

SHOP PACKET - EASW

4+2

REFERENCE	HW35D100	ODR. QTY	2928 2688	RS: 2+1 (QC TEST)	ISSUED DATE	04/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX 4/12 Net	LOT NO.	A20401	
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	04/01/2022	
PREPARED BY	NAME : SITI ASMAH DATE : 04/01/2022	ODR. NO	A002	EXP. DATE	2024-01	
		VERIFIED BY	NAME : RATNASEGARAN Net DATE : 04/01/2022	INT. ORDER	IO/VMD/040122/01	
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 :	10:30 Am	2694 Net				
DATE :	04-01-22	2688+3 2694				
TIME COMPLETE :	6:30 PM	4/1/22				
DATE :	04-01-22					
UDI PRINTING (Label/Box/Carton)						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						
SOLUTION FILLING & CAPPING						
TIME START :	11:25AM	2694 Net				
DATE :	07-01-22	2688+3 2694				
TIME COMPLETE :	4:55PM	4/1/22				
DATE :	07-01-22					
LABELLING						
TIME START :	11:25AM	2694 Net				
DATE :	07-01-22	2688+3 2694				
TIME COMPLETE :	4:55PM	4/1/22				
DATE :	07-01-22					
PRINTING LOT NUMBER						
TIME START :	11:25AM	2694 Net				
DATE :	07-01-22	2688+3 2694				
TIME COMPLETE :	4:55PM	4/1/22				
DATE :	07-01-22					
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 :	11:25AM	2694 Net				
DATE :	07-01-22	2688+3 2694				
TIME COMPLETE :	4:55PM	4/1/22				
DATE :	07-01-22					
CARTON PACK						
TIME START :	9:45 AM	112				
DATE :	08-01-22	ctn				
TIME COMPLETE :	1:00 PM	112				
DATE :	08-01-22	ctn				
UDI LABELLING						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						

QUANTITY PRODUCED : 2694 lots

QUANTITY FOR QC / RETAIN SAMPLE : 2+1 2+1 btl

SHIPMENT QUANTITY PCS / CTNS : 2694 lots / 112 ctns

FINAL SHIPMENT DATE :

COMPLETE / PARTIAL : COMPLETE PARTIAL

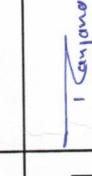
Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : RATNASEGARAN Date : 8/1/2022	Name : RONALD OTHMAN Date : 12/1/2022	Name : MARTINI Designation : QC DEPT Date : 08/01/2022 Stamp : RELEASED
Remarks: REDUCED QTY FROM 2928 TO 2688 TO ALLOW INCREASE QTY FOR LOT # A20400. Net		

VIGIENZ®

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

Doc. No	QC-LC002
Rev.	00

Item Description	Holocyn Aqua, 500ml (bottle cap closure)
Reference	Hu 35 D100
Lot No.	A20401

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"/>	 893 07/01/2022	 wak 7.1.22	N A	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 checked="" type="checkbox"/>	<input type="checkbox"/>	 893 07/01/2022	 wak 7.1.22	N A	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"/>	 Contra 07/11/22	 wak 7.1.22	N A	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"/>	 Contra 07/11/22	 wak 7.1.22	N A	Production

Title:

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

Document type:
FORMDoc Id:
QC-IP002-09
Issue Date:
15/11/2021
Page:
1(3)

Item Description	Hydrogen Peroxide, 500mL (Bottle cap closure)		
Reference / Lot No.	HWW35000	/	A20401
Order Qty	2688		
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
10/10	515 mL	✓	✓	✓	✓	PASS
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL
1/300	515 mL	✓	✓	✓	✓	FAIL

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	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL

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: 1(3)

Item Description	Hydrocyn Aquas 500ml (Bothe cap closure)		
Reference / Lot No.	H/W35D100	/	A20401
Order Qty	2688		
Volume Specification	5.15	±	5 ml

A. Filling Process

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
1/300	515 mL	✓	✓	✓	□
1/300	515 mL	✓	✓	✓	□
1/283-1/284	515 mL	✓	✓	✓	□
		N/A			□
					□
					□

