

2021 24th

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY (PCS)	1,824	RS: 2 + 1(QC TEST)	ISSUED DATE	15/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX	LOT NO.	AC2508	
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	15/01/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 15/01/2022	VERIFIED BY	ODR. NO A104 NAME : RATNASEGARAN DATE : 15/01/2022	EXP. DATE	2024-01	INT. ORDER
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	EPOC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START:	9:30 Am					
DATE:	24-01-22					
TIME COMPLETE:	5:00Pm					
DATE:	24-01-22					
UDI PRINTING (Label/Box/Carton)						
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						
SOLUTION FILLING & CAPPING						
TIME START:	10:00 AM					
DATE:	25-01-22					
TIME COMPLETE:	1:22 PM					
DATE:	25-01-22					
LABELLING						
TIME START:	10:00 AM					
DATE:	25-01-22					
TIME COMPLETE:	1:22 PM					
DATE:	25-01-22					
PRINTING LOT NUMBER						
TIME START:	10:00 AM					
DATE:	25-01-22					
TIME COMPLETE:	1:22 PM					
DATE:	25-01-22					
CAP SEALING (Applicable for 100mL)						
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						
FINAL CONTROL						
TIME START:	10:00 AM					
DATE:	25-01-22					
TIME COMPLETE:	1:30 PM					
DATE:	25-01-22					
CARTON PACK						
TIME START:	3:00 PM					
DATE:	25-01-22					
TIME COMPLETE:	5:30 PM					
DATE:	25-01-22					
UDI LABELLING						
TIME START:						
DATE:						
TIME COMPLETE:						
DATE:						

QUANTITY PRODUCED	1827 btl
QUANTITY FOR QC / RETAIN SAMPLE	2+1 btl
SHIPMENT QUANTITY PCS / CTNS	1824 bts / 76ctns
FINAL SHIPMENT DATE	
COMPLETE / PARTIAL	COMPLETE PARTIAL

Checked by (PR), Signature: <i>[Signature]</i> Name: <i>KRISHNA LAL</i> Date: <i>26/1/22</i>	Approved by (QA), Signature: <i>[Signature]</i> Name: <i>Rohamiza Othman</i> Date: <i>27/1/2022</i>	Released by (QC), Signature: <i>[Signature]</i> Name: <i>MARTINI</i> Designation: <i>QC DEPT</i> Date: <i>27/1/2022</i> Stamp: <i>[Stamp]</i>
Remarks:		

BACTIGUARD (S.E.A) SDN BHD • RELEASED • QUALITY CONTROL

VIGILENZ®

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

Doc. No QC-LC002
Rev. 00

Item Description	<i>Hydrogen Peroxide, 500 ml (Bottle cap cleaning)</i>			
Reference	<i>HWS5.D100</i>			
Lot No.	<i>A21508</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>Kyodan 25/01/22</i>	<i>Poly 25/01/22</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)	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 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>Camjana 25/01/22</i>	<i>Poly 25/01/22</i>	<i>NA</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>Camjana 25/01/22</i>	<i>Poly 25/01/2022</i>	<i>NA</i>	Production

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: 1(3)		

Item Description	<i>Hydrogen Peroxide, 900 ml (Bottle cap closure)</i>	
Reference / Lot No.	<i>Hu35 D100/A 21508</i>	
Order Qty	<i>1824</i>	
Volume Specification	<i>515</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
PASS						FAIL
<i>10/10</i>	<i>520 ml</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>12/60</i>	<i>520 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>11/60</i>	<i>520 mL</i>	<i>✓</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>10/60</i>	<i>520 mL</i>	<i>✓</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>10/60</i>	<i>520 mL</i>	<i>✓</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>11/60</i>	<i>520 mL</i>	<i>✓</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>12/60</i>	<i>520 mL</i>	<i>✓</i>	<i>-</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/217</i>	<i>520 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
PASS					FAIL
<i>10/10</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>12/60</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>11/60</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>10/60</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>11/60</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>12/60</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/217</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bactiguard	Issue Date: 15/11/2021	Page: 1(3)
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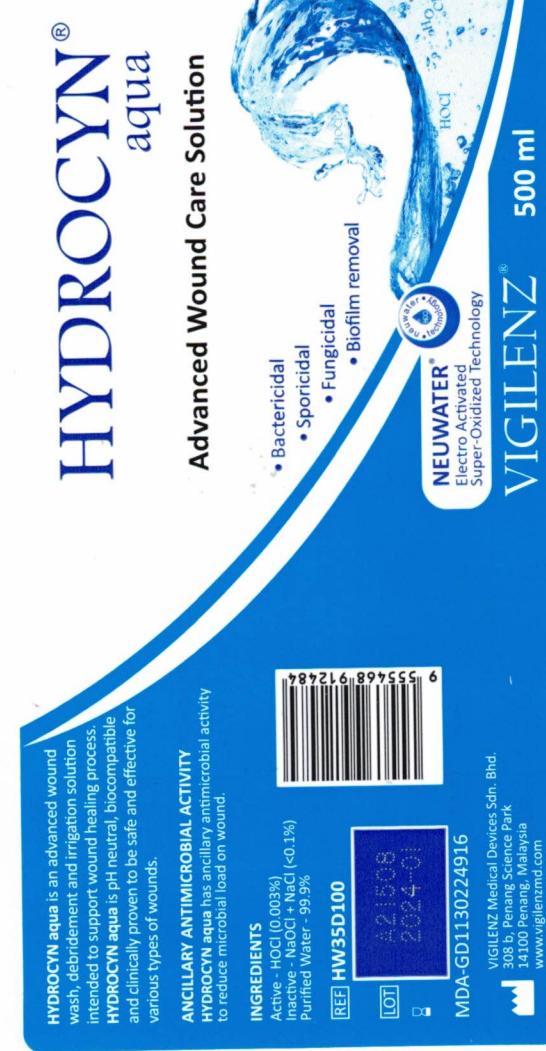
Item Description	
Reference / Lot No.	
Order Qty	
Volume Specification	± ml

