Frequency | Weight of Sample (g) | | | | | Test Disposition (PASS / FAIL) |
|----------------------|--|----------------|----------------|----------------|----------------|--------------------------------|
| | Instrument No.: <u>QC-WB-01</u> Calibration due date: <u>5/05/2022</u> | | | | | |
| | 1 | 2 | 3 | 4 | 5 | |
| <u>5/5</u> | <u>149.9 g</u> | <u>147.1 g</u> | <u>146.2 g</u> | <u>145.2 g</u> | <u>144.2 g</u> | <u>pass</u> |
| <u>1/5</u> | <u>153.7 g</u> | <u>144.1 g</u> | <u>146.9 g</u> | <u>145.8 g</u> | <u>145.5 g</u> | <u>pass</u> |
| <u>2/5</u> | <u>146.0 g</u> | <u>142.5 g</u> | <u>141.6 g</u> | <u>144.7 g</u> | <u>147.5 g</u> | <u>pass</u> |
| <u>3/5</u> | <u>146.6 g</u> | <u>148.0 g</u> | <u>145.3 g</u> | <u>145.1 g</u> | <u>143.5 g</u> | <u>pass</u> |
| <u>4/5</u> | <u>144.0 g</u> | <u>142.8 g</u> | <u>142.2 g</u> | <u>144.1 g</u> | <u>144.1 g</u> | <u>pass</u> |
| <u>5/5</u> | <u>145.0 g</u> | <u>142.9 g</u> | <u>148.8 g</u> | <u>150.0 g</u> | <u>146.0 g</u> | <u>pass</u> |

100g, 15

E. Capping Process

| VIGILENZ [®] | QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua [®] GEL SPRAY (BOV) | | Doc. No | QC-IP006 |
|-----------------------|---|--|---------|----------|
| | | | Rev. | 00 |

| Sampling / Frequency | Actuators are properly fixed onto the canister | Functionality of actuator | Caps are properly fit onto the canister | Test Disposition (PASS / FAIL) |
|----------------------|--|---------------------------|---|--------------------------------|
| 5/5 | ✓ | ✓ | ✓ | pass |
| 1/5 | ✓ | ✓ | ✓ | pass |
| 2/5 | ✓ | ✓ | ✓ | pass |
| 3/5 | ✓ | ✓ | ✓ | pass |
| 4/5 | ✓ | ✓ | ✓ | pass |
| 5/5 | ✓ | ✓ | ✓ | pass |

F. Labelling & Printing Process

| Sampling / Frequency | Print Information must be Clear / Legible and Conforms to Specifications as Stated in Approved Artwork | Ref No., Lot No. & Expiry Date Corresponds to Shop Packet and Approved Artwork | Correct Label Position | Correct Printing Position | Test Disposition (PASS / FAIL) |
|----------------------|--|--|------------------------|---------------------------|--------------------------------|
| 5/5 | ✓ | ✓ | ✓ | ✓ | pass |
| 1/5 | ✓ | ✓ | ✓ | ✓ | pass |
| 2/5 | ✓ | ✓ | ✓ | ✓ | pass |
| 3/5 | ✓ | ✓ | ✓ | ✓ | pass |
| 4/5 | ✓ | ✓ | ✓ | ✓ | pass |
| 5/5 | ✓ | ✓ | ✓ | ✓ | pass |

G. Attachment (Label)



BACTIGUARD
WOUND CARE GEL SPRAY

Μία διαγινώξιμο απορροφήσιμη υδρογέλης που βοηθά στη διατήρηση ενός υγιούς περιβάλλοντος πληγών και υποστηρίζει την επώλυσή τους. Η γέλη αυξάνει την υγρασία στην πληγή και βοηθά στη διαδικασία επώλυνσης, ειδικά σε έλξεις. Τα αποτελέσματα της υδρογέλης αναστέλλουν βακτηριακή ανάπτυξη στο πληγμένο τμήμα της πληγής, επιταχύνοντας με τη διατήρησή της την επούλωση.

CE 2292



Bactiguard®

ENAVEN

Για την ενυδάτωση και τον καθαρισμό σε οξεία και χρόνια τραύματα όπως σε έληκ σταθίου Ι-ΙV, φλεβικά & διαβητικά έληκ, χειρουργικά τραύματα, εγκαύματα (1ου - 2ου βαθμού) και έληκ κατάκλισης.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

Καθίστατε το τραύμα πριν την εμφάνισή της υβέρνηση. Ψεκάζετε συνεχώς την υβέρνηση στο τραύμα, διατηρώντας απόσταση 10-15 εκτοκισμών από το σημείο του τραυματισμού για ομοιογενή εμφάνιση. Καλύπτει με κατάλληλη γάζα τραυματισμό. Χρησιμοποιείτε την υβέρνηση μεταξύ των αλλαγών των γάζων για να διατηρήσετε τη βέλτιστη υγρασία στο τραύμα. Ο διαποτισμός της γάζας με υβέρνηση θα βοηθήσει στην αφαίρεση της υβέρνησης μπορεί να χρησιμοποιήσει ως παράγοντα απομακρυντικό εάν είναι απαραίτητο. Συμβουλευτείτε πάντα ένα αναπληρωτή.

