

## SHOP PACKET - EASW

REFERENCE	HW34E100	ODR. QTY (PCS)	4,000	RS(2) QC(2)	ISSUED DATE	14/02/2022
ITEM CODE	H0100006	PACK SIZE	50/Box	LOT NO.	B21405	
ITEM DESCRIPTION	Hydroc Aqua, 250ml (Bottle Cap Closure)	CUSTOMER	VMD	MFG. DATE	14/02/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 14/02/2022	8R	ODR. NO VERIFIED BY	NAME : RATNASEGARAN DATE : 14/02/2022	EXP. DATE INT. ORDER	2024-02 IO/VMD/110222/01
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:	8:30PM					
DATE:	16-02-22	4004	4004	Nil	Roshni 893	TANK 1000L/FF 03HB/160222043
TIME COMPLETE:	10:15AM					
DATE:	16-02-22					
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						
SOLUTION FILLING & CAPPING						
TIME START:	1:30 PM					
DATE:	17-02-22	4004	3979	25	Dewi (11126)	Wah 8:10PM 17-2-22
TIME COMPLETE:	8:10 PM					
DATE:	17-02-22					
LABELLING						
TIME START:	1:30 PM					
DATE:	17-02-22	4004	3976	28	Netra (1103)	Wah 8:10PM 17-2-22
TIME COMPLETE:	8:10 PM					
DATE:	17-02-22					
PRINTING LOT NUMBER						
TIME START:	1:30 PM					
DATE:	17-02-22	4004	4004	Nil	Netra (1103)	Wah 8:10PM 17-2-22
TIME COMPLETE:	8:10 PM					
DATE:	17-02-22					
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:						
FINAL CONTROL						
TIME START:	1:30 PM					
DATE:	17-02-22	4004	4004	Nil	Huang (1049)	Wah 8:30PM 17-2-22
TIME COMPLETE:	8:10 PM					
DATE:	17-02-22					
CARTON PACK						
TIME START:	1:30 PM					
DATE:	18-02-22	80 Ctn	80 Ctn	Nil	Rabin (1088) Vister (1022) Jenus (1023)	Jinder 18/02/2022
TIME COMPLETE:	6:15 PM					
DATE:	18-02-22					
UDI LABELLING						
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED : 4004 btl  
 QUANTITY FOR QC / RETAIN SAMPLE : 2+2 btl  
 SHIPMENT QUANTITY PCS / CTNS : 4000 btl / 80 ctn  
 FINAL SHIPMENT DATE :    
 COMPLETE/ PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature: 	Approved by (QA), Signature: 	Released by (QC), Signature: 
Name : P. T. R. M. S. A. T. A. M. A. Date : 19/2/22	Name : Rohamza Othman Date : 22/2/2022	Name : MARTIN Designation : QC DEPT Date : 19/2/22 Stamp :
Remarks:		

## VIGILENZ®

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

Item Description

Hydrogen Peroxide, 250ml (Bottles cap closure)

HWP34E100

Rev.

QC-LC002  
00

Reference

B214045

Lot No.

17/02/22

Item Description	Hydrogen Peroxide, 250ml (Bottles cap closure)
Reference	HWP34E100
Lot No.	B214045

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"/>	<u>Wah</u> 17/02/2022	<u>Wah</u> 17.2.22	<u>N/A</u>	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 type="checkbox"/>	<input checked="" type="checkbox"/>	<u>Wah</u> 17/02/2022	<u>Wah</u> 17.2.22	<u>N/A</u>	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"/>	<u>Praj</u> 17/02/22	<u>Praj</u> 17/02/22	<u>N/A</u>	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"/>	<u>Cayuan</u> 17/02/22	<u>Praj</u> 17/02/22	<u>ND</u>	Production

Title:

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

Document type:  
FORMIssue Date:  
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Item Description	Hydrogen Peroxide, 250ml (Bottle cap closure)	Doc Id: QC-IP002-09	Bactiguard
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Reference / Lot No.	HW34E100 / B01405
Order Qty	4000
Volume Specification	255 ± 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	260ml	✓	✓	✓	✓	FAIL
1/200	260ml	-	✓	✓	✓	PASS
1/400	260ml	-	✓	✓	✓	PASS
1/100	260ml	-	✓	✓	✓	PASS
1/600	260ml	-	✓	✓	✓	PASS
1/500	260ml	-	✓	✓	✓	PASS
1/300	260ml	-	✓	✓	✓	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
10/10	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS

