

SHOP PACKET - EASW

REFERENCE	HW34E700	ODR. QTY	1,350	RS: 4 + 4(QC TEST)	ISSUED DATE	28/02/2022
ITEM CODE	H0100024	PACK SIZE	50/BOX	LOT NO.	A22713	
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Spray Mist)	CUSTOMER	PROJECTMED TOMASZ SUROWIEC	MFG. DATE	28/02/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 28/02/2022	ODR. NO	A161	EXP. DATE	28/01/2024	
		VERIFIED BY	NAME : RATNASEGARAN DATE : 28/02/2022	INT. ORDER	IO/PRO/004582/01	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	07333330201193	UDI-DI NO. (2nd Packaging) - Carton	17333330201190			
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)07333330201193 (17)28012024	(11)2802022 (10)A22713	UDI-PI NO. (2nd Packaging) - Carton	(01)17333330201190 (17)28012024	(11)28022022 (10)A22713	

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	2:20 PM 09-03-22	1358	1358	Nil	Ryanden 893	Poshni 5:00pm 09/03/22
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :	7:15PM 10-03-22	1360	1360	18	Nisyah 980	Poshni 8:45pm 10/03/2022
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	10:40 AM 10-03-22	1358	1359	Nil	LINA (1131)	Poshni 12:45 PM 11/03/2022
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	10:40 AM 11-03-22	1358	1345	13	Sofia (1139)	Poshni 12:45 AM 11/03/2022
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	10:40 AM 10-02-22	1358	1358	Nil	Era (932)	Poshni 12:45 AM 11/03/2022
CAP SEALING (Applicable for 1000mL)						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 10-03-22	1358	1358	Nil	Era (932) Sofia (1139)	Poshni 2:30PM 10/02/2022
BOX PACKING & PRINTING (Applicable for 1000ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 1000 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :						
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 10-03-22	1358	1358	Nil	Sofia (1138)	Poshni 12:40 PM 11/03/22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 12-03-22	27 ctn	27 ctn	Nil	Rubin (1088) Hadiq (1053) Fazil (1054)	Nurin 12/31/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 12-03-22	24 ctn	24 ctn	Nil	Rubin (1088)	Nurin 12/31/2022

QUANTITY PRODUCED	1358 Lts
QUANTITY FOR QC / RETAIN SAMPLE	252 + 261
SHIPMENT QUANTITY PCS / CTNS	1350 Lts / 27 ctn
FINAL SHIPMENT DATE	
COMPLETE/ PARTIAL	COMPLETE

Checked by (PR), Signature : Name : KAMAL REHMAN Date : 15/3/22	Approved by (QA), Signature : Name : Rohansa Osman Date : 15/3/2022	Released by (QC), Signature : Name : MARTINI Designation : IPQC SUPERVISOR Date : 14/3/2022 Stamp : 
Remarks:		

VIGILENZ®

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

Doc. No	QC-LC002
Rev.	00

Item Description Hydrogen Peroxide, 250ml (spray mist)

Reference HW34EF00

Lot No.

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>John 893</i> 10/03/2022	<i>Umesh</i> 10/3/2022	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>John 893</i> 10/03/2022	<i>Umesh</i> 10/3/2022	N/A	Technician
i)	Starwheel	<input type="checkbox"/>	<input type="checkbox"/>				
ii)	Nozzle	<input type="checkbox"/>	<input type="checkbox"/>				
iii)	Stopper Insertor	<input type="checkbox"/>	<input type="checkbox"/>				
iv)	Cap Dispenser	<input type="checkbox"/>	<input type="checkbox"/>				
v)	Cap Pusher	<input 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>Conjunto</i> 10/03/2022	<i>Prajy 10/03/2022</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>Conjunto</i> 10/03/2022	<i>Prajy 10/03/2022</i>	N/A	Production

Document type: FORM	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	 Bactiguard	Issue Date: 15/11/2021	Page: 1(3)
Doc Id: QC-IP002-09				

Item Description	<u>Hydrogen Peroxide, 250ml (spray mist)</u>
Reference / Lot No.	<u>HWP34C 100</u>
Order Qty	<u>1350</u>
Volume Specification	255 ± 5 ml

