

SHOP PACKET - EASW

REFERENCE	HW34E100 BW34E100	ODR. QTY	30	RS: 2 + 2(QC TEST)	ISSUED DATE	07/01/2022
ITEM CODE	H0100006	PACK SIZE	50/BOX	LOT NO.	A20800	
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Bottle Cap Closure)	CUSTOMER	FARMABAN PARMABAN (SPANISH)	MFG. DATE	10/01/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 07/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 07/01/2022	EXP. DATE	2024-01	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton		INT. ORDER	I0/VMD/060122/01	
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-PI NO. (2nd Packaging) - Carton				

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	10:15 AM 08-01-22	34	34	NIL	Kyanday (893)	Wah 1037 5:25 PM 08-01-22
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :					N/A	UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	11:25 AM 10-01-22 11:35 AM 10-01-22	34	34	NIL	Faith (1051) Kali (1078)	Wah 11:35AM 10-01-22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	5:00 PM 11-01-22 5:15 PM 11-01-22	34	32	2	FARAH (1061) NINIE (1097)	Wah 5:15PM 11-01-22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	5:00PM 11-01-22 5:15PM 11-01-22	34	34	NIL	FARAH (1051) NINIE (1097)	Wah 5:15 11-01-22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :					N/A	
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :					N/A	
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 :	5:00PM 11-01-22 5:15PM 11-01-22	34	34	NIL	FARAH (1051) NINIE (1097)	Wah 5:20 PM 11-01-22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	5:30 PM 11-01-22 5:40 PM 11-01-22	1 Ctn	1 Ctn	NIL	ERA (922)	JINWA 11/01/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :					N/A	UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 34 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 2+2 btl
 SHIPMENT QUANTITY PCS / CTNS : 30 btl / 1 ctn
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : DATTA SEAGRAM Date : 11/1/22	Name : Rohamza Othman Date : 12/1/22	Name : MARTINI Designation : QA/QC DEPT Date : 11/01/2022 Stamp : 11/01/2022
Remarks: SPLIT FROM SHOP PACKET A20718 AS SAMPLE FOR FARMABAN. REFER EMAIL ATTACHED.		



VIGILENZ®

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

Item Description	Hgienic Areas, 250 ml Bottles after closure)		
Reference	BW34E00		
Lot No.	A20800		

No.	Checklist	Yes	No
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"/>
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"/>

No.	Checklist	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"/> Lyndar 10/01/22	<input type="checkbox"/> work 1037 10/01/22	<input type="checkbox"/> 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"/> Lyndar 10/01/22	<input type="checkbox"/> work 1037 10/01/22	<input type="checkbox"/> N/A	Technician
i) Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ii) Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
iii) Stopper Insertor	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
iv) Cap Dispenser	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
v) Cap Pusher	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<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"/> 'Canyon' 10/01/22	<input type="checkbox"/> work 10/01/22	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"/> 'Canyon' 10/01/22	<input type="checkbox"/> work 10/01/22	Production

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	<i>Hydrocyn Aqua, 250ml C/Bottle cap closure.)</i>		
Reference / Lot No.	<i>BIN 34E100</i>	/	<i>A 20800</i>
Order Qty	<i>34</i>		
Volume Specification	<i>255</i>	\pm	<i>5</i> 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	
						PASS	FAIL
10/10	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/24	260 mL	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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



