

SHOP PACKET - EASW 16/2/22 10 10

REFERENCE	HW34E100	ODR. QTY (PCS)	4,000 2000 btl	RS(2) QC(2)	ISSUED DATE	14/02/2022
ITEM CODE	H0100006	PACK SIZE	50/Box		LOT NO.	B21407
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Bottle Cap Closure)	CUSTOMER	VMD		MFG. DATE	14/02/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 14/02/2022	ODR. NO	B068		EXP. DATE	2024-02
		VERIFIED BY		NAME : RATNASEGARAN DATE : 14/02/2022	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 :	11:20 Am 21-02-22 2:40 PM 21-02-22	2008	2008	NIL	Wah	Tank 500L IT5 03HB210222049 TANK 1000L IT7 03HB210222051
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 :	9:50 am 02-02-22 12:25pm 02-02-22	2008	2004	4	MIRA (1118)	Wah 12:25PM 22-2-22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	9:50 am 22-02-22 12:25pm 22-02-22	2008	2008	NIL	Dewi (1126)	Wah 12:25PM 22-2-22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	9:50 am 22-02-22 12:25pm 22-02-22	2008	2008	NIL	Dewi (1126)	Wah 12:25PM 22-2-22
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 :	9:50 AM 22-02-22 12:25PM 22-02-22	2008	2008	NIL	Dewi (1126)	Wah 12:45 PM 22-02-2022
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	3:00 pm 22-02-22 9:20 pm 23-02-22	40 eth	40 eth	NIL	Mangku Jenius (1620)	Nurin 4/3/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 2008 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 44 btl
 SHIPMENT QUANTITY PCS / CTNS : 2000 btl
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : Mohd Idris Date : 4/3/2022	Name : Pohamza Othman Date : 4/3/2022	Name : MARTIN Designation : IPQC SUP Date : 4/3/2022 Stamp :
Remarks:		

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

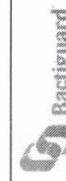
Doc. No	QC-LC002
Rev.	00

Item Description	<i>Hydrocyn Aqua, 250 mL (Bottle cap closure)</i>		
Reference	<i>Hw34E100</i>		
Lot No.	<i>B21407</i>		

No.	Checklist	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	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>Wah 293</i> 22/02/2022	<i>Wah</i> 22/02/2022	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Wah 293</i> 22/02/2022	<i>wah</i> 22/02/2022	N/A	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>Wah 22/02/22</i>	<i>Wah</i> 22/02/22	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"/>	<i>Wah 22/02/22</i>	<i>Wah</i> 22/02/22	N/A	Production

Title:

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

Document type:
FORMDoc Id:
QC-IP002-09Issue Date:
15/11/2021Page:
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Item Description	<i>Hydronyn Aqua, 250 mL C bottle cap closure J</i>	
Reference / Lot No.	<i>MW34E100 / B21407</i>	
Order Qty	<i>2000</i>	
Volume Specification	<i>255</i>	<i>± 5 ml</i>

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
<i>10/6</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>260 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

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
<i>10/10</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/200</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

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	Hydrocyn Aquas 250 mL (Bottle cap closure)		
Reference / Lot No.	H/W34E100	/	B21407
Order Qty	2000		
Volume Specification	255	±	5 ml

A. Filling Process

B. Labelling. Lot No. Manufacturing Date and Fyniry 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: 1(3)
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Item Description	
Reference / Lot No.	
Order Qty	M/14
Volume Specification	± ml

A. Filling Process

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

file:

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

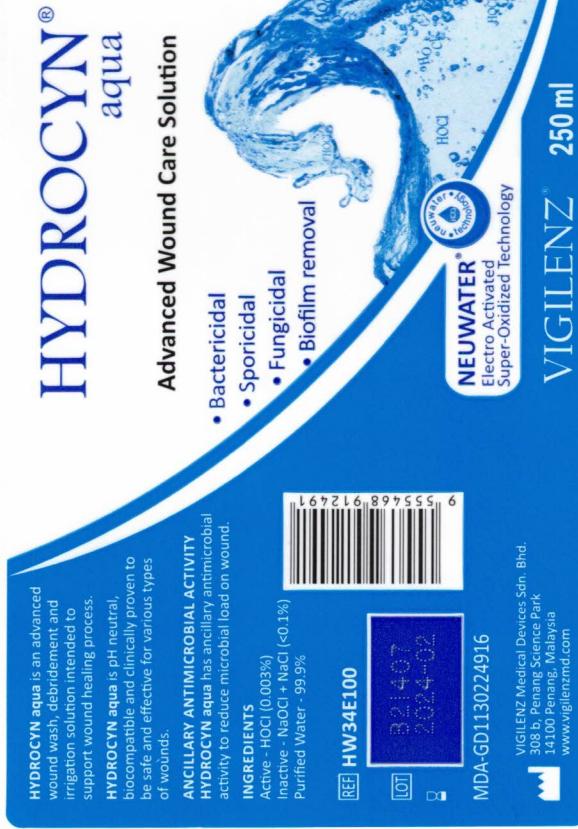
Document type:
FORM

Doc Id:
QC-IP002-09

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15/11/2021

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

REF HW34E100

321407
2024-02

MDA-GD1130224916

[LOT]

Q

VIGILENZ Medical Devices Sdn Bhd.