A. Filling Process

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

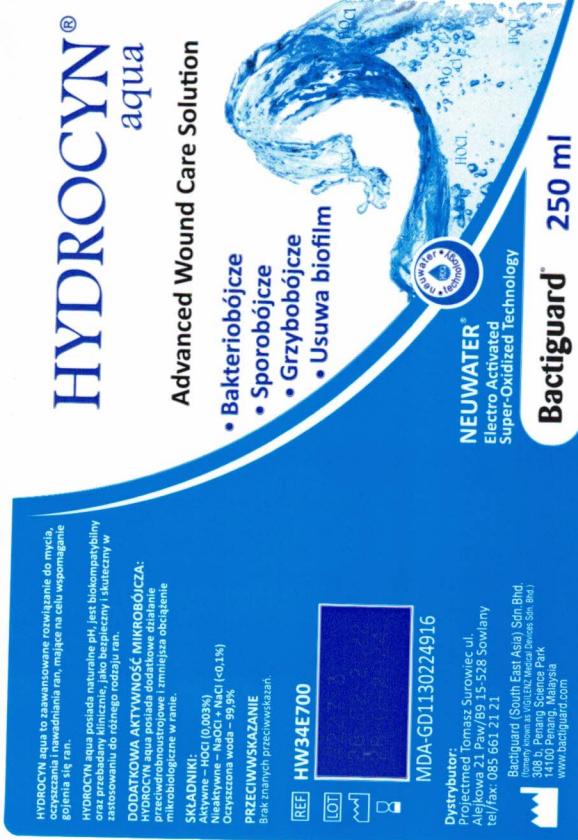
Sampling / Frequency	Label printing is clear and legible (inclusive of special printing when applicable)	Reference No, Lot No, Manufacturing Date and Expiry Date are corresponding to Shop	Correct Position of Labelling on Packaging	Correct UDI number printing on labelling (Product Code, Manufacturing Date,	Test Disposition	
					PASS	FAIL
10/100	✓	✓	✓	✓	✓	□
1/300	✓	✓	✓	✓	✓	□
1/300	✓	✓	✓	✓	✓	□
1/300	✓	✓	✓	✓	✓	□
1/300	✓	✓	✓	✓	✓	□
1/144	✓	✓	✓	✓	✓	□
				NA		□

FORM
100-1000

SECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

WOMEN

Attachment (First Printed Label)



EX-OXIDIZED WATER (EASW)	 Bactiguard	Issue Date:	Page:
Doc Id: QC-IP002-09		15/11/2021	2(3)

Disposition of the Lot :

