

SHOP PACKET - EASW

REFERENCE	HW3SD100	ODR. QTY (PCS)	4,008	RSC QC(1) 6 3 N/A	ISSUED DATE	15/02/2022
ITEM CODE	H010001	PACK SIZE	24/Box		LOT NO.	B21561
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD		MFG. DATE	15/02/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 15/02/2022	VERIFIED BY		NAME : RATNASEGARAN DATE : 15/02/2022	EXP. DATE	2024-02
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton			INT. ORDER	IO/VMD/110222/01
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 : DATE : TIME COMPLETE : DATE :	1:30 pm 14-02-22	4014+3	4014+3	Nil Kyander (893)	Wah 14.2.22	Tank 1000L/T6 C3HB140222038 TANK 1000L/T7 03HB150222039
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :						TANK 500L/T5 03HB09022038 UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	9:30am 16-02-22	4017	4010	7 M. Bashiru (1117)	Wah 16.2.22	- 7 Bottle lot (reject) replace with new bottles
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	9:30am 16-02-22	4017	4005	10 FARAH (1051)	Wah 16.2.22	- 12 Label printing not ok (reject) Replace with new label
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	9:30am 16-02-22	4017	4017	Nil FARAH (1051)	Wah 16.2.22	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 :	9:30am 16-02-22	4017	4017	Nil FARAH (1051)	Wah 4:35PM 16.2.22	N/A
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	9:00 am 17-02-22	167 etc	167 etc	X11 Labin (1088) Jenius (1122) Vlister (1123)	Lind 17/2/22 Labin 17/2/22	
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 4017 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 6 + 3 btl
 SHIPMENT QUANTITY PCS / CTNS : 10008 btl / 16 Fuchs
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>Abd</i> Name : <i>Razwan Segaran</i> Date : <i>18/2/2022</i>	Approved by (QA), Signature : <i>Jm</i> Name : <i>Rohanaiza Ahmad</i> Date : <i>18/2/2022</i>	Released by (QC), Signature : <i>z</i> Name : <i>MARTIN</i> Designation : <i>QC DEPT</i> Date : <i>18/2/2022</i> Stamp :
Remarks:		
		

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

Item Description	<i>Hydracyn Aqua, 500ml (Bottle cap closure)</i>	Doc. No	QC-LC002
Reference	HU 35D100	Rev.	00
Lot No.	B21561		

Item Description	<i>Hydracyn Aqua, 500ml (Bottle cap closure)</i>
Reference	HU 35D100
Lot No.	B21561

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>Wach 293 16/02/2022</i>	<i>Wach 16. 2. 22</i>	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			<i>Wach 293 16/02/2022</i>	<i>Wach 16. 2. 22</i>	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"/>	<i>1. Canyon 16/02/22</i>	<i>Wach 16. 2. 22</i>	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"/>	<i>1. Canyon 16/02/22</i>	<i>Wach 16. 2. 22</i>	N/A	Production

Title:

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

Document type:
FORM

Bactiguard

Issue Date:
15/11/2021Page:
1(3)

Item Description	Hydrocyn Aqus, 500 ml (Bottle cap closure)		
Reference / Lot No.	HW35000	/ B 21561	
Order Qty	4008		
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	520 ml	✓	✓	✓	✓	PASS
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 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)		
Document type:	Doc Id:	Issue Date:	Page:
FORM	QC-IP002-09	15/11/2021	1(3)

Item Description	Hydrocyn Aquus, 50ml (Bottle cap closure)
Reference / Lot No.	H/UV35.D00
Order Qty	4008
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
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS
1/300	500 ml	✓	✓	✓	✓	PASS

