

SHOP PACKET - EASW

REFERENCE	HW3CE700	ODR. QTY (PCS)	500	RS(2) QC(5)	ISSUED DATE	12/02/2022
ITEM CODE	H0100004	PACK SIZE	50/Box	LOT NO.	B21205	
ITEM DESCRIPTION	Hydrocyn Aqua, 100ml (Spray Mist)	CUSTOMER	VMD	MFG. DATE	12/02/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 12/02/2022	ODR. NO	B060	EXP. DATE	2024-02	
		VERIFIED BY	NAME : RATNASEGARAN DATE : 12/02/2022	INT. ORDER	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 : DATE : TIME COMPLETE : DATE :	1:30 PM 14-02-22 8:40 PM 14-02-22	500+7 500+7 500+7 507	Nil	Ryanden (893)	Roshni 8:40 PM 14/02/22	TANK 1000Ltr 03HB14033038
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 :	11:15 AM 15-02-22 12:00 PM 15-02-22	507	507	nil	Roshni 12:00PM 15/02/22	NA
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	11:15 AM 15-02-22 12:00 PM 15-02-22	507	502	5	Farah (1051)	Roshni 12:00PM 15/02/22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	11:15 AM 15-02-22 12:00 PM 15-02-22	507	507	nil	Farah (1051)	Roshni 12:00 pm 15/02/22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :	11:30 AM 15-02-22 1:35 PM 15-02-22	507	507	nil	Erali (#32)	Roshni 1:35 PM 15/02/22
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :	1:00 pm 15-02-22 4:08 PM 15-02-22	507	507	Nil	KALI (#78)	Roshni 4:08 PM 15/02/22
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 :	3:09 PM 15-02-22 4:00 PM 15-02-22	507	507	nil	Roshni (1078)	Roshni 4:10 pm 15/02/22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	6:15 PM 15-02-22 7:00 PM 15-02-22	10 ctn	10 ctn	Nil	tgy (887) marju (846)	Nurin 17/2/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :					N/A	UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 507 Uts
 QUANTITY FOR QC / RETAIN SAMPLE : 2 RS + 5 BH
 SHIPMENT QUANTITY PCS / CTNS : 500 Uts / 10 ctn
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>Net</i> Name : RATNASEGARAN Date : 19/2/2022	Approved by (QA), Signature : <i>JMS</i> Name : Johamia Ahmad Date : 22/2/2022	Released by (QC), Signature : <i>3daw</i> Name : MATINIS Designation : QC DEPT Date : 19/2/2022
Remarks:		



Doc. No : PR-SP007, Rev : 07

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

Item Description	Hydrogen Peroxide, 100ml (spray mist)
Reference	HVO3CEP00
Lot No.	B1-A105 <i>15/2/22</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>Abdul 893 15/02/2022</i>	<i>Praj 15/02/22</i>	<i>N/p</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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Abdul 893 15/02/2022</i>	<i>Praj 15/02/22</i>	<i>N/p</i>	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 Canjeero 15/02/22</i>	<i>Praj 15/02/22</i>	<i>N/p</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>1 Canjeero 15/02/22</i>	<i>Praj 15/02/22</i>	<i>N/p</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)

		 Bactiguard	
Item Description	Hydrogen Peroxide (spray mist)		
Reference / Lot No.	HWT001021xx		
Order Qty	500		
Volume Specification	105	±	5 mI

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
				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	PASS
				<input checked="" type="checkbox"/>	<input type="checkbox"/>	FAIL
10/10	105 ml	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	105 ml	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/97	105 ml	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

A. Filling 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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/97	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

Sampling / Frequency	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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/300	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/97	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Date:

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

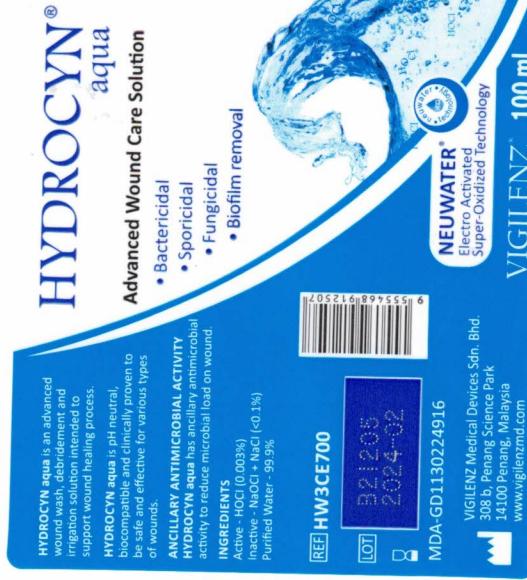
Document type:
FORM

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
2(3)

