

SHOP PACKET - HYDROCYN AQUA GEL SPRAY (BOV)

REFERENCE	HW42E800	ODR. QTY	250	RS 2 + 1 (QC TEST)	ISSUED DATE	04/02/2022
ITEM CODE	H0100029	PACK SIZE	50/BOX		LOT NO.	B20406
ITEM DESCRIPTION	Hydrocyn Aqua Gel Spray (BOV) 50g	CUSTOMER	BD		MFG. DATE	04/02/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 04/02/2022	VERIFIED BY	NAME : MUHD ARIFUDDIN DATE : 04/02/2022		EXP. DATE	2023-08
					INT. ORDER	IO/CYN/060505/01

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 8:07 PM DATE : 19/02/22 TIME COMPLETE : 1:48 PM DATE : 18/02/22	253 253	253 253	NIL NIL	Fareeh (1051) Fareeh (1051)	Roshni 1:18pm 18/02/22	N/A
GASSING AND CRIMPING						
TIME START : 9:45 PM DATE : 19-02-22 TIME COMPLETE : 0230 PM DATE : 19-02-22	253	253	NIL	Bashirai (1117) Dewi (1126)	Roshni 19/02/2022 2.30pm	N/A
GEL FILLING						
TIME START : 8:50 AM DATE : 19/02/22 TIME COMPLETE : 10:00 am DATE : 19/02/22	253	252	1	Bashirai (1117) Dewi (1126)	Roshni 10.00am 19/02/22	-1 can repeat replace with new can
INSERT AND TEST ACTUATOR						
TIME START : 8:50 AM DATE : 19-02-22 TIME COMPLETE : 10:00 AM DATE : 29-02-22	253	253	NIL	Dewi (1126)	Roshni 10.00am 29/02/22	N/A
CAPPING						
TIME START : 8:50 AM DATE : 29-02-22 TIME COMPLETE : 10:00 AM DATE : 19-02-22	253	253	NIL	Dewi (1126)	Roshni 10.00am 19/02/22	N/A
LABELLING						
TIME START : 4:15PM DATE : 20-05-03 TIME COMPLETE : 4:40pm DATE : 20-05-03	253	246 246	7	FARAH (1051) ISMACH (1174)	Roshni 4:40pm 20/5/2022	ND
PRINT LOT NUMBER & EXPIRY DATE						
TIME START : 4:15PM DATE : 20-05-03 TIME COMPLETE : 4:40pm DATE : 20-05-03	253	253	NIL	FARAH (1051) ISMACH (1174)	Roshni 4:40 pm 20/5/2022	ND
FINAL CONTROL						
TIME START : 4:15PM DATE : 20-05-03 TIME COMPLETE : 4:40PM DATE : 20-05-03	253	253	NIL	FARAH (1051)	Roshni 4:40 pm 20/5/2022	ND
CARTON PACK						
TIME START : 3:15 PM DATE : 24-05-22 TIME COMPLETE : 3:30 PM DATE : 24-05-22	5 ctn	5 ctn	NIL	DARMA 1192	J MVM 24/5/2022 25/05/22	QMF 25/05/22

QUANTITY PRODUCED : 253
 QUANTITY FOR QC / RETAIN SAMPLE : RS 2716H
 SHIPMENT QUANTITY PCS / CTNS : 250 / 5 ctn
 COMPLETE/PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : Nur Shahira Date : 25/5/2022	Name : Rohamiza Darmen Date : 06/06/2022	Name : Martin Designation : IPQC supervisor Date : 02/06/2022
Remarks:	Stamp :	

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HYDROCYN aqua® GEL - RECORDS OF PREPARATION

Equipment ID	
QC-56	HSM-01
Purified Water (L)	3.0 - 3.1
Lithium Magnesium Sodium Silicate (g)	120 ± 1
Sodium Hypochlorite (ml)	30.0 ± 0.05
PDV Salt (g)	3.0 ± 0.1

Date : 18/05/2022

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QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua®
GEL SPRAY (BOV)

Reference / Lot No.	BWY01800 / BWY0106	Doc. No	QC-IP000
Order Qty.	250	Rev.	00

Sampling / Frequency	Instrument No.: Q11-130	(50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)				
		1	2	3	4	5

A. Before Filling

Batch No.	Container No.	pH (9.00 – 10.50)	FAC (100 – 200 ppm)	Viscosity (8,000 – 10,000 cps)	Gel is Clear and Free from Contamination	Test Disposition (PASS / FAIL)
		Instrument No.: Q11-130 Calibration due date: 09/06/2023	Instrument No.: Q11-130 Calibration due date: 10/10/2023	Instrument No.: Q11-130 Calibration due date: 01/07/2023		
01B/8022005	675	9.73	copy	8412	✓	pass
01B/8022006	676	9.73	copy	8412	✓	pass
				NA		

B. Gassing Process

Sampling / Frequency	Instrument No.: Q11-130	Pressure (50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)					Test Disposition (PASS / FAIL)
		1	2	3	4	5	
5/5	0.7 mpa	0.8 mpa	0.8 mpa	0.8 mpa	0.8 mpa	0.8 mpa	pass
1/5	0.8 mpa	0.8 mpa	0.9 mpa	0.9 mpa	0.9 mpa	0.9 mpa	pass
2/5	0.9 mpa	0.9 mpa	0.7 mpa	0.8 mpa	0.8 mpa	0.8 mpa	pass
3/5	0.8 mpa	0.7 mpa	0.9 mpa	0.7 mpa	0.7 mpa	0.7 mpa	pass
4/5	0.8 mpa	0.8 mpa	0.9 mpa	0.8 mpa	0.8 mpa	0.7 mpa	pass
5/5	0.8 mpa	0.8 mpa	0.8 mpa	0.7 mpa	0.9 mpa	0.9 mpa	pass

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QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

Doc. No

QC-IP006

Rev.

