

SHOP PACKET - EASW

REFERENCE	HW34E100	ODR. QTY (PCS)	2,000	RS(2) QC(2)	ISSUED DATE	16/02/2022
ITEM CODE	H0100006	PACK SIZE	50/Box		LOT NO.	B21605
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Bottle Cap Closure)	CUSTOMER	VMD		MFG. DATE	16/02/2022
PREPARED BY	NAME : NUR SHAHIRA <i>S.H.</i> DATE : 16/02/2022	ODR. NO	B105		EXP. DATE	2024-02
		VERIFIED BY	NAME : RATNASEGARAN <i>N.R.</i> DATE : 16/02/2022		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 : <i>5:00</i> DATE : <i>16-02-22</i>	<i>2004</i>	<i>2004</i>	<i>NIL</i>	<i>Ryandean (893)</i>	<i>Rashni</i>	<i>JUNK 500L/5 0348160222042</i>
TIME COMPLETE : <i>8:30 PM</i> DATE : <i>16-02-22</i>						
UDI PRINTING (Label/Box/Carton)						
TIME START : <i></i> DATE : <i></i>						
TIME COMPLETE : <i></i> DATE : <i></i>						UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : <i>9:50 AM</i> DATE : <i>17-02-22</i>	<i>2004</i>	<i>1974</i>	<i>30 ADH</i>	<i>Devi (1107)</i>	<i>Wah 11:00 PM 17-02-22</i>	<i>- 30 Blue Cap reject replace with new Blue cap</i>
TIME COMPLETE : <i>1:00 PM</i> DATE : <i>17-02-22</i>	<i>2004</i>	<i>2004</i>	<i>ADH</i>			
LABELLING						
TIME START : <i>9:50 AM</i> DATE : <i>17-02-22</i>	<i>2004</i>	<i>1986</i>	<i>18 NIL</i>	<i>Netra (1103)</i>	<i>Wah 11:00 PM 17-02-22</i>	<i>- 18 Label reject replace with new label</i>
TIME COMPLETE : <i>1:00 PM</i> DATE : <i>17-02-22</i>		<i>2004</i>				
PRINTING LOT NUMBER						
TIME START : <i>9:50 AM</i> DATE : <i>17-02-22</i>	<i>2004</i>	<i>2004</i>	<i>NIL</i>	<i>Netra (1103)</i>	<i>Wah 11:00 PM 17-02-22</i>	<i>N/A</i>
TIME COMPLETE : <i>1:00 PM</i> DATE : <i>17-02-22</i>						
CAP SEALING (Applicable for 100mL)						
TIME START : <i></i> DATE : <i></i>						
TIME COMPLETE : <i></i> DATE : <i></i>						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : <i></i> DATE : <i></i>						
TIME COMPLETE : <i></i> DATE : <i></i>						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : <i></i> DATE : <i></i>						
TIME COMPLETE : <i></i> DATE : <i></i>						UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : <i>9:50 AM</i> DATE : <i>17-02-22</i>	<i>2004</i>	<i>2004</i>	<i>NOL</i>	<i>Netra (1103)</i>	<i>Wah 4:55 PM 17-2-2022</i>	<i>N/A</i>
TIME COMPLETE : <i>1:00 PM</i> DATE : <i>17-02-22</i>						
CARTON PACK						
TIME START : <i>10:00 AM</i> DATE : <i>18-02-22</i>	<i>40 ctn</i>	<i>40 ctn</i>	<i>NIL</i>	<i>Rabin (1088) Vester (1022) Jenus (1023)</i>	<i>Nurin 18/2/2022</i>	<i>Kym 18/02/22</i>
TIME COMPLETE : <i>12:00 PM</i> DATE : <i>18-02-22</i>						
UDI LABELLING						
TIME START : <i></i> DATE : <i></i>						
TIME COMPLETE : <i></i> DATE : <i></i>						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : *2604 btl*
 QUANTITY FOR QC / RETAIN SAMPLE : *2+2 btl*
 SHIPMENT QUANTITY PCS / CTNS : *2000 bts / 40ctn*
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : *COMPLETE* *PARTIAL*