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)		
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C. Attachment (First Printed Label)



Bactiguard
Issue Date:
15/11/2021

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 also helps in moistening wound and controls 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.

Use by 30 days of opening
REF ID: OBELIS S.A.
BD. GENERAL AVANIS 53
1030 BRUSSELS, BELGIUM
1/10/2020
CE 2292

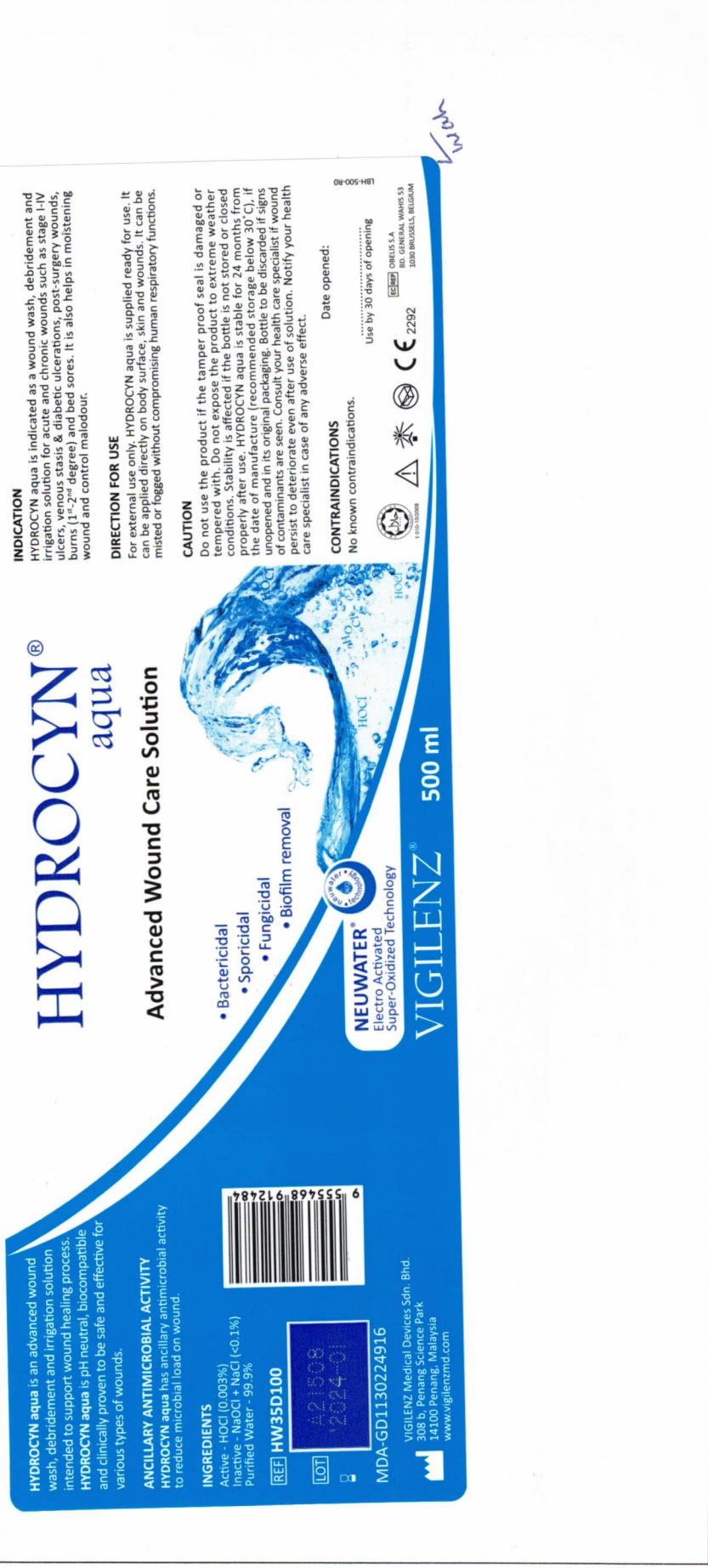
Disposition of the Lot : PASS FAIL

PASS FAIL

Inspected by : Poly
Name : Pengint
Date : 25/11/2021

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

D. Attachment (Last Printed Label)



Disposition of the Lot: PASS FAIL

Inspected by : Woh
Name : Woh
Date : 25.0

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ITEM DESCRIPTION : *Wash*
25.01.22

Doc. No.	QC-FC004
Rev.	09

REFERENCE : *Hu35D100*

QTY. PRODUCED (pcs)	: <i>1824</i>
RETAIN SAMPLE QTY. (pcs)	: <i>2</i>

LOT NO.

