

SHOP PACKET - EASW						
REFERENCE	HW34E100	ODR. QTY	3,970	RS: 2 + 2(QC TEST)	ISSUED DATE	07/01/2022
ITEM CODE	H0100006	PACK SIZE	50/BOX	VMD (MALAYSIA) S.A. PARMABAN (SPANISH)	LOT NO.	A20718
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Bottle Cap Closure)	CUSTOMER			MFG. DATE	10/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 07/01/2022	ODR. NO	A030		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	IPOC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	10:15 Am 08-01-22 5:25 Pm 08-01-22	3974	3974	Nil	Kyandean (893)	wah 8.1.2022 03HB080122004
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 :	11:25 AM 10-01-22 5:30 PM 10-01-22	3974	3974	Nil	Icali (1078)	wah 10.01.22 NA
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	11:25AM 10-01-22 5:30PM 10-01-22	3974	3940	34	FARAH (1051)	wah 5:30PM 10.01.22 34 -label reject replace with new Label
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	11:25AM 10-01-22 5:30PM 10-01-22	3974	3974	Nil	FARAH (1051)	wah 5:30PM 10.01.22 N/A
CAP SEALING (Applicable for 100mL )						
TIME START : DATE : TIME COMPLETE : DATE :						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	11:26AM 10-01-22 5:30PM 10-01-22	3974	3974	Nil	FARAH (1051)	wah 5:40PM 10.01.22 NA
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	9:00 AM 01-01-22 5:45 PM 11-01-22	80 ctn	80 ctn	Nil	ERA (932) YATI HAUNG (1049)	Jinya 11/01/22 kyan 11/01/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 3974 btl  
 QUANTITY FOR QC / RETAIN SAMPLE : 2+2 btl  
 SHIPMENT QUANTITY PCS / CTNS : 3970 btl / 80 ctms  
 FINAL SHIPMENT DATE :    
 COMPLETE/ PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : RAHMA ABBAS RATHNA Date : 12/1/2022	Name : Robariza Ghazali Date : 13/1/2022	Name : MARTINI Designation : QC DEPT Date : 12/01/2022 Stamp :
Remarks:		



VIGILENZ®

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

<b>Item Description</b>	<i>Hydrocyn Aquos 250 mL C</i>
<b>Reference</b>	<i>Hlu 34E 100</i>
<b>Lot No.</b>	<i>A 20 #18</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>wah 1037 10/01/2022</i>	<i>N/A</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>wah 1037 10/01/2022</i>	<i>wah 1037 10/01/2022</i>	<i>N/A</i>	Technician
	i) Starwheel	<input type="checkbox"/>	<input type="checkbox"/>				
	ii) Nozzle	<input type="checkbox"/>	<input type="checkbox"/>				
	iii) Stopper Insertor	<input type="checkbox"/>	<input type="checkbox"/>				
	iv) Cap Dispenser	<input type="checkbox"/>	<input type="checkbox"/>				
	v) Cap Pusher	<input 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>Mayau 10/1/22</i>	<i>wah 1037 10/01/22</i>	<i>N/A</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>Mayau 10/1/22</i>	<i>wah 10/01/22</i>	<i>N/A</i>	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	<i>Hydracyn Aqua, 250 ml C Bottle Cap closure</i>	
Reference / Lot No.	<i>HW34E100</i>	<i>A20718</i>
Order Qty	<i>3970</i>	
Volume Specification	<i>255</i>	<i>± 5 ml</i>

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
<i>10%</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>260mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>260mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>260mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>260mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>260mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS

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
<i>10%</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<input checked="" type="checkbox"/> PASS

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	Hypocyan Flows, 250 ml (Bottle cap closure)
Reference / Lot No.	H/W 346100 / 120718
Order Qty	3970
Volume Specification	255 ± 5 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)  
Document type:  
FORM

C. Attachment (First Printed Label)



	Bactiguard
Issue Date:	Page:
15/11/2021	2(3)

**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<sup>st</sup>, 2<sup>nd</sup> 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 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:  
.....  
LBH-250-PR0  
Use by 30 days of opening