REF BW4CG800

107

4231500
2013-07

Bactiguard (South East Asia) Sdn. Bhd.
(formerly known as VIGILENZ Medical
Devices Sdn. Bhd.)
308 b, Penang Science Park,
14100 Penang, Malaysia. com

Διανομέας: LIFECYN AE
Καζαντζάκη 4 & Αγ. Παντελεήμιωνος
13561 Αγία Ανάργυρος, Αττική
Τηλ.: +(30) 210 8313616
email: info@lifecyn.com
Αρ. Εγκριτοποίησης ΕΟΦ: 130621/23-1

WOUND CARE

Καταπραϋντική &
Βακτηριοστατική δράση

Εκνέφωμα Γέλης

100 g

ΠΡΟΣΟΧΗ Περιεχόμενο υπό πίεση. Μην τρυπάτε ή/και μην πετάτε τη συσκευασία στη φωτιά ακόμη και όταν είναι άδεια. Να φυλάσσεται μακριά από τα παιδιά.

Φυλάσσετε σε δροσερό και ξηρό μέρος σε θερμοκρασία δωματίου. Μην εκθέτετε το προϊόν σε υψηλή θερμοκρασία ή σε άμεσο ηλιακό φως. Μόνο για εξωτερική χρήση, ενημερώστε τον επαγγελματία υγείας σας σε περίπτωση αντισυμβαλλόμενων ενεργειών.

ΣΥΣΤΑΤΙΚΑ

Υποχλωριώδες νάτριο (0,05%),
Χλωριούχο Νάτριο και Λιθιο-Μαγνήσιο-
Νάτριο Πυριτικό.




F. Conclusion

Overall in-process inspection: **PASS / FAIL**

Inspected by: Wah

Name : Nicholas

Date : 25.3.22

| | | | |
|---|-------------------------------|---|----------------------|
| Title: FINAL CONTROL TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV) | |  Bactiguard | |
| Document type: FORM | Doc Id: QC-FC009-01 | Issue Date: 15/11/2021 | Page: 1(1) |

REF : B0040800 : QTY PRODUCED (pcs) : 45


LOT NO : A231800 : RETAIN SAMPLE QTY (pcs) : 2

| No. | Inspection Criteria | Sampling Details | Sample size | AQL | | Results | | Status (Pass / Fail) |
|-----|---|------------------|-------------|--------|--------|---------|--------|----------------------|
| | | | | Accept | Reject | Accept | Reject | |
| 1. | Legible and correct printing of label. | S2, 0.15 | 45 | 0 | 1 | 45 | 0 | pass |
| 2. | Free from contamination, deformed or damage on packaging. | S2, 0.15 | 45 | 0 | 1 | 45 | 0 | pass |

| | | |
|--|---|-----------------------------------|
| Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa) | | Test Disposition (PASS / FAIL) |
| Instrument No: <u>QC-120</u> | Calibration due date: <u>16/12/2023</u> | |
| Sample 1 <u>0.8mpa</u> | Sample 2 <u>0.8mpa</u> | |

REMARKS: N/A

| | | | |
|----------------|-------------------|---------------|--------------------|
| Inspected By : | <u>Pady</u> | Approved By : | <u>M. J. J. J.</u> |
| Name : | <u>ROSHNA</u> | Name : | <u>RAJATINI</u> |
| Date : | <u>25/11/2022</u> | Date : | <u>26/12/2022</u> |

| | | | |
|--|--|---|----------------------------------|
| Title: PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV) | |  Bactiguard | |
| Document type: FORM | | Doc Id: QC-PC011-01 | Issue Date: 15/11/2021 |
| | | Page: 1(1) | |

| | | |
|---|------------------------------------|---|
| Description bactiguard woundcare, gel spray (BOV) 100g. | Reference No. Bactiguard | Date of Inspection 25/03/2022 |
| | Lot No. A 231500 | Sample Size 1011 X 100g |

| Packing Integrity (Visual Inspection) | | | Chemical Testing | | Test Disposition |
|---------------------------------------|--|-----------------------------|---------------------|---|------------------|
| Correct and Legible Printing of Label | Free from Contamination / Deformed / Damaged | Proper Crimping and Capping | Ability to Dispense | pH (9.00 – 10.50) Instrument No.: 810-78 Calibration due date: 12/03/2022 | |
| ✓ | ✓ | ✓ | ✓ | pH (100 – 200 ppm) Instrument No.: 280024 Calibration due date: N/A | PASS / FAIL |
| | | | | 9.67 comply pass | |

√ = Pass X = Fail

N/A

REMARKS:

CONCLUSION:

| | |
|-------------------------------------|---------|
| <input checked="" type="checkbox"/> | RELEASE |
| <input type="checkbox"/> | ON-HOLD |

Inspected By : Paty

Name : Pasine

Date : 25/03/2022

Approved By : [Signature]

Name : M A K T M

Date : 25/03/2022