Checked by (PR), Signature : <i>A.P.</i> Name : RAJINISURESH Date : 19/2/2022	Approved by (QA), Signature : <i>E.M.S.</i> Name : Rohamza Othman Date : 22/2/2022	Released by (QC), Signature : <i>MARTINI</i> Name : MARTINI Designation : QC DEPT Date : 19/2/2022 Stamp :
Remarks:		



VIGILENZ®

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

Doc. No QC-LC002
Rev. 00

Item Description	<i>Hydrogen Peroxide 25ml (cap closed)</i>
Reference	<i>MW34E100</i>
Lot No.	<i>B1105</i>

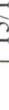
No.	Checklist	Yes	No	Performed by (Signature / Date)	Verified by QC (Signature / Date)	Remarks	Responsibility
1	Flush machine HD-01 with approximately 20L of RODI water & 10L of EASW solution before each production batch	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Abd 88 17/02/2022</i>	<i>Praj 17/02/22</i>	<i>NP</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>Abd 293 17/02/2022</i>	<i>Praj 17/02/22</i>	<i>NP</i>	Technician
	i) Starwheel	<input type="checkbox"/>	<input type="checkbox"/>				
	ii) Nozzle	<input type="checkbox"/>	<input checked="" type="checkbox"/>				
	iii) Stopper Insertor		<input type="checkbox"/>				
	iv) Cap Dispenser	<input type="checkbox"/>	<input checked="" type="checkbox"/>				
	v) Cap Pusher	<input type="checkbox"/>	<input checked="" type="checkbox"/>				
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Canjaro 17/02/22</i>	<i>wah 17.2.22</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>Canjaro 17/02/22</i>	<i>wah 17.2.22</i>	<i>N A</i>	Production

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, 250 ml (Bottles open closure)		
Reference / Lot No.	FH034E100	/	031605
Order Qty	2000		
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)		 Bactiguard	Page: 1(3)
Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/1/2021	

Item Description	Hydrogen Peroxide, 250 ml (Bottle cap closure)		
Reference / Lot No.	HW 34E100	/	B 21605
Order Qty	2000		
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)

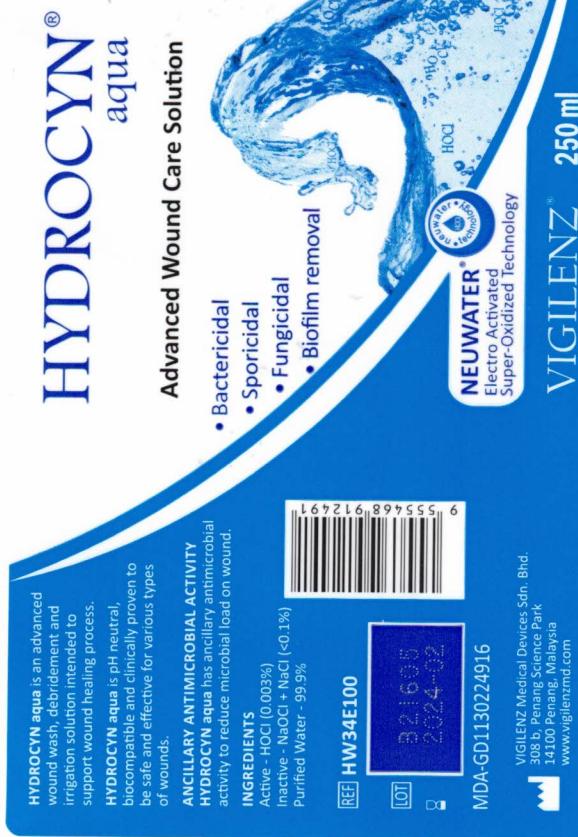
Document type:
FORM

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
2(3)

C. Attachment (First Printed Label)



HYDROCYN® aqua is an advanced wound wash, debridement and irrigation solution intended to support wound healing process.