CE 2292  
EUROPE  
ORIEL S.A.  
RD. GENERAL WATIS 53  
1000 BRUSSELS, BELGIUM

✓/33

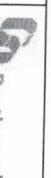
Inspected by : Woh  
Name : Woh  
Date : 10.01.2022

PASS     FAIL

PASS     FAIL

**Disposition of the Lot :**

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)**



Disposition of the Lot :

PASS     FAIL

Inspected by : Wah

Name

Date : 10.01.22

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
ITEM DESCRIPTION	Hydrocyn Aqua, 250 mL	Doc. No.	QC-FC004
REFERENCE	HVN 34E100	Rev.	09
LOT NO.	A 20718		
QTY. PRODUCED (pcs)	3974		
RETAIN SAMPLE QTY. (pcs)	2		

No.	Inspection Criteria	Sampling Details	Sample Size	AQL			Results	Status ( PASS/FAIL )
				Accept	Reject	Accept		
1	Legible and clean printing of label.	S <sub>3</sub> , 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S <sub>3</sub> , 0.15	80	0	1	80	0	pass
3	Proper sealing and no leaking.	S <sub>3</sub> , 0.15	80	0	1	80	0	pass
4	Free from contamination / particle / foreign materials on product solution.	S <sub>3</sub> , 0.15	80	0	1	80	0	pass
5	Correct volume filled (against reference sample).	S <sub>3</sub> , 0.15	80	0	1	80	0	pass

Remarks : N/A

Inspected By : lucash  
Name : M A R T I N I  
Date : 10.01.22

Approved By : M A R T I N I  
Name : M A R T I N I  
Date : 10/01/2022

## VIGILENZ®

## RAW MATERIAL LOADING FORM (RMLF)

Doc. No.  
Rev.

DATE :	08/01/2022
REF :	HW34E100
LOT NO. :	A20718

SHOP PACKET QTY (pes) : 3970  
 CUSTOMER : VMD (MALAYSIA)  
 I.O NO. : 10/VMD/060122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H012210602	pes	3974	3974	3974	<u>V. Cuyatua</u>
2	P0100200	Blue Cap for 500ml HDPE Plastic Container	0	H020210601	pes	3974	3974	3974	<u>V. Cuyatua</u>
3	P0100357	DROPPER STOPPER (500ML & 250ML BOTTLE)		H078210401	pes	3974	3974	3974	<u>V. Cuyatua</u>
4		STOCK SOLUTION	N/A	03HBS0122004	ltr	1034	1034	1034	<u>V. Cuyatua</u>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100642	LBH-250-R0 Hydrocyn Aqua 250ml Cap Closure, Size : 170mm x 77mm, Material : White PP		1184210701/2		3975			<u>V. Cuyatua</u>
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	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100566	DSN-H-009(A) - VIG-003-CTN-HYDROCYN 250ml(Cap Closure), Size: 330x330x305mm, Mat: T180/M/T180 BA Flute		H060210801	79	<u>Marcel</u>
2	P0100567	DSN-H-009(B) - VIG-901-ASY HYDROCYN 250ml NL & NS 312 x 90mm(4pcs each), Mat: T150/T150 B Flute		H069210901	159	<u>Marcel</u>
3	P0100568	DSN-H-009(C) - VIG-901-ASY HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute		H070211102	79	<u>Marcel</u>

## (4) SPECIAL REQUIREMENT

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	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 : LOVIN  
 Name : LOVIN  
 Date : 08/01/2022

VERIFIED BY (PR) :   
 Signature : ERIN ASZ CARAN  
 Name : ERIN ASZ CARAN  
 Date : 12/11/2022

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrocyn Aqua, 250ml (Bottle Cap Closure )	Reference No.	Hu34E100	Date of Inspection	12/01/2022
Lot No.	420718	Sample Size	25H x 250ml		

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: > 850	Spec: 95-140	Result	Instrument	
7.44	882	92-67	113	OC-80	Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : Raj  
Name : Roshni  
Date : 12/01/2022

