

SHOP PACKET - EASW


SHOP PACKET - EASW						
REFERENCE	HW36D100	ODR. QTY (PCS)	50	RS: 2 + 1 (QC TEST)	ISSUED DATE	22/01/2022
ITEM CODE	H0100007	PACK SIZE	12/BXS		LOT NO.	A222S00
ITEM DESCRIPTION	Hydrocyn Aqua, 1000ml (Bottle Cap Closure)	CUSTOMER	BD (PRIZMA TRADE SERBIA)		MFG. DATE	22/01/2022
		ODR. NO	A144		EXP. DATE	2024-01
PREPARED BY	NAME : UDHAYESREE DATE : 22/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 22/01/2022		INT. ORDER	10/BD/200122/04
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:	8:45 AM	53	53	Nil	K. Vaidya (893)	Roshni 4:00pm 24/01/2022	Tank 1000L/17 03H B200122015
DATE:	24-01-22						
TIME COMPLETE:	4:00 PM						
DATE:	24-01-22						
UDI PRINTING (Label/Box/Carton)							
TIME START:					N/A		UDI NOT REQUIRED FOR THIS LOT
DATE:							
TIME COMPLETE:							
DATE:							
SOLUTION FILLING & CAPPING							
TIME START:	4:30 PM	53	53	Nil	Netra (1103)	Roshni 5:15pm 25/01/22	NA
DATE:	25-01-22						
TIME COMPLETE:	5:15 PM						
DATE:	25-01-22						
LABELLING							
TIME START:	5:15 PM	53	53	Nil	bahira	Roshni 5:40pm 25/01/22	NA
DATE:	25-01-22						
TIME COMPLETE:	5:40 PM						
DATE:	25-01-22						
PRINTING LOT NUMBER							
TIME START:	5:15 PM	53	53	Nil	Netra (1103)	Roshni 5:40 pm 25/01/22	ND
DATE:	25-01-22						
TIME COMPLETE:	5:40 PM						
DATE:	25-01-22						
CAP SEALING (Applicable for 100mL)							
TIME START:					N/A		
DATE:							
TIME COMPLETE:							
DATE:							
BOX PACKING & PRINTING (Applicable for 100ml only)							
TIME START:					N/A		
DATE:							
TIME COMPLETE:							
DATE:							
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)							
TIME START:					N/A		UDI NOT REQUIRED FOR THIS LOT
DATE:							
TIME COMPLETE:							
DATE:							
FINAL CONTROL							
TIME START:	5:15 PM	53	53	Nil	Netra (1103)	Wah 5:45PM 25.01.22	NA
DATE:	25-01-22						
TIME COMPLETE:	5:40 PM						
DATE:	25-01-22						
CARTON PACK							
TIME START:	3:45 PM	5 ctn	5 ctn	Nil	HEED1 (1053)	Nurin 26/1/22	Kym 25/01/2022
DATE:	20-01-22						
TIME COMPLETE:	4:00 PM						
DATE:	20-01-22						
UDI LABELLING							
TIME START:					N/A		UDI NOT REQUIRED FOR THIS LOT
DATE:							
TIME COMPLETE:							
DATE:							

QUANTITY PRODUCED :	53 btl
QUANTITY FOR QC / RETAIN SAMPLE :	2+1 btl
SHIPMENT QUANTITY PCS / CTNS :	50 btl / 5 ctn
FINAL SHIPMENT DATE :	
COMPLETE/ PARTIAL :	COMPLETE

Checked by (PR), Signature: <i>[Signature]</i> Name: Ratnasegaran Date: 25/1/22	Approved by (QA), Signature: <i>[Signature]</i> Name: Rohanra Chandra Date: 27/1/22	Released by (QC), Signature: <i>[Signature]</i> Name: AARTINI Designation: QC DEPT Date: 27/01/2022 Stamp:
Remarks: SAMPLE REQUEST BY CUSTOMER PRIZMA TRADE SERBIA		



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)	

Item Description	Hydrogen Peroxide, 1000 mL (bottle cap closure)
Reference / Lot No.	HUG0100 / A222500
Order Qty	50
Volume Specification	1020 ± 20 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	1030 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/43	1030 ml	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>

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
10/10	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1/43	✓	✓	✓	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>

VIGILENZ®	CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No	QC-LC002
			Rev.	00

Item Description	Hydrocyn Aqua, 1000ml (Bottle cap closure)
Reference	HU 36 D100
Lot No.	A 222500

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"/>	Hyndan 25/01/22	Wah 25.01.22	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) Starwheel ii) Nozzle iii) Stopper Insertor iv) Cap Dispenser v) Cap Pusher	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	N A Hyndan 25/01/22	N A	N A	Technician
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Hyndan 25/01/22	Wah 25.01.22	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"/>	Hyndan 25/01/22	Wah 25.01.22	N A	Production

Handwritten signature
25/01/22

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: 2(3)

C. Attachment (First Printed Label)

HYDROCYN aqua

Advanced Wound Care Solution

- Bactericidal
- Sporicidal
- Fungicidal
- Biofilm removal

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%)
Inactive - NaOCl + NaCl (<0.1%)
Purified Water - 99.9%

REF HW36D100

LOT A222800
2024-01

MDA-GD1130224916

VIGILENZ Medical Devices Sdn. Bhd.
308 b, Penang Science Park
14100 Penang, Malaysia
www.vigilenzmd.com

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.