C. Attachment (First Printed Label)



INDICATION
HYDROCYN aqua is indicated as a wound wash, irrigant solution as a wound wash, for acute and chronic wounds, such as stage I-V ulcers, venous stasis & diabetic ulcerations, burns, venous burns (1st-2nd degree) and bed sores. It also helps in moistening wound and control malodour.

DIRECTION FOR USE

For external use only. HYDROCYN aqua is supplied in a spray bottle. It can be applied directly on body surfaces or skin and wounds, care must be taken 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 product is stored or closed properly after use. If HYDROCYN aqua is not stored or closed properly below 30°C, if unopened and in its original packaging. Bottle to be discarded if signs of contaminants are present to deteriorate even after use of solution, consult your health care specialist if wound area shows any adverse effect.

CONTRAINDICATIONS

No known contraindications.

Date opened:
L8H-100-090
Use by 30 days of opening



1



PASS



FAIL



FAIL

Disposition of the Lot :



PASS



FAIL

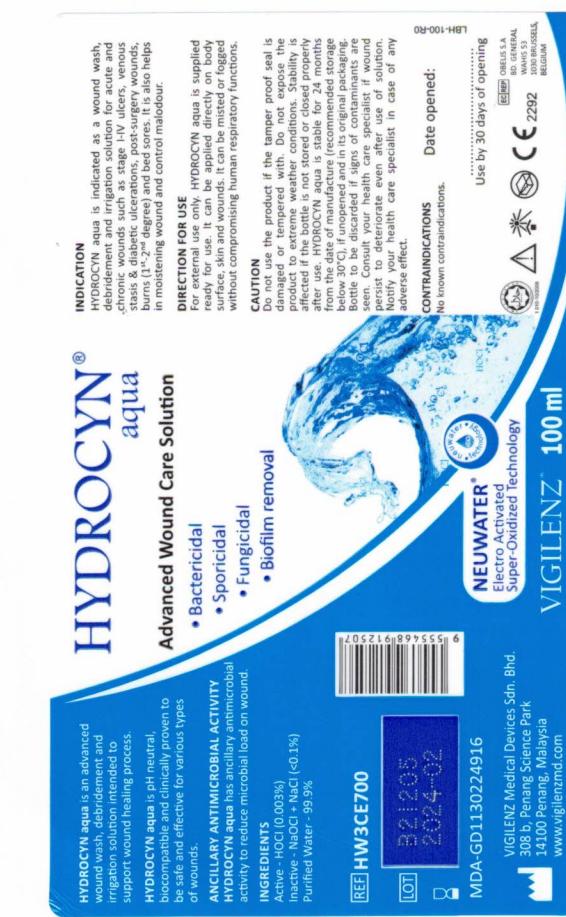
Inspected by : Roly

Name : Roshni

Date : 5/11/2021

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

D. Attachment (Last Printed Label)



B21205
2024-02

Bactiguard	Issue Date: 15/11/2021	Page: 3(3)
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Inspected by : Pray
 Name : Roshni
 Date : 15/11/2021

Disposition of the Lot : PASS FAIL

VIGILENZ®

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

Doc. No.

QC-FC004

Rev.