PASS FAIL

Inspected by : Mch
Name : Mch mch
Date : 11/03/22

1. IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)
Document type:
FORM

C. Attachment (First Printed Label)

HYDROCYN®
aqua
Advanced Wound Care Solution

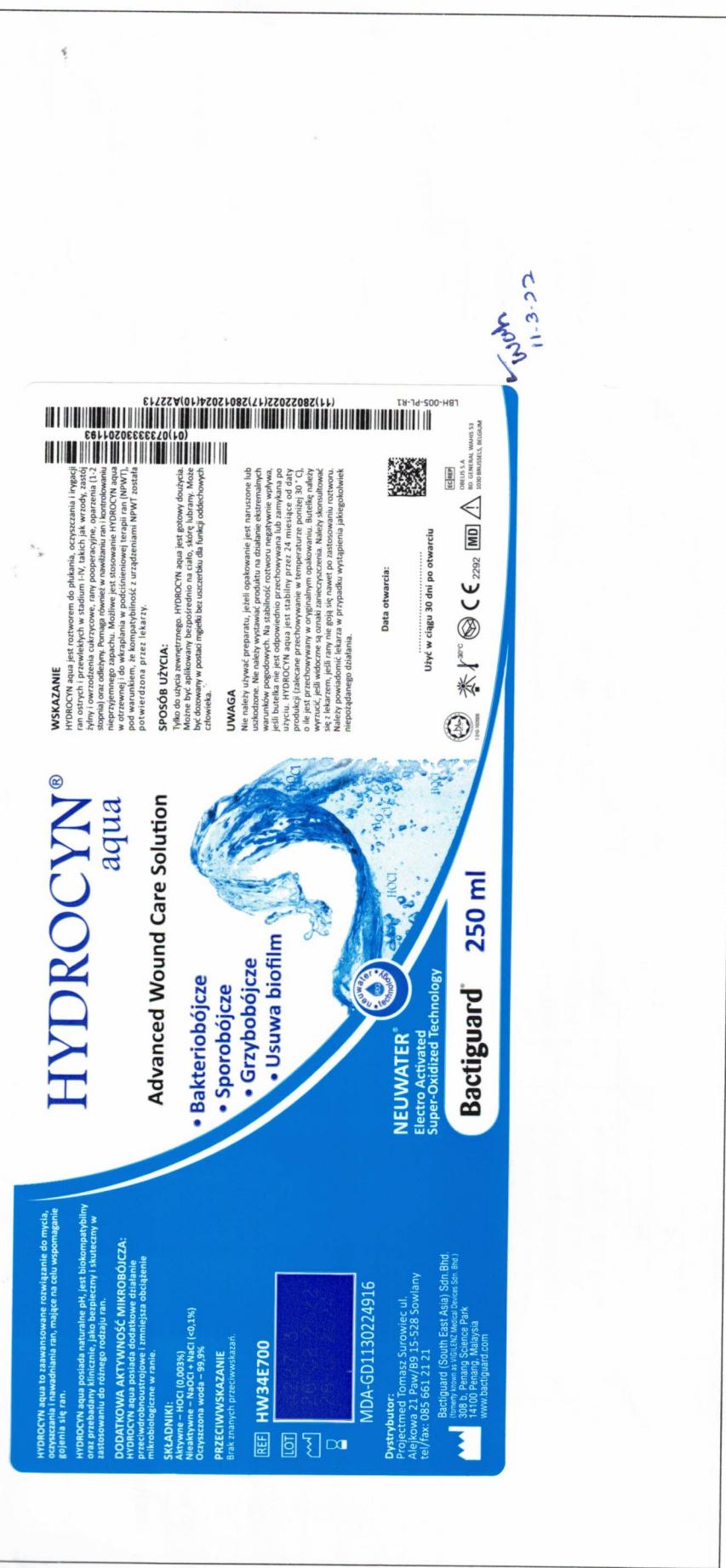
Bactiguard

Doc Id:
QC-IP002-09

Issue Date:
15/11/2021

Page:
2(3)

IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	
Doc Id: QC-IP002-09	Issue Date: 15/11/2021
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Disposition of the Lot : PASS FAIL

PASS FAIL

Inspected by : Lich

Name

Date

: Wojciech

: 11.03.22

DATE :	03/02/2022
REF :	HW34E700
LOT NO. :	A22713

SHOP PACKET QTY (pes)	:	1350
CUSTOMER	:	PROJECTMED TOMASZ SUROWIEC (POLAND)
I.O NO.	:	IOPRO/004582/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pes)		KGS
						REQUIRED	ISSUED	
1	P0100578	271-2441(0VG)	250ml HDPE Round Container (Natural Color)	H09090301	pes	1354	1354	1354
2	P0100563	JQ-24A-PP (11cm)	24410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP: PP, TUBE:110mm	H091200402	pes	1354	1354	1354
3		STOCK SOLUTION		D2H/Bog 032207	ltr	352	352	352

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capsule (For 100ml /250ml Hydrocyn) - Size: 47 x 0.04 x 55 mm (1C-PP)	H019210901	1355	✓ Layupaq
2	P0100543	LBH-005-PL-R0 - Hydrocyn 250ml (mist sprayer) Polish Sticker, Size: 170mm x 77mm, Material: White PP	L200200802	1355	✓ Layupaq
3		#N/A		3	P0100568
4		#N/A			
5		#N/A			
6		#N/A			
7		#N/A		2	

(4) SPECIAL REQUIREMENT

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

ISSUED BY (MM) :

Signature :

Name : OVIN

Date : 03/02/2022

VERIFIED BY (PR) :

Signature :

Name : Unnamed Person

Date : 14/3/22

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

		Doc. No.	QC-FCC04
		Rev.	09

ITEM DESCRIPTION :