HYDROCYN® aqua is pH neutral, biocompatible and clinically proven to be safe and effective for various types of wounds.

ANCILLARY ANTIMICROBIAL ACTIVITY
HYDROCYN® aqua has ancillary antimicrobial activity to reduce microbial load on wound.

INGREDIENTS

Active - HOCl (0.003%)
Purified Water - 99.9%

Inactive - NaOCl + NaCl (<0.1%)

Purified Water - 99.9%

REF: HW34E100

Lot: 321635
2024-02

MDA-GD1130224916

VIGILENZ® 250ml

9 555468 912491

Barcode

Use by 30 days of opening

LBH-250-RD

ESPP ORELUS 5.4

RD, GENERAL WAHIS 53

1030 BRUSSELS, BELGIUM

www.vigilenzmd.com

v

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 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.

LBH-250-RD
ESPP ORELUS 5.4
RD, GENERAL WAHIS 53
1030 BRUSSELS, BELGIUM

✓ *Rosina*

Disposition of the Lot : PASS FAIL

FAIL

Inspected by : *Rosina*
Name : *Rosina*
Date : *16/11/2021*

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: 3(3)

D. Attachment (Last Printed Label)



Inspected by : Lewk
Name : Lewk Lewk
Date : 17.02.2022

Disposition of the Lot : PASS FAIL

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

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

REFERENCE

: HW34E100

QTY. PRODUCED (pcs) :

2004

LOT NO.

: B21605

RETAIN SAMPLE QTY. (pcs) :

2

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

Inspected By

: Woh

Name

Date

Approved By : Eng. M. A. R. T. M.
 Name : M. A. R. T. M.
 Date : 17/2/2022

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE :	16/02/2022	RS
REF :	HW34E100	VMD (MALAYSIA)
LOT NO. :	21/16/2022 - 821605	10/VMD/11/0222/01

SHOP PACKET QTY (pes) : 2000
 CUSTOMER : VMD (MALAYSIA)
 I.O. NO. : 10/VMD/11/0222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pes)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H012210602	pcs	2004	2004	<i>✓ Cawaua</i>
2	P01002813	#N/A	#N/A	H020210601	pcs	2004	2004	<i>✓ Cawaua</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	2004	2004	<i>✓ Cawaua</i>
4		STOCK SOLUTION	<i>02/14/2022</i>	<i>02/14/2022</i>	ltr	521	521	<i>✓ Cawaua</i>

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100642	LBH-250-RHydrocyen Aqua 250ml Cap Closure, Size : 170mm x 77mm, Material : White PP	L184211002	2005	<i>✓ Cawaua</i>
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) - V/G-003-CTN-HYDROCYN 250ML(Cap Closure), Size: 330x330x305mm, Mat: T180/M/T180 BA Flute		H060211102	40	<i>✓ m adler</i>
2	P0100567	DSN-H-009(B) - V/G-901-ASY, HYDROCYN 250ml NL & NS: 312 x 90mm(4pics each), Mat: T150/T150 B Flute		H069211101	80	<i>✓ m adler</i>
3	P0100568	DSN-H-009(C) - V/G-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute		H070211102	40	<i>✓ m adler</i>

(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) :

✓ Lovin
 Signature :
 Name : LOVIN
 Date : 16/02/2022

VERIFIED BY (PR) :

✓ Lovin
 Signature :
 Name : MTC USG CPTM
 Date : 10/12/2022

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide 250ml (Bottle Cap Closure)	Reference No.	HWE100	Date of Inspection	18/01/2022
Lot No.	B01605	Sample Size	250 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: ≥ 850	Spec: 95 - 140	Instrument	Result	Instrument
7.31	852	10-61	114	10-80	Pass

- RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Raj*
 Name : *Rajeshni*
 Date : *19/01/2022*

Approved By : *A.R.T.M.*
 Name : *A.R.T.M.*
 Date : *18/01/2022*



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	Name : MARTINI BINTI GHAZALI	Name : MR.JEEVANEND
Date: 17/02/2022	Date: 17/2/22	Date : 27/2/2022

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