09

ITEM DESCRIPTION : hydrogen peroxide, 100ml (spray mist)REFERENCE : HU 06700LOT NO. : 021105

QTY. PRODUCED (pes) :

RETAIN SAMPLE QTY. (pes) :

501
2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results	Status
				Accept	Reject		
1	Legible and clean printing of label.	S3, 0.15	80	0	1	80	0
2	Free from contamination, deformed or damaged on packaging.	S3, 0.15	80	0	1	80	0
3	Proper sealing and no leaking.	S3, 0.15	80	0	1	80	0
4	Free from contamination / particle / foreign materials on product solution.	S3, 0.15	80	0	1	80	0
5	Correct volume filled (against reference sample).	S3, 0.15	80	0	1	80	0

Remarks : N/AInspected By : Rony
Name : Rony
Date : 15/12/2019Approved By : M. A. R. T. T. M.
Name : M. A. R. T. T. M.
Date : 15/12/2019

RAW MATERIAL LOADING FORM (RMLF)

DATE :	14/02/2022
REF :	HW3CE700
LOT NO. :	B21205

SHOP PACKET QTY (pes) : 500
 CUSTOMER : VMD (MALAYSIA)
 LO NO. : IOVMD/110222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100288	100ML HDPE BOTTLE	(NATURAL COLOUR WITH VIGILENZ LOGO)	H075211201	pes	507*	507	507	1 Cengkuang
2	P0100287	JG-24A-PP	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP, PP, TUBE:90mm	H018200701	pes	507	507	507	1 Cengkuang
3	N/A	STOCK SOLUTION	N/A	03-HG140322038	ltr	53	53	53	1 Chayauer

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capsal (For 100ml/250ml Hydrocyan) - Size: 47 x 0.04 x 55 mm (1C+P)	H019210901	508	1 Cengkuang
2	P0100640	LBH-100-R0 - Hydrocyan Aqua 100ml Spray Mist Label, Size: 120mm x 70mm, Material: White PP	L187220103	508	1 Cengkuang
3	P0100639	100ml Hydrocyan Box (Printed) - Material : ArtCard S Coated 300gsm, Size : 40mmx40mmx148mm	H020210901	508	1 Cengkuang
4		#N/A			
5		#N/A			
6		#N/A			
7		#N/A			

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyan Aqua Carton-440L X 220W X 156H	H164220101			10	Lee
2	P0100682	100ml LAYER PAD-	H043211202			90	Lee
3							

(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyan Aqua Carton-440L X 220W X 156H	H164220101	10	Lee
2	P0100682	100ml LAYER PAD-	H043211202	90	Lee

(4) SPECIAL REQUIREMENT

NO	SYSTEM CODE	ITEM DESCRIPTION 1	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 :
 Name : YOWIN
 Date : 14/02/2022

VERIFIED BY (PR) :

Signature :
 Name : SECA
 Date : 19/2/22

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide 100 ml. (Bottle Spray m/s)	Reference No.	HW3 CE 700	Date of Inspection	17/2/2021
Lot No.	B2/205	Sample Size	5 x 100 ml		

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: 7850	Result	Instrument	Result	Instrument
7.52	Qc-78	860	QC-67	119	QC-80
					Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *S. J. M.*
Name : *M. R. T. N.*
Date : *17/2/2021*

Approved By : *S. J. M.*
Name : *B. A. C.*
Date : *17/2/2021*



Rework Instruction No. : R1-PM12-22036									
Reference Code	HW3CE700	Lot No.	B21205	Lot Quantity (pcs)	507	Quantity Affected (pcs)			
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	/	Not Required	Trainer : N/A				
Rework Operator	<i>Farah</i>								
Required Tools	N/A								
Rework Step		Verified by (PR)	Inspection Details			Verified by (QAQC)			
1) Segregate the affected bottles		<i>Layana 15/02/22</i>	All the bottles were verified			<i>Revy 15/02/22</i>			
2) Remove the damage labels (Misalignment printing)		<i>Layana 15/02/22</i>	All the labels were removed from the bottles			<i>Revy 15/02/22</i>			
3) Replace with new labels		<i>Layana 15/02/22</i>	New labels were replaced			<i>Revy 15/02/22</i>			
4) Re-print again the Expiry date and Lot number at correct position		<i>Layana 15/02/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Revy 15/02/22</i>			
5) Proceed to Cap Sealing Process		<i>Layana 15/02/22</i>	Verified in Cap Sealing process and complies with all the specifications			<i>Revy 15/02/22</i>			
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 : <i>Not</i>	Acknowledge By : <i>3 fm</i>	Approved By : <i>f dm 8</i>
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI	Name : MR.JEEVANEND
Date: 15/02/2022	Date: <i>16/02/2022</i>	Date : <i>18/02/2022</i>

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