Approved By : Eduardo  
Name : MATWINI  
Date : 12/01/2022



VIGILENZ® REWORK INSTRUCTION Doc. No PR-RI001  
Rev 04

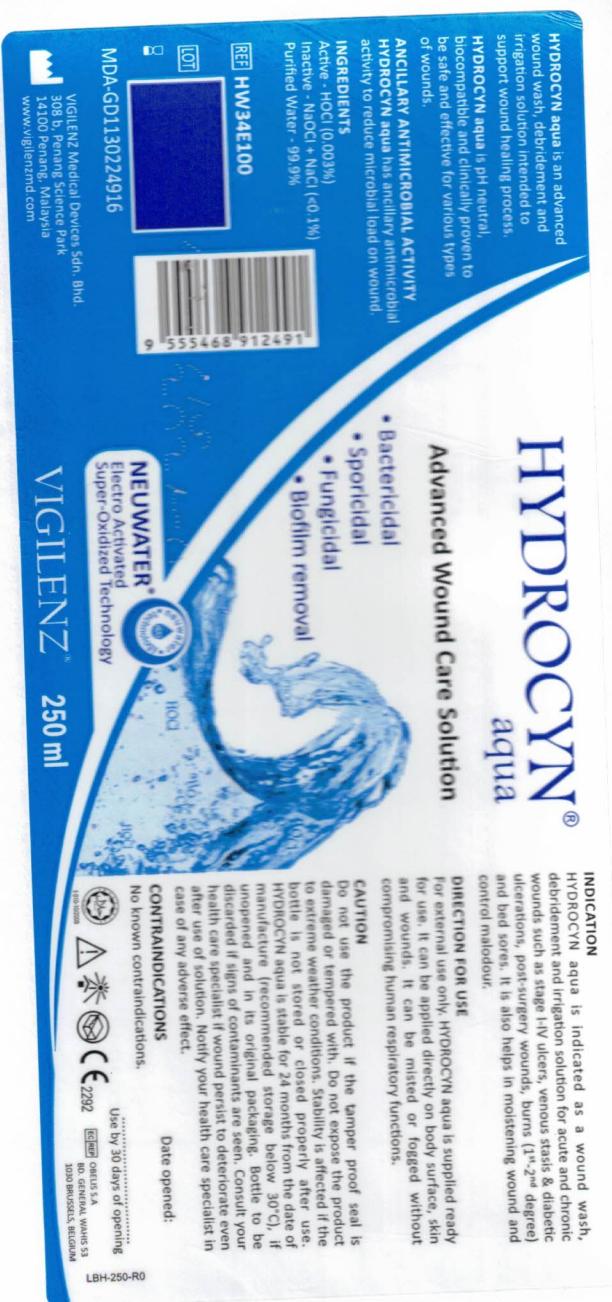
#### Rework Disposition :

**Rework Disposition :**  
Production had completed all the rework steps and proceed to final control process. QC had verified during all the rework steps and call complies with the specification.

Complies with the specification.		
Prepared By : <u>MR.RATNA</u>	Acknowledge By : <u>MARTINI BINTI GHAZALI</u>	Approved By : <u>MR.JEEVANEND</u>
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI	Name : MR.JEEVANEND
Date: 11/01/2022	Date: 11/01/2022	Date : 18/1/2022

# REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD		 Bactiguard	Page: 1(1)
Document type: FORM	Doc ID: QC-OI001-03	Issue Date: 15/11/2021	

SHIPMENT	<u>✓</u>
GAMMA	<input type="text"/>
PROPOSED DATE	<u>11/01/2021</u>
SHIPMENT DATE	<u>N/A</u>
RETURN DATE	<u>N/A</u> (Applicable for Gamma only)
VEHICLE NO.	<u>N/A</u>
TOTAL LOTS	<u>1</u>
TOTAL CARTONS	<u>80</u>
TOTAL BOX QUANTITY	<u>3640</u>
QC COMPLETION DATE	<u>11/01/2021</u>
CUSTOMER	<u>N/A</u>

Inspected by : J.  
 Name : J. Novak  
 Date : 11/01/2022

I

Verified by \_\_\_\_\_  
Name \_\_\_\_\_ Date \_\_\_\_\_