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

Document type:
FORM

C. Attachment (First Printed Label)

Doc Id:	QC-IP002-09	Issue Date:	15/11/2021	Page:	2(3)
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 BACTIGUARD WOUND CARE Una solución avanzada para el lavado, desbridamiento e irrigación de heridas agudas y crónicas como úlceras en estadio I-IV, estasis venosa y úlcera diabética, heridas posquirúrgicas, quemaduras (1º a 2º grado) y úlceras por decubito. También ayuda a humedecer la herida y a controlar el mal olor. INSTRUCCIONES DE USO Sólo para uso externo. Se suministra lista para usar. Puede vaporizarse o nebulizarse sin comprometer las funciones respiratorias humanas. CONTRADICIONES No se conocen contraindicaciones.	INDICACIONES Solución de lavado, desbridamiento e irrigación de heridas agudas y crónicas como úlceras en estadio I-IV, estasis venosa y úlcera diabética, heridas posquirúrgicas, quemaduras (1º a 2º grado) y úlceras por decubito. También ayuda a humedecer la herida y a controlar el mal olor. INSTRUCCIONES DE USO Sólo para uso externo. Se suministra lista para usar. Puede vaporizarse o nebulizarse sin comprometer las funciones respiratorias humanas. CONTRADICIONES No se conocen contraindicaciones.
FECHA DE APERTURA Usar antes de 30 días después de la apertura	PRECAUCIONES No utilice el producto si el sello instantáneo está dañado o roto. No exponga el producto a temperaturas extremas. Almacenamiento recomendado por debajo de 30 °C. El producto es estable durante 24 meses a partir de la fecha de fabricación si se guarda en su embalaje original. La botella debe descartarse si se observan signos de contaminantes. Consulte a su especialista en atención médica si la herida persiste y se deteriora. Siempre deberá comunicar a su profesional sanitario cualquier incidente grave o adverso derivado del uso del producto
 WOUND CARE Favorece el proceso de cicatrización de las heridas. Bactericida, Esporícidica, Fungicida. Eliminación de hipopelículas.	
SOLUCIÓN 250 ml	
<small>REF: BW34E100 LOT: A20800 2024-QI</small>	
<small>VIGILENZ Medical Devices Sdn Bhd 30B, Penang Science Park 14100 Penang, Malaysia Importado por: FARMABAN S.A Pol. Ind. Santa Anna, C/Villa de Claret, 6 E-08272 Sant Feliu de Bages - España www.farmaban.com</small>	