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

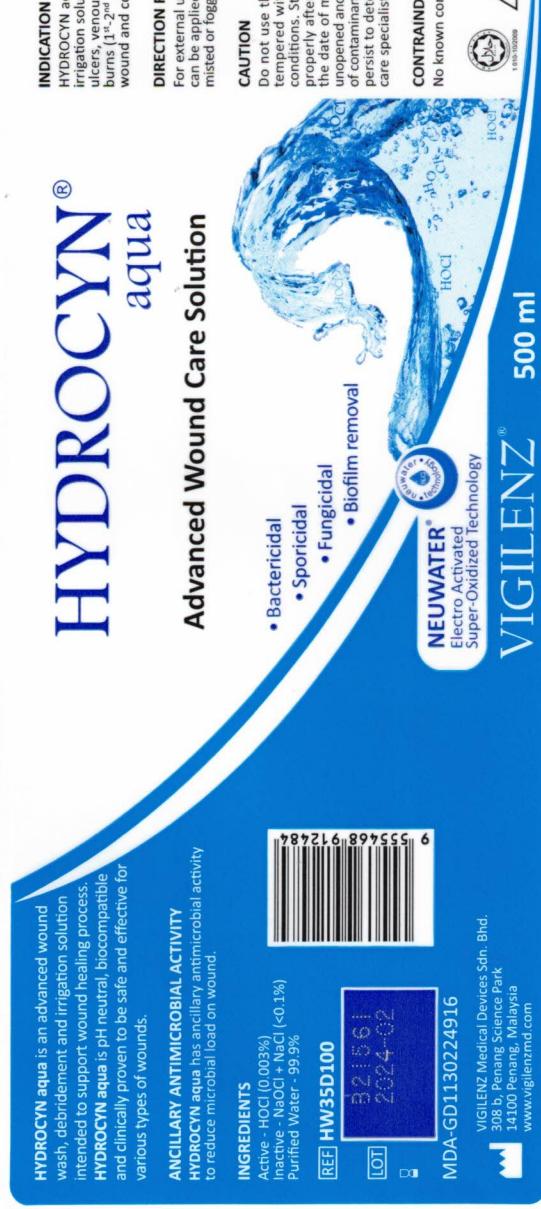
Sampling / Frequency	Label printing is clear and legible (inclusive of special printing when applicable)	Reference No, Lot No, Manufacturing Date and Expiry Date are corresponding to Shop	Correct Position of Labelling on Packaging	Correct UDI number printing on labelling (Product Code, Manufacturing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

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: 15/11/2021	

Item Description	Hydrogen Peroxide 500ml (Bottle cap closure)		
Reference / Lot No.	HW350100 / B215G1		
Order Qty	4008		
Volume Specification	515	±	5 ml

A. Filling Process

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

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 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 signs 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

1/3/22



CE
1990/1992/EEC

0300 500000

1030 BRUSSELS, BELGIUM

CHILIS S.A.

BD. GENERAL VAHIS 53

1030 BRUSSELS, BELGIUM

Disposition of the Lot : PASS FAIL

Inspected by : Luck

Name : Luck

Date : 16.02.2022

Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	 Bactiguard	Issue Date: 15/11/2021	Page: 3(3)
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D. Attachment (Last Printed Label)



Disposition of the Lot :

PASS

Inspected by : L. V. K.

Name _____

Date _____

16.2.2

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

Doc. No. QC-FC004
Rev. 09

ITEM DESCRIPTION : Hydrogen Aqua, 500mL

REFERENCE : HCU35D100

LOT NO. : B215G1

Woh
16.02.22

QTY. PRODUCED (pes) :

RETAIN SAMPLE QTY. (pes) :

6

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status
				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 : Woh
Name : Woh Woh
Date : 16.02.2022

Approved By : E. Sajid
Name : MARTINI
Date : 16/2/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.

Rev.

DATE :	15/02/2022
REF :	HW35D100
LOT NO. :	B21561

SHOP PACKET QTY (pes)	: 4008
CUSTOMER	: VMD (MALAYSIA)
LO NO.	: IOVMD/10222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010220101	pes	4012 4017	4011 4017	4019	4019	✓ Cangkaq
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210901	pes	4011 4017	4011 4017	4017	4017	✓ Cangkaq
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078220101	pes	4011 4017	4011 4017	4017	4017	✓ Cangkaq
4	N/A	STOCK SOLUTION	N/A	3H-B440222038 B40150222034 6360000222031	ltr	2081 2085	2085	2089	2089	✓ Cangkaq