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

Document type:  
FORM

Issue Date:  
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Doc Id:  
QC-IP002-09

<b>Item Description</b>	<i>Hydrogen Peroxide, 250ml (bottle cap closure)</i>	
<b>Reference / Lot No.</b>	<i>HuzyE00 / B1105</i>	
<b>Order Qty</b>	<i>4000</i>	
<b>Volume Specification</b>	<i>25</i>	<i>± 5 ml</i>

**A. Filling Process**

<b>Sampling / Frequency</b>	<b>Volume Inspected (ml)</b>	<b>No contamination of foreign material / dirt</b>	<b>Functionality of Sprayer or Dispenser (applicable to bottle only)</b>	<b>Proper Cap Sealing/Stopper</b>	<b>No Leaking Observed</b>	<b>Test Disposition</b>
<i>1/300</i>	<i>260ml</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>255ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>255ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>255ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>255ml</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

**B. Labelling, Lot No, Manufacturing Date and Expiry Date Process**

<b>Sampling / Frequency</b>	<b>Label printing is clear and legible (inclusive of special printing when applicable)</b>	<b>Reference No, Lot No, Manufacturing Date and Expiry Date are corresponding to Shop</b>	<b>Correct Position of Labelling on Packaging</b>	<b>Correct UDI number printing on labelling (Product Code, Manufacturing Date,</b>	<b>Test Disposition</b>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

Title: 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: 15/1/2021	

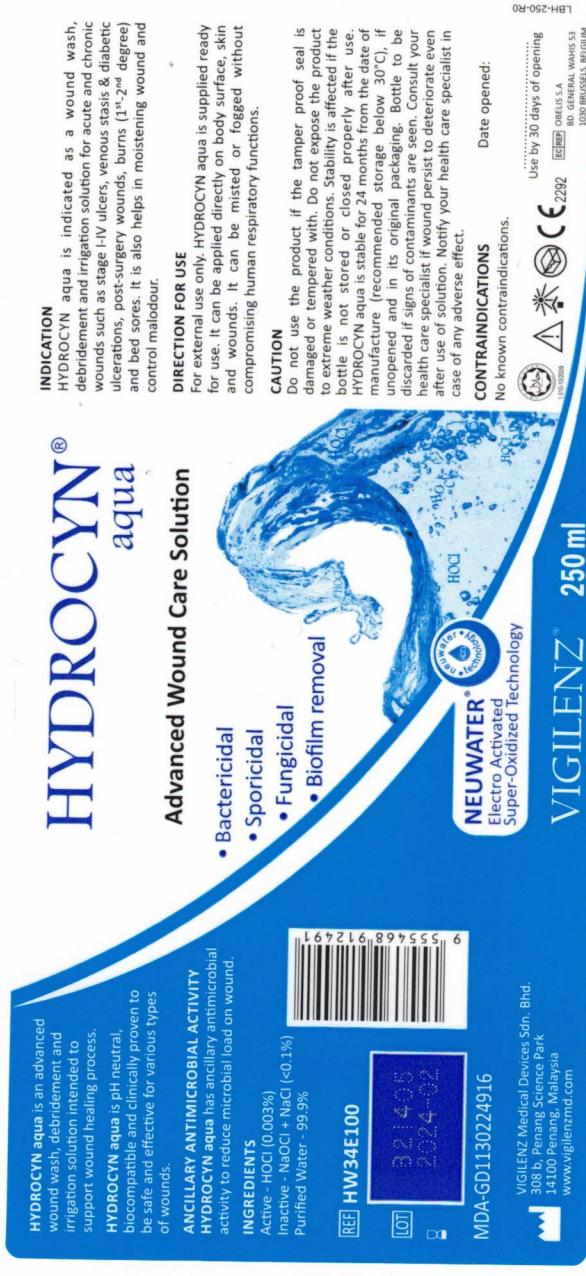
Item Description	Reference / Lot No.	Order Qty	Volume Specification
		NP	± ml