Disposition of the Lot : PASS FAIL

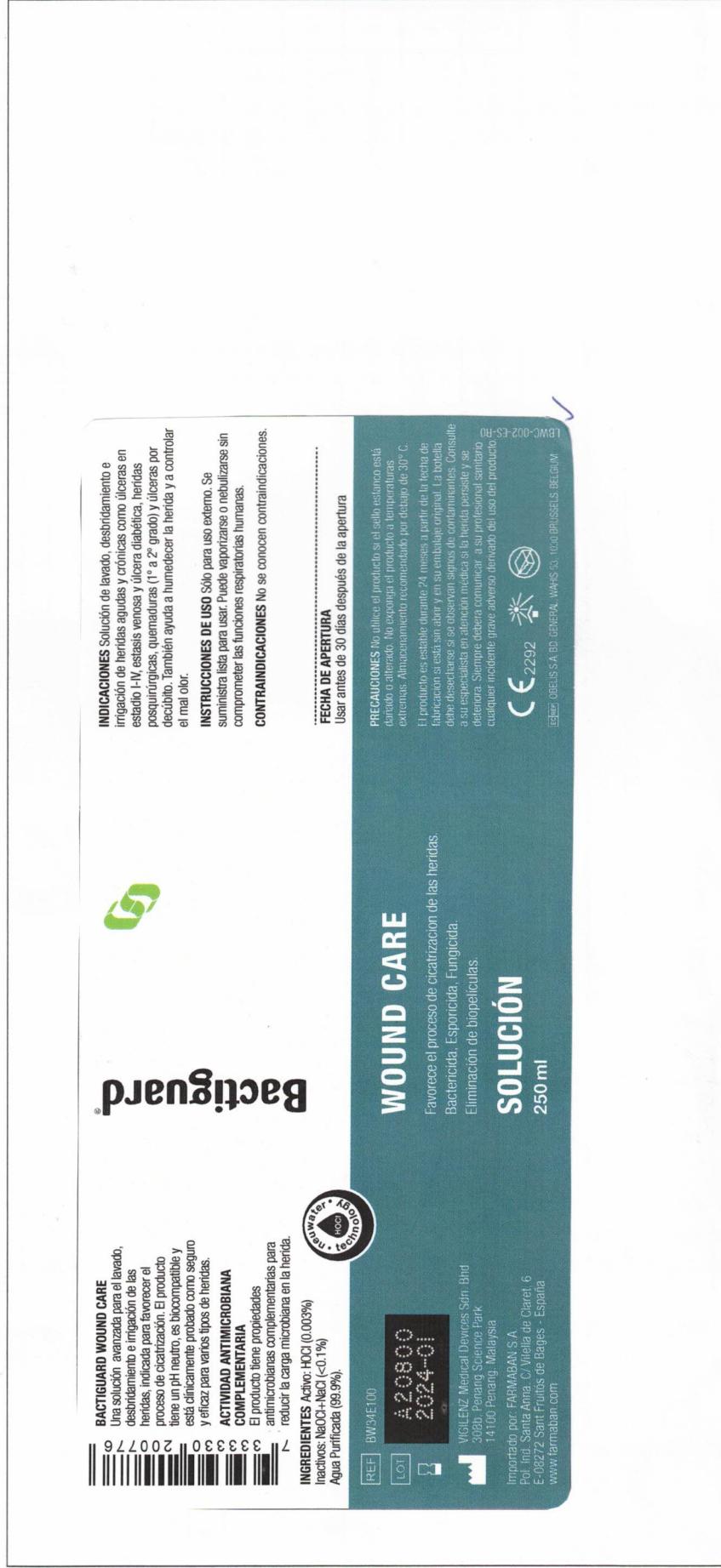
PASS FAIL

Inspected by : Pray
 Name : Peshaw
 Date : 1/10/2022

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
Document type:	Doc Id:	Bactiguard	Issue Date:

FORM
3333330

D. Attachment (Last Printed Label)



Inspected by : Lah
Name : wah wah
Date : 11.01.22

Disposition of the Lot : PASS FAIL

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No. Rev.	QC-FC004 09
ITEM DESCRIPTION : <i>WICH 11.01.22</i>	BuW 34 E 100 Hydracyn Aqua 250mL			

REFERENCE : BuW 34 E 100 QTY. PRODUCED (pcs) : 34
 LOT NO. : A20 800 RETAIN SAMPLE QTY. (pcs) : 2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL			Status (PASS/FAIL)
				Accept	Reject	Accept	
1	Legible and clean printing of label.	S3, 0.15	34	0	1	34	0
2	Free from contamination, deformed or damaged on packaging.	S3, 0.15	34	0	1	34	0
3	Proper sealing and no leaking.	S3, 0.15	34	0	1	34	0
4	Free from contamination / particle / foreign materials on product solution.	S3, 0.15	34	0	1	34	0
5	Correct volume filled (against reference sample).	S3, 0.15	34	0	1	34	0

Remarks : N/A

Inspected By : *Aashish*
 Name : *MARTINI*
 Date : *11/01/2022*

Approved By : *Martini*
 Name : *MARTINI*
 Date : *11/01/2022*

Ratnasegaran Mahendran

From: Kelvin Neoh
Sent: Friday, 7 January, 2022 11:01 AM
To: Fatin; 'Kamalia'; Ratnasegaran Mahendran; Jeevanend Arumugam; Wong Meeleng
Cc: 'Mirda'; Wawa; 'Ana'; Vanetha; Sathish Subramaniam
Subject: RE: Sample Requisition Form

Importance: High

Dear Ms Mee Leng,

Thank you for your support in providing us the Bactiguard Wound Care 250ml (Bottle Cap Closure) (Item No: BW34E100) 30pcs by morning of 11 Jan 2022. We must courier it out on the same day, so appreciate that you will look into having the FG, completed released by QC ready on the morning of 11 Jan 2021.

Thank you.

