

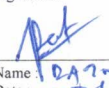



287-2711

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY (PCS)	912	RS: 2 + 1(QC TEST)	ISSUED DATE	15/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX		LOT NO.	A21510
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	15/01/2022
		ODR. NO	A106		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 15/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 15/01/2022		INT. ORDER	10/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 :	5:30pm 25-01-22 8:55Am 26-01-22	915	915	Nil	Kyanden 893	Tank 1000L/177 wah 8:55am 26/01/22 03HB250122018
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 :	9:10am 27-01-22 10:40am 27-01-22	915	915	NIL	SHAHIRA (964)	Roshni 10:40am 27/01/22 NA
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	9:10am 27-01-22 10:40am 27-01-22	915	915	NIL	FARAH (10519)	Roshni 10:40pm 27/01/2022 NA
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	9:10am 27-01-22 10:40am 27-01-22	915	915	NIL	FARAH (1051)	Roshni 10:40am 27/01/2022 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		
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 :	9:10am 27-01-22 10:40am 27-01-22	915	915	NIL	FARAH (1051)	Roshni 10:50am 27/01/22 NA
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 am 27-01-22 12:45 pm 27-01-22	38 ctn	38 ctn	Nil	FASLI (1054) HEROI (1053) KABIN (1088)	Nurin 27/1/2022 27/01/2022
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 :	2 RS + 1 btl
SHIPMENT QUANTITY PCS / CTNS :	912 btl / 38 ctn
FINAL SHIPMENT DATE :	
COMPLETE/ PARTIAL :	COMPLETE

Checked by (PR), Signature:  Name: RATNASEGARAN Date: 27/1/22	Approved by (QA), Signature:  Name: Rohanita Omar Date: 4/2/2022	Released by (QC), Signature:  Name: KARTINI Designation: QC DEPT Date: 27/01/2022 Stamp: 
Remarks:		

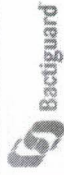
VIGILENZ®		CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No	QC-LC002
				Rev.	00

Item Description	Hydrocyn Aqua, 500 ml (Bottle cap closure)
Reference	HW 353000
Lot No.	A21510

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>[Signature]</i> 873 27/01/2022	Wah 1037 27.01.2022	NA	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 checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>[Signature]</i> 873 27/01/2022	Wah 1037 27.01.2022	NA	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>[Signature]</i> 27/01/22	<i>[Signature]</i> 27/01/22	N/D	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>[Signature]</i> 27/01/22	<i>[Signature]</i> 27/01/22	N/D	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	Hydrogen Aqua 500ml (Bottle cap closure)	
Reference / Lot No.	HW35D100	A21510
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	
						PASS	FAIL
10/10	520 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	520 mL	-	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	520 ml	-	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/305	520 ml	-	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
			NP			<input type="checkbox"/>	<input type="checkbox"/>
						<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
10/10	✓	✓	✓		<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	✓	✓	✓		<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	✓	✓	✓		<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/305	✓	✓	✓		<input checked="" type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
		NP			<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>

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

C. Attachment (First Printed Label)

HYDROCYN aqua

Advanced Wound Care Solution

- Bactericidal
- Sporicidal
- Fungicidal
- Biofilm removal

NEUWATER®
Electro Activated
Super-Oxidized Technology

VIGILENZ® 500 ml

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 | A21510

MDA-GD1130224916

VIGILENZ Medical Devices Sdn. Bhd.
308 b, 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 (1°-2° 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 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 persist 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

LBH-500-R0
CE 2292
GHS S.A.
INDUSTRIAL PARK, MAIRIAUX 43
1000 BRUSSELS, BELGIUM

Disposition of the Lot :



PASS



FAIL

Inspected by : Wah

Name : Wah Wah

Date : 27.11.2022

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

D. Attachment (Last Printed Label)

HYDROCYN[®]
aqua

Advanced Wound Care Solution

- Bactericidal
- Sporidical
- Fungicidal
- Biofilm removal

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%

REE HW35D100

LOT A21510
2024-01

MDA-GD1130224916

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

Barcode: 553468912484

NEUWATER[®]
Electro Activated
Super-Oxidized Technology

VIGILENZ[®] 500 ml

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 affected if the bottle is not stored or closed properly. HYDROCYN aqua is stable for 14 months from the date of manufacture (repackaging, post-surgery wounds, 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.

Date opened: _____
Use by 30 days of opening

08-005-HB1

CE 2292

ISO 9001:2015

ISO 13485:2015

ISO 14001:2015

ISO 45001:2018

ISO 27001:2017

ISO 28001:2017

ISO 29001:2018

ISO 31000:2018

ISO 34000:2018

ISO 35000:2018

ISO 36000:2018

ISO 37000:2018

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VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No.	QC-FC004
			Rev.	09

ITEM DESCRIPTION : Hydrogen Ag 100, 500ml

REFERENCE : HW35D180

QTY. PRODUCED (pcs) : 91411

LOT NO. : A21510

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 ₁ , 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S ₂ , 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/P

Inspected By : Pohay
 Name : POHAY
 Date : 27/01/2022

Approved By : MA RTINI
 Name : MA RTINI
 Date : 27/01/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. :
Rev. :

DATE : 20/01/2022
REF : HW3SD100
LOT NO. : A21510

SHOP PACKET QTY (pcs) :
CUSTOMER :
LO NO. :

912
VMD (MALAYSIA)
IO/VMD/130122/01

RS

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100242	500ml HDPE Plastic Container (New Version)	(g/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010211101	pcs	915	915	Kanyaju
2	P0100200	Blue Cap for 500ml HDPE Plastic Container	0	H020210601	pcs	915	915	Kanyaju
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078211101	pcs	915	915	Kanyaju
4	N/A	STOCK SOLUTION	N/A	03HDB25012208	ltr	475	475	Kanyaju

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100633	LBH-500-R0 - Hydrocyn Aqua 500ml Label, Size: 71mm X 210mm, Material: White PP + Gloss Lamination	L18J211201	916	Kanyaju
2		#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 (pcs)	RECEIVED BY
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H165211103	38	malul
2	P0100680	500ml nesting short and long-	H065211103	38	malul
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)			
2		#N/A			

ISSUED BY (MM) :

Signature :
Name : LOVIN
Date : 20/01/2022

VERIFIED BY (PR) :

Signature :
Name : RATHNASEKARAN
Date : 27/1/22