## A. Filling Process

### B. Labelling, Lot No. Manufacturing Date and Expiry Date Process

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	
Document type: FORM	Doc Id: QC-IP002-09

C. Attachment (First Printed Label)



Disposition of the Lot :

PASS       FAIL

Inspected by : EUCH

Name

: With wdy

Date : 17.2.2022

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**D. Attachment (Last Printed Label)**



Inspected by : Raj  
Name : Rashmi  
Date : 17/2/2023

FAIL

PASS

### **Disposition of the Lot**

VIGILENZ®

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

ITEM DESCRIPTION :	Hydrocyn Aqua, 250mL	Doc. No.	QC-FC004
REV.:	09	Rev.:	09

ITEM DESCRIPTION :

Hydrocyn Aqua, 250mL

REFERENCE :

Hlu 34E100

LOT NO. :

B21405

QTY. PRODUCED (pes) :

4004

RETAIN SAMPLE QTY. (pes) :

2

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

Remarks : N/A

Inspected By : Wahid  
Name : A. A. R. TIN  
Date : 17.2.2022

Approved By : Rajesh  
Name : A. A. R. TIN  
Date : 18/2/2022

## RAW MATERIAL LOADING FORM (RMLF)

DATE :	16/02/2022
REF :	HW34E100
LOT NO. :	B21405

SHOP PACKET QTY (pes) : 4000  
 CUSTOMER : VMS (MALAYSIA)  
 LOT NO. : IO/NMD/1/0222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		RECEIVED BY
							ISSUED	CONSUMPTION	
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H012211201	pcs	4004	4004	4004	✓ <i>Cayjenor</i>
2	P0100200	Blue Cap for 500ml HDPE Plastic Container	0	H020211201	pcs	4004	4004	4004	✓ <i>Cayjenor</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078220101	pcs	4004	4004	4004	✓ <i>Cayjenor</i>
4		STOCK SOLUTION		13/H/B/160222045	ltr	1041	1041	1041	✓ <i>Cayjenor</i>

(3) OVER WRAPPING AND CARTON PACK									
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	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		H060211102	80	✓ <i>Mashah</i>			
2	P0100567	DSN-H-009(B) - VIG-901-ASY, HYDROCYN 250ml, NL & NS:312 x 90mm(4pes each), Mat:T150/T150 BA Flute		H069211103	160	✓ <i>Mashah</i>			
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 BA Flute		H070211102	80	✓ <i>Mashah</i>			
(4) SPECIAL REQUIREMENT									
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	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			#N/A				

VERIFIED BY (PR) : *Afif*  
 Signature : *MARSHAH CAYJENOR*  
 Name : *MASHAH CAYJENOR*  
 Date : *19/2/2022*

ISSUED BY (MM) : *JW*  
 Signature : *TOMIN FIRDAUS*  
 Name : *TOMIN FIRDAUS*  
 Date : *16/02/2022*

VIGILENZ®

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

Doc No.	QC-PC00
Rev.	06

Description <i>(B0H1e Cap Closure)</i>	Hydrogen hours, 250m/ Reference No. <i>B034E100</i>	Date of Inspection <i>18/02/2022</i>
Lot No.	Sample Size <i>25H X 250ml</i>	

*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	Instrument
7.27	855	95-67	1/8	1/8	1/8
					Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : *Praj*  
Name : *Prafull*  
Date : *18/02/2022*

Approved By : *S. Almarai*  
Name : *S. Almarai*  
Date : *18/02/2022*



#### **Rework Disposition :**

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.

Prepared By :	Acknowledge By :	Approved By :
Name : MR.RATNA Date: 17/02/2022	Name : MARTINI BINTI GHAZALI Date: 18/02/2022	Name : MR.JEEVANEND Date : 28/2/2022

## REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



### 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 tampered 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.

L8H-250-R0  
Use by 30 days of opening  
REF: ORELIS S.A.  
RD. GENERAL VANDIS 33  
1020 BRUSSELS, BELGIUM



ISO 9001

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