(2) PRODUCT PACKAGING

(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	QTY REQUIRED (pes)	RECEIVED BY	
1	P0100633	LBH-500-RO - Hydrocyn Aqua 500ml Label ,Size: 71mm X 210mm, Material: White PP + Gloss Lamination	#N/A	1	500ml Hydrocyn Aqua carton -469L X 31.5W X 219H (BAF)	P0100679	4012 + 6	✓ Cangkaq	H165211201	167	✓ Cangkaq
2				2	500ml nesting short and long-	P0100680			H065220101	167	✓ Cangkaq
3				3			#N/A				
4											
5											
6											
7											

ISSUED BY (MM) :

Signature :

Name :

Date :

VERIFIED BY (PR) :

Signature :

Name :

Date :

John Firdaus
15/02/2022

Abdul Razak
15/02/2022

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

		Doc No.	QC-PC007
		Rev.	06

Description	Hydrogen Peroxide 500ml (Bottle Cap Closure)	Reference No.	HW35D100	Date of Inspection	7/02/2022
Lot No.	B21561	Sample Size	1x 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: > 850	Spec: 95 - 140			
Result	Instrument	Result	Instrument	Result	Instrument
7.21	Qc-78	862	Qc-67	108	Qc-80
					✓

RO water and product bioburden meeting the acceptance criteria.

Remarks : 75 / 03/14 E0902202033

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : John
Name : John N V
Date : 17/02/2022

Approved By : BB
Name : BB
Date : 17/02/2022



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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide (Bottle Cap Closure)	Reference No.	HW 350100	Date of Inspection	17/2/2022
Lot No.	B21561	Sample Size	1 x 500 ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH Spec: 6.50 - 8.00	Instrument Result	ORP (mV) Spec: 7/-850	FAC (ppm)		
			Spec: 95 - 140	Result	Instrument
7.20	Qc-78	864	Qc-67	114	Qc-80

RO water and product bioburden meeting the acceptance criteria.

Remarks : 17/02/2022 03:00

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *M.A.K.T.I.N.I*
Name : *M.A.K.T.I.N.I*
Date : *17/2/2022*

Approved By : *D.B.*
Name : *D.B.*
Date : *17/2/2022*

Approved By : *D.B.*
Name : *D.B.*
Date : *17/2/2022*

Approved By : *D.B.*
Name : *D.B.*
Date : *17/2/2022*



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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Aqua 500ml (bottle cap closure)	Reference No.	HW35D100	Date of Inspection	17/2/2022
Lot No.	B21S61	Sample Size	1 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: 7/850	Spec: 95 - 140	Result	Instrument	Instrument
7.22	872	Qc-67	119	Qc-80	Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : 17/03/2022-039

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Z. Pham
Name : W.K.T.W.L
Date : 17/2/2022

Approved By :

D.S.

Name :

R.A.U.C.U

Date :



Rework Instruction No. : R1-PM12-22038					
Reference Code	HW35D100	Lot No.	B21561	Lot Quantity (pes)	4011
				Quantity Affected (pes)	12
Process / Operation	Labelling & Printing Lot No.				
Type of Rework	Replace New label, Re-do the printing of the Lot number and Expiry date				
Reason for Rework	Misalignment printing of Lot No and Expiry date on labels				
Potential Adverse Effect (Filled by QA)	Scratch marks on bottles				
Training / Trainer (Tick whichever applicable)	<input type="checkbox"/> Required	<input checked="" type="checkbox"/> Not Required	Trainer : N/A		
Rework Operator	Farah				
Required Tools	N/A				
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)
1) Segregate the affected bottles	Kanjana 16/02/22	All the bottles were verified			Farz 16/2/22
2) Remove the damage labels (Misalignmant printing)	Kanjana 16/02/22	All the labels were removed from the bottles			Farz 16/2/22
3) Replace with new labels	Kanjana 16/02/22	New labels were replaced			Farz 16/2/22
4) Re-print again the Expiry date and Lot number at correct position	Kanjana 16/02/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			Farz 16/2/22
5) Proceed to Cap Sealing Process	Kanjana 16/02/22	Verified in Cap Sealing process and complies with all the specifications			Farz 16/2/22
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 : Name : MR.RATNA Date: 16/02/2022	Acknowledge By : Name : MARTINI BINTI GHAZALI Date: 18/2/2022	Approved By : Name : MR.JEEVANEND Date : 18/2/2022			

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