Date opened: _____
Use by 30 days of opening

CE 2292

1 010 102009

NEUWATER®
Electro Activated
Super-Oxidized Technology

VIGILENZ® 1000 ml

9 55544681915720

OBELIS S.A.
BD. GENERAL WAHIS 53
1030 BRUSSELS, BELGIUM

Disposition of the Lot :	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL
Inspected by :	Pohay	
Name :	Pohay	
Date :	25/01/2022	

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: 3(3)

D. Attachment (Last Printed Label)

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Inactive - NaOCl + NaCl (<0.1%)
Purified Water - 99.9%

LOT A222800
2024-01

REF HW36D100

MDA-GD1130224916


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14100 Penang, Malaysia
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HYDROCYN[®]

aqua

Advanced Wound Care Solution

- Bactericidal
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NEUWATER[®]
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CONTRAINDICATIONS
No known contraindications.

Date opened:

Use by 30 days of opening

CE 2292

ORTELIS S.A.
RD. GENERAL WAHIS 53
1050 BRUSSELS, BELGIUM

LBH-1000-R0

SAMPLE
NOT FOR SALE

Disposition of the Lot :

☒ PASS

☐ FAIL

Inspected by : Wah

Name : Wah Wah

Date : 25.01.2022

2022-10-25

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No.	QC-FC004
			Rev.	09

ITEM DESCRIPTION : Hydrogen Peroxide 1000mL

REFERENCE : HW3G3100

LOT NO. : A222800

QTY. PRODUCED (pcs) : 53

RETAIN SAMPLE QTY. (pcs) : 2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	S ₃ , 0.15	53	0	1	53	0	pass
2	Free from contamination, deformed or damaged on packaging.	S ₃ , 0.15	53	0	1	53	0	pass
3	Proper sealing and no leaking.	S ₃ , 0.15	53	0	1	53	0	pass
4	Free from contamination / particle / foreign materials on product solution.	S ₃ , 0.15	53	0	1	53	0	pass
5	Correct volume filled (against reference sample).	S ₃ , 0.15	53	0	1	53	0	pass

Remarks : N/A

Inspected By : wah
Name : wah wah
Date : 25.01.2022

Approved By : [Signature]
Name : MA RTINI
Date : 26/01/2022

RAW MATERIAL LOADING FORM (RMLF)

DATE : 25/01/2022

REF : HW36D100

LOT NO. : A222S00

SHOP PACKET QTY (pcs) : 50

CUSTOMER : BD (PRIZMA TRADE SERBIA)

LO NO. : IO/BD/200122/04


NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100799	1000ml HDPE Plastic Container	0	H01C211201	pcs	53	53	Kanjand
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210901	pcs	53	53	Kanjand
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078220101	pcs	53	53	Kanjand
4		STOCK SOLUTION		03H020022015	ltr	59	59	Kanjand

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100582	DSN-H-011(A) - VIG-001-CTN,Printed Carton for Hydrocyn 1000ml,Size: 380 x 290 x 220mm(E), Mat: T180M/T180 BA FLUTE	H103211101	4	metes
2	P0100583	DSN-H-011(B) - VIG-904-ASY,NL: 377 x 145mm (2pcs) & NS: 282 x 145mm(3pcs) for Carton E, Mat: T150/T150 B Flute	H041200401	4	metes
3	P0100584	DSN-H-011(C) - VIG-904-ASY, Layer Pad for Carton E, Size: 377 x 282mm, Mat: T150/T150 B Flute	H042210601	4	metes

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100643	LBH-1000-R0 -Hydrocyn Aqua 1000ml Cap Closure, Size : 250mm x 110mm, Material : White PP	L18H200501	54	Rayano
2		#N/A			
3		#N/A			

(4) SPECIAL REQUIREMENT					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	-NA-	53	KANJAND
2		#N/A			

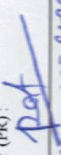
ISSUED BY (MM) :

Signature : 

Name : FIRDAUS

Date : 25/01/2022

VERIFIED BY (PR) :

Signature : 

Name : KANJAND

Date : 26/1/22

VIGILENZ®	PRODUCT RELEASE TEST REPORT – ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc No.	QC-PC007
			Rev.	06

Description	Hydrocyn Aqua 500ml (Bottle Cap Closure)	Reference No.	HW26D100	Date of Inspection	26/01/2022
		Lot No.	A232500	Sample Size	1btl x 1000ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)						Test Disposition (PASS / FAIL)
pH		ORP (mV)		FAC (ppm)		
Spec: 6.50 - 8.00		Spec: ≥ 850		Spec: 95-140		
Result	Instrument	Result	Instrument	Result	Instrument	pass
7.02	QC-78	862	QC-67	108	QC-80	

☒ RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : ☒ RELEASE ☐ ON-HOLD

Analyzed By : Ravi
Name : POHNE
Date : 26/01/2022

Approved By : [Signature]
Name : A. M. KOTANI
Date : 26/01/2022