Kelvin Neoh

Business Development Manager



Disclaimer

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From: Fatin <fatin.aswani@vigilenzmd.com>

Sent: Wednesday, 5 January, 2022 6:03 PM

To: Kelvin Neoh <kelvin.neoh@bactiguard.com>; 'Kamalia' <marketing@vigilenzmd.com>; Ratnasegaran Mahendran <Ratnasegaran.Mahendran@bactiguard.com>; Jeevanend Arumugam <jeevanend.arumugam@bactiguard.com>

Cc: 'Mirda' <marketing1@vigilenzmd.com>; Wawa <corpcom@vigilenzmd.com>; Wong Meeleng <Wong.Meeleng@bactiguard.com>; 'Ana' <ana.mustafa@vigilenzmd.com>; Vanetha <vanetha.bhaskaran@vigilenzmd.com>; Sathish Subramaniam <sathish.subramaniam@bactiguard.com>

Subject: RE: Sample Requisition Form

Hi Kelvin,

For this week, we don't have any plan to run for 250ml bottle cap closure. I have include this size for next week planning since we have order from Tee Pham and to top up safety stock quantity.

Hi Mr Jeeva,

Currently SCM have 850 bottles for this size in safety stock – English label with blue cap.

Since BD is request Spain label with white cap, please advise if we can do rework 30 bottles from this safety stock.

DATE :	17/11/2021
REF :	BW34E100
LOT NO. :	A20800

SHOP PACKET QTY (pes) : 30
 CUSTOMER : FARMABAN (SPANISH)
 LO NO. : 10VMD/060122/01

ITEM DESCRIPTION 1		DESCRIPTION 2		UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2						
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	pc	34	34	34	34	Carjanaq
2	P0100814	White Cap for 250ml/500ml HDPE Plastic Container - Bactigard Woundcare	0	pc	34	34	34	34	Carjanaq
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	pc	34	34	34	34	Carjanaq
4	N/A	STOCK SOLUTION	N/A	ltr	9	9	9	9	Carjanaq

(2) PRODUCT PACKAGING

NO. SYSTEM CODE

ITEM DESCRIPTION 1

LOT NO.

QTY REQUIRED (pes)

RECEIVED BY

1	-	HYDROCYN AQUA 250ml CAP CLOSURE LABEL (SPANISH)	H01210602	35	Carjanaq
2					
3					
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7					

NO. SYSTEM CODE

ITEM DESCRIPTION 1

LOT NO.

QTY REQUIRED (pes)

RECEIVED BY

1	P0100566	DSN-H-009(A) - VIG-003-CTN-HYDROCYN 250ML(Cap Closure), Size: 330x330x 305mm, Mat: T180/M/T180 BA Flute	H060211102	1	Carjanaq
2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS 31.2 x 90mm(4pes each), Mat:T150/T150 B Flute	H069211001	1	Carjanaq
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 31.2 x 312mm, Mat: T150/T150 B Flute	H070211102	1	Carjanaq

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	#N/A	
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NO. SYSTEM CODE

ITEM DESCRIPTION 1

LOT NO.

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QTY REQUIRED (pes)

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrocyan Aquag, 250ml (botto Cap closure)	Reference No.	BW 34100	Date of Inspection	11/01/2022
Lot No.	A 20800	Sample Size	250ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)						Test Disposition (PASS / FAIL)
pH	ORP (mV)	FAC (ppm)	Spec: 95 - 140			
Result	Instrument	Result	Instrument	Result	Instrument	
8.66 11/01/2022 7.34	868 OC-18	8.68 OC-17	112	8.68 OC-80		

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Hawwa Nawar
Name : Martini
Date : 11/01/2022



Approved By : Martini
Name : Martini
Date : 11/01/2022

Rework Disposition :

Production had completed all the rework steps and proceed to final control process. Qc had verified during all the rework steps and complies with the specifications.

Prepared By :

Name : MR.RATNA

Date: 11/01/2022

Acknowledge By : 

Name : MARTINI BINTI GHAZALI

Date: 11/12/2023

Approved By:

Name : MR. JEEVANEND

Name _____

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