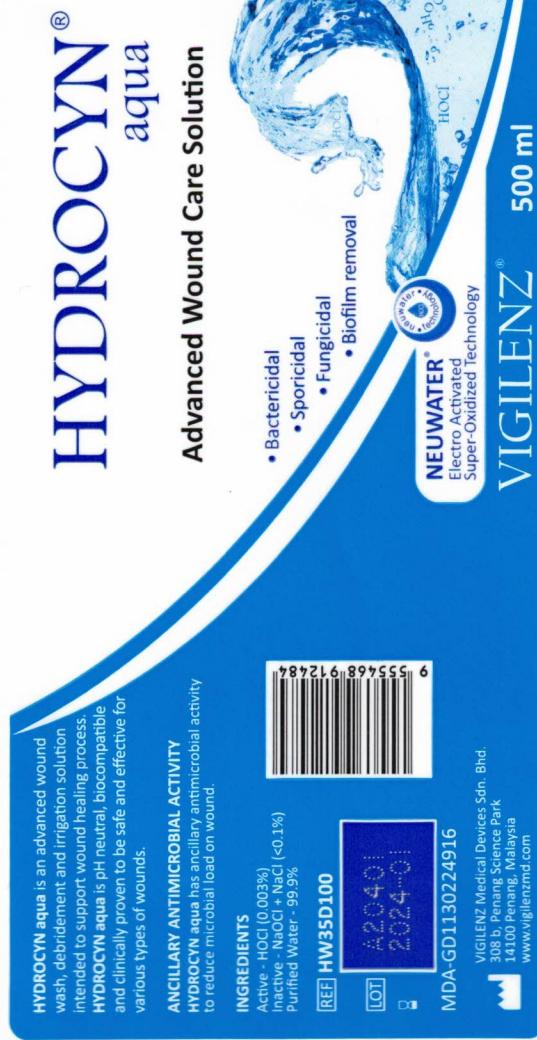
B. Labelling, Lot No, Manufacturing Date and Expiry Date Process

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
1/300	✓	✓	✓	□	□
1/300	✓	✓	✓	□	□
4283 1/284	✓	✓	✓	□	□
				□	□
				□	□
				□	□
	NA			□	□
				□	□

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
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FORM
QC-IP002-09

C. Attachment (First Printed Label)



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 properly after use. HYDROCYN aqua is stable for 24 months from the date of manufacture (recommended storage at 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

18H-500-H0
18H-500-H0
REF: 18H-500-H0
OBILIS S.A.
RD. GENERAL WATIS 53
1030 BRUSSELS, BELGIUM

✓
Vigilenz
VIGILENZ

Disposition of the Lot : PASS FAIL

PASS FAIL

Inspected by : Lick
Name : Adeh Wuk
Date : 7.01.22

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

D. Attachment (Last Printed Label)



Disposition of the Lot:

PASS

Inspected by : Arch
Name : Arch Arch
Date : 01.01.2022

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

ITEM DESCRIPTION	: Hydrocyn Aqua, 500 mL	Doc. No.	QC-FC004
REV.	09	Rev.	09

ITEM DESCRIPTION

: Hydrocyn Aqua, 500 mL

REFERENCE

: HW 35 D/00

LOT NO.

: A 20401

QTY. PRODUCED (pes) : 2693 2694 ৩০৫

RETAIN SAMPLE QTY. (pes) : 4

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	S ₃ , 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S ₃ , 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/A

Inspected By

: বুক

Name : K. RITWI

Date : ০৫.০১.২০২২

Approved By

: মুনির

Name : K. RITWI

Date : ০৫.০১.২০২২

DATE :	05/01/2022
REF :	HW35D100
LOT NO. :	A20401

SHOP PACKET QTY (pes) : 2928
 CUSTOMER : VMD (MALAYSIA)
 I.O.NO. : 10VMD040122/01

RECEIVED BY	
:	
:	
:	

NO.	SYSTEM CODE	ITEM DESCRIPTION 1		DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 2							
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010211101	pes	2931	2931	2931		
2	P0100290	Blue Cap for 500ml HDPE Plastic Container	0	H020210601	pes	2931	2931	2931		
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078211101	pes	2931	2931	2931		
4	N/A	STOCK SOLUTION	N/A							