308 b, Penang Science Park
14100 Penang, Malaysia
www.vigilenz.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 (Ist-IInd 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-R20
Use by 30 days of opening
REF HW34E100
Δ ☛ ☚ € 2292
LBB-03/2020
GELUS S.A.
NO. GENERAL WATIS 53
1000 BRUSSELS, BELGIUM

Woh

Disposition of the Lot : PASS FAIL

PASS FAIL

Inspected by : *Woh*

Name

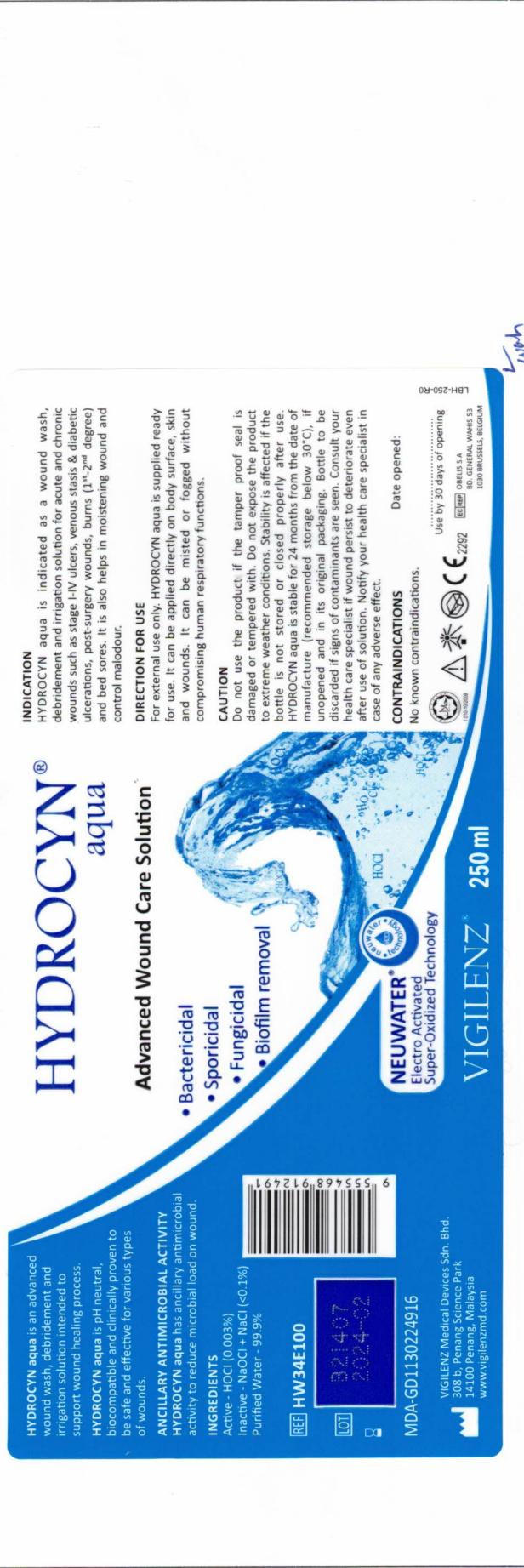
WohWoh

Date

22/01/22

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Document type:	Doc Id:	Bactiguard	Page:
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D. Attachment (Last Printed Label)



Inspected by : Wah
 Name : Wah Wah
 Date : 22.01.22

Disposition of the Lot : PASS FAIL

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
ITEM DESCRIPTION	Hydrogen Peroxide 250 mL	Doc. No.	QC-FC004

REFERENCE	HAN 34E 00	Rev.	09
LOT NO.	B21407		
QTY. PRODUCED (pcs)	2008		

RETAIN SAMPLE QTY. (pcs) : 4

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

Remarks : N/A

Inspected By : Lokesh
 Name : KIRTIN
 Date : 22.02.2022

Approved By : Rajesh
 Name : KIRTIN
 Date : 4/3/2022

DATE :	16/02/2022
REF :	HW34E100
LOT NO. :	B21407

SHOP PACKET QTY (pes) :
CUSTOMER : VMD (MALAYSIA)
LO. NO. : I0VMD110222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H012210602	pes	2004		2004	2004	✓ Caujauq
2	P01002813	#N/A		H020210601	pes	2004		2004	2004	✓ Caujauq
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pes	2004		2004	2004	✓ Caujauq
4		STOCK SOLUTION		034B210222049 034B210222051	ltr	521	521	521	521	✓ Caujauq

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100642	LBH-250-RHydrocyn Aqua 250ml Cap Closure, Size : 170mm x 77mm, Material : White PP	L134211002	2005	✓ Caujauq
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	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/Fuite	H060211102	40	meily
2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS: 312 x 90mm(4pes each), Matt/T150/T150 B Flute	H069211101	80	meily
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Matt/T150/T150 B Flute	H070211102	40	meily

(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	#N/A	NA
2			#N/A		

ISSUED BY (MM):
Signature : Lovin _____
Name : Lovin _____
Date : 16/02/2022

VERIFIED BY (PR):
Signature : P. Mohd. Yusof _____
Name : P. Mohd. Yusof _____
Date : 16/02/2022

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

Doc No.	QC-PC007
Rev.	06

Description	Hypochlor Doser, 250ml (Bottle cap closure)	Reference No.	HW34E100	Date of Inspection	23/3/2013
Lot No.	B01407			Sample Size	20ml 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
7.34	Qc-78	879	Qc-67	110	Qc-80
					PASS

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 500L/15 0848210022049

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Raj
Name : Rajini
Date : 23/03/2013

Approved By : *Rajini*
Name : Rajini
Date : 23/03/2013



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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide, 250mL (Both cap closure)	Reference No.	H024E100	Date of Inspection	23/01/2014
Lot No.	B21407	Sample Size	250mL 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
7.24	ORP 78	850	ORP 67	116	ORP 80 pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000L/r7 03H/B 21022005/

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rajiv

Name : Parineet
Date : 23/01/2014



Approved By : M A RTRN
Name : 23/01/2014
Date :