Hydrogen Power, 250 ml

REFERENCE :

Hydrogen Power

LOT NO. :

10215

QTY. PRODUCED (pcs) :

1354

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.	53, 0.15	80	0	1	80	0	pass	pass
2	Free from contamination, deformed or damaged on packaging.	53, 0.15	80	0	1	80	0	pass	pass
3	Proper sealing and no leaking.	53, 0.15	80	0	1	80	0	pass	pass
4	Free from contamination / particle / foreign materials on product solution.	53, 0.15	80	0	1	80	0	pass	pass
5	Correct volume filled (against reference sample).	53, 0.15	80	0	1	80	0	pass	pass

Remarks :

N/A

Inspected By : Raj
Name : Roshni
Date : 11/03/2022

Approved By : S. Jaiswal
Name : MA RTIN
Date : 14/3/2022

Title: OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD	 Bactiguard	Doc ID: QC-O1001-04	Issue Date: 09/07/2022	Page: 2(2)
Document type: FORM				

A. Attachment (Carton UDI label)



PRODUCT : Hydrocyn Aqua, 250ml
QUANTITY : 50 PCS

Manufacturer:

Bactiguard (South East Asia) Sdn Bhd
(formerly known as VIGILENZ Medical Devices Sdn Bhd)
308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia



REF **HW34E700**

LOT A22713

28-01-2024



(01)17333330201190(11)28022022(17)28012024(10)A22713

*Only print this sheet for medications with 1/2's

Inspected by : Nurin
 Name : Nurin
 Date : 12/3/2012

Verified by : _____
 Name : _____
 Date : _____

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Title: OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD		 Bactiguard	
Document type: FORM		Doc ID: QC-OI001-04	Page: 1(2)
		Issue Date: 09/02/2022	

SHIPMENT	<u>1</u>
GAMMA	<u>1</u>
TOTAL LOTS	: <u>1</u>
TOTAL CARTONS	: <u>27</u>
SAMPLING DETAILS	: <u>I AQL 1.5</u>

RETURN DATE
AVAILABILITY
SAMPLES

YES /NO
(Applicable for Gamma only)

Please print addition sheet if required

Inspected by _____
Name _____ Date _____

Page

Verified by _____
Name _____ Date _____

BB *Friday* *12/10/2021*

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide 500 ml (spray mist)	Reference No.	HWE700	Date of Inspection	12/03/2022
Lot No.	000713	Sample Size	1611 x 250ml		

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
7.19	Qc-78	860	Qc-67	118	Qc-80 Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rony Rosnwl
Name : MARTINI
Date : 12/03/2022

Approved By : Mr. Martin
Name : MARTINI
Date : 12/03/2022



Rework Instruction No. :						R1-PM12-22057
Reference Code	HW34E700	Lot No.	A22713	Lot Quantity (pcs)	1354	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	<input type="checkbox"/> / <input type="checkbox"/>	Not Required	Trainer : N/A	
Rework Operator	<i>Era</i>					
Required Tools	N/A					
Rework Step		Verified by (PR)	Inspection Details			Verified by (QAQC)
1) Segregate the affected bottles		<i>I Canjana 11/03/22</i>	All the bottles were verified			<i>Rej 11/03/22</i>
2) Remove the damage labels (Misalignmant printing)		<i>I Canjana 11/03/22</i>	All the labels were removed from the bottles			<i>Rej 11/03/22</i>
3) Replace with new labels		<i>I Canjana 11/03/22</i>	New labels were replaced			<i>Rej 11/03/22</i>
4) Re-print again the Expiry date and Lot number at correct position		<i>I Canjana 11/03/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Rej 11/03/22</i>
5) Proceed to Final Control Process		<i>I Canjana 11/03/22</i>	Verified in Final Control process and complies with all the specifications			<i>Rej 11/03/22</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>M. Arifuddeen</i>	Acknowledge By : <i>Martini Binti Ghazali</i>			Approved By : <i>Nurul Balkis Zamri</i>		
Name : MUHD. ARIFUDDINEEN	Name : MARTINI BINTI GHAZALI			Name : NURUL BALKIS ZAMRI		
Date: 11/03/2022	Date: 11/03/2022			Date : 11/03/2022		

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