(2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1		LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 2							
1	P0100633	LBH-500-RO - Hydrocon Aqua 500ml Label , Size : 71mm X 210mm , Material : White PP + Gloss Lamination	L18121102	2932			P0100679	H165211102	122	
2			#N/A				P0100680	H065211102	122	
3			#N/A				3	#N/A		
4			#N/A							
5			#N/A							
6			#N/A							
7			#N/A							

(3) OVERWRAPPING AND CARTON PACK

NO.	SYSTEM CODE	ITEM DESCRIPTION 1		ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 2				
				500ml Hydrocon Aqua carton -469L X 31.5W X 219H (BAF)			
				500ml Hydrocon short and long-			
				#N/A			

(4) SPECIAL REQUIREMENT

NO.	SYSTEM CODE	ITEM DESCRIPTION 1		ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 2				
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)					
2			#N/A				

VERIFIED BY (PR) :

Signature : _____
 Name : _____
 Date : _____

ISSUED BY (MM) :

Signature : 
 Name : _____
 Date : 05/01/2022

DATE :	05/01/2022
REF :	HW35D100
LOT NO. :	A20401

SHOP PACKET QTY (pcs) :
 CUSTOMER : **VMD MALAYSIA**
 I.O NO. : **10BAGS20210122101**

RS	2688
DATE :	05/01/2022
REF :	10BAGS20210122101

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010211101	pcs	2691		2691	<u>Carjana</u>
2	P0100200	Blue Cap for 500ml HDPE Plastic Container		0		H020210601	pcs	2691	<u>Carjana</u>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078211101	pcs	2691		2691	<u>Carjana</u>
4	N/A	STOCK SOLUTION		N/A	ltr	1400		1400	<u>Carjana</u>

(3) OVER WRAPPING AND CARTON PACK									
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	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		L18J211002	2692	<u>Carjana</u>	P0100679	500ml Hydrocyn Aqua carton -469L X 31.5W X 21.9H (BAF)	H165211102
2		#N/A					P0100680	500ml nesting short and long-	H065211102
3		#N/A					3	#N/A	

(4) SPECIAL REQUIREMENT									
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY			
5		#N/A							
6		#N/A							
7		#N/A							

ISUED BY (MM) : LOVIN
 Signature : LOVIN
 Name : LOVIN
 Date : 05/01/2022

VERIFIED BY (PR) : AP
 Signature : Karen Sng
 Name : Karen Sng
 Date : 05/01/2022

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

		Doc No.	QC-PC007
		Rev.	06

Description	Hydrogen Aquag 500mL (Bottle Cap closure)	Reference No.	HW35D/00	Date of Inspection	8/01/2022
Lot No.	A20401	Sample Size	100 X 500mL		

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: ≥ 950	Spec: 95- 140			
Result	Instrument	Result	Instrument	Result	Instrument
7.34	Q1-78	871	Q1-67	10.8	01-80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *K/n*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *wah wah*
Name : *louh*
Date : *08/01/2022*

Approved By : *Ma RTini*
Name : *Ma RTini*
Date : *08/01/2022*

• BACKGUARD •
• Quality Assurance Department •
• APPROVED •
• Quality Assurance Department •

VIGILENZ®	PRODUCT RELEASE TEST REPORT – ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
	Doc No.	QC-PC007	Rev.

Description	Hydrogen Aqua, 500ml (Bottle Cap Closure)	Reference No.	HW 35D100	Date of Inspection	8/01/2022
Lot No.	120401	Sample Size	16H x 500 ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)				Test Disposition (PASS / FAIL)		
pH	ORP (mV)	FAC (ppm)	Spec: 95 - 140	Instrument	Result	Instrument
Spec: 6.50 - 8.00	Spec: ≥ 850					
Result	Instrument	Result	Spec: 95 - 140	Instrument	Result	Instrument
7.00	Q1-78	871	91-67	Q1-80	111	pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *n/a*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Umesh*
Name : *KR TTINI*
Date : *08/01/2022*

Approved By : *E. John*
Name : *KR TTINI*
Date : *08/01/2022*



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

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.

Prepared By :	Acknowledge By :	Approved By :
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI	Name : MR.JEEVANEND
Date: 07/01/2022	Date: 07/01/2022	Date : 10/01/2022

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