Sampling Details	Sample Size	AQL	Results	Status
S ₃ , 0.15	80	0	1	80 0 <i>pass</i>
S ₃ , 0.15	80	0	1	80 0 <i>pass</i>
S ₃ , 0.15	80	0	1	80 0 <i>pass</i>
S ₃ , 0.15	80	0	1	80 0 <i>pass</i>
S ₃ , 0.15	80	0	1	80 0 <i>pass</i>
S ₃ , 0.15	80	0	1	80 0 <i>pass</i>

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

Remarks : *N/A*Inspected By : *Wach*
Name : *MARTINI*
Date : *25.01.2022*Approved By : *Martini*
Name : *MARTINI*
Date : *25/01/2022*

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE :	20/01/2022
REF :	HW35D100
LOT NO. :	A21508

SHOP PACKET QTY (pes)	: 1824	RS
CUSTOMER	: VMD (MALAYSIA)	
LO NO.	: IOVMD130122/01	

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		RECEIVED BY
							ISSUED	CONSUMPTION	
1	P0100242	500ml HDPE Plastic Container (New Version)	(C/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010211101	pcs	1827	1827	1827	<i>1827</i>
2	P0100200	Blue Cap for 500ml HDPE Plastic Container		H020210601	pcs	1827	1827	1827	<i>1827</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078211101	pcs	1827	1827	1827	<i>1827</i>
4	N/A	STOCK SOLUTION		N/A	ltr	950	950	950	<i>950</i>
				03HB2401202015					

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)
1	P0100679	500ml Hydrogen Aqua carton -469L X 315W X 219H (BAF)		H165211103	76
2	P0100680	500ml nesting short and long-		H065211103	76
3		#N/A		#N/A	
(4) SPECIAL REQUIREMENT					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)			
2		#N/A		#N/A	

ISSUED BY (MM) : *LOVIN*
Signature : *LOVIN*
Name : *LOVIN*
Date : 20/01/2022

VERIFIED BY (PM) : *Ad*
Signature : *Ad*
Name : *Ad*
Date : 26/1/22

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Aqua 500ml (bottle & closure)	Reference No.	HU25D100	Date of Inspection	25/01/2023
Lot No.	A21508	Sample Size	1btlx 500ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	FAC (ppm)			Test Disposition (PASS / FAIL)
Spec:	Spec: >850	Instrument	Result	Instrument	
7.0	855	Q1-78	Q1-67	114	PASS

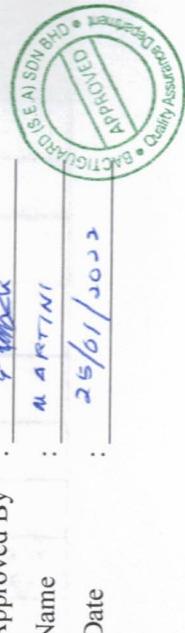
- RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Roy*
Name : *POSTNII*
Date : *25/01/2023*

Approved By : *M. Ariffiani*
Name : *M. Ariffiani*
Date : *25/01/2023*



Rework Instruction No. : R1-PM12-22023						
Reference Code	HW35D100	Lot No.	A21508	Lot Quantity (pcs)	1827	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 checked="" type="checkbox"/> Not Required	Trainer : N/A			
Rework Operator	<i>Nehru</i>					
Required Tools	N/A					
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)	
1) Segregate the affected bottles	<i>Kayawu 25/01/22</i>	All the bottles were verified			<i>Raj 25/01/22</i>	
2) Remove the damage labels (Misalignment printing)	<i>Kayawu 25/01/22</i>	All the labels were removed from the bottles			<i>Raj 25/01/22</i>	
3) Replace with new labels	<i>Kayawu 25/01/22</i>	New labels were replaced			<i>Raj 25/01/22</i>	
4) Re-print again the Expiry date and Lot number at correct position	<i>Kayawu 25/01/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Raj 25/01/22</i>	
5) Proceed to Final Control Process	<i>Kayawu 25/01/22</i>	Verified in Final Control process and complies with all the specifications			<i>Raj 25/01/22</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>R. M.</i>	Acknowledge By : <i>M. B.</i>		Approved By : <i>J. E.</i>			
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI		Name : MR.JEEVANEND			
Date: 25/01/2022	Date: 25/01/2022		Date : 26/01/2022			

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