00

C. Crimping Process

Sampling / Frequency	Crimp width and depth (mm) – 50g / 100g					Test Disposition (PASS / FAIL)				
	Depth Specifications: ≥ 5.1 mm									
	Width Specifications: ≥ 27.1 mm									
Instrument No.: Q6-128	Instrument No.: Q6-129	Calibration due date: N/A	Calibration due date: N/A	1	2	3				
Calibration due date: N/A	Calibration due date: N/A	4	5	1	2	3				
1	2	3	4	5	1	2				
5/5	5.2 mm	5.2 mm	5.3 mm	5.2 mm	5.3 mm	27.8 mm	27.7 mm	27.8 mm	27.6 mm	pass
1/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.7 mm	27.7 mm	27.6 mm	27.6 mm	pass
2/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.6 mm	27.7 mm	27.6 mm	27.6 mm	pass
3/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.8 mm	27.8 mm	27.7 mm	27.7 mm	pass
4/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.7 mm	27.7 mm	27.6 mm	27.7 mm	pass
5/5	5.2 mm	5.2 mm	5.2 mm	5.2 mm	5.2 mm	27.7 mm	27.7 mm	27.6 mm	27.7 mm	pass

D. Filling Process

Weight Specifications:
50g : 76.0g – 83.0g
100g: 139.0 – 154.0g

Sampling / Frequency	Weight of Sample (g)					Test Disposition (PASS / FAIL)	
	Instrument No.: 0301						
	1	2	3	4	5		
5/5	79.0 g	79.6 g	79.9 g	80.8 g	79.9 g	pass	
1/5	80.0 g	80.6 g	80.0 g	81.3 g	81.0 g	pass	
2/5	80.3 g	80.8 g	78.3 g	81.9 g	82.1 g	pass	
3/5	80.4 g	81.8 g	81.3 g	83.0 g	82.5 g	pass	
4/5	80.9 g	80.4 g	81.7 g	82.2 g	81.5 g	pass	
5/5	82.4 g	81.4 g	81.3 g	82.5 g	81.8 g	pass	

E. Capping Process

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QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

Doc. No	QC-IP006
Rev.	00

Sampling / Frequency	Actuators are properly fixed onto the canister	Functionality of actuator	Caps are properly fit onto the canister	Test Disposition (PASS / FAIL)
✓/5	✓	✓	✓	pass
✓/5	✓	✓	✓	pass
✓/5	✓	✓	✓	pass
✓/5	✓	✓	✓	pass
✓/5	✓	✓	✓	pass
✓/5	✓	✓	✓	pass

F. Labelling & Printing Process

Sampling / Frequency	Print Information must be Clear / Legible and Conforms to Specifications as Stated in Approved Artwork	Ref No., Lot No. & Expiry Date Corresponds to Shop Packet and Approved Artwork	Correct Label Position	Correct Printing Position	Test Disposition (PASS / FAIL)
✓/5	✓	✓	✓	✓	pass
✓/5	✓	✓	✓	✓	pass
✓/5	✓	✓	✓	✓	pass
✓/5	✓	✓	✓	✓	pass
✓/5	✓	✓	✓	✓	pass
✓/5	✓	✓	✓	✓	pass

G. Attachment (Label)

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QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua® GEL SPRAY (BOV)

Doc. No	QC-IP006
Rev.	00



F. Conclusion

Overall in-process inspection: PASS / FAIL

Inspected by : Play
 Name : Postnu
 Date : 23/12 / 2016/2017

Document type: FORM	Doc Id: QC-FC009-01	Issue Date: 15/11/2021	Page: 1(1)
Title: FINAL CONTROL TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)	 Bactiguard		

REF

LOT NO

Day 20
Butcher 800 Hwy 800

B 2090

QTY PRODUCED (pcs)

RETAIN SAMPLE QTY (pcs)

10

No.	Inspection Criteria	Sampling Details	Sample size	AQL	Results	Status (Pass / Fail)
				Accept	Reject	
				Accept	Reject	
1.	Legible and correct printing of label.	83, 0.15	80	0	1	Pass
2.	Free from contamination, deformed or damage on packaging.	83, 0.15	80	0	1	Pass

Pressure

(50g canister: 0.7-0.9 mPa/ 100g canister: 0.7-0.9 mPa)

Calibration due date: 16/09/2022

Sample?

110

E-θ

Test Disposition
(PASS / FAIL)

REMARKS:

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Inspected By _____
Name _____ Date _____

May *Rosant* *20/05/2012*

Approved By : *John* At RT : 06/05
Name : _____ Date : _____

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RAW MATERIAL LOADING FORM (RMLF)

Doc.
Rev.

DATE :	20/05/2022
REF :	HW425800
LOT NO. :	B20406

SHOP PACKET QTY (pes) : 250
 CUSTOMER : BD
 L.O.NO. : IO/CYN/06/05/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100657	35 X 110mm, Aluminium can (KOSMETEK)	BOV: 50ml; Capacity: 90ml size of can : 35 X 110mm	A10210401	pes	253	253	253	<u>fr</u>
2	P0100344	Plastic Acuator (EVER BRIGHT)	0.46mm (Orifice)	H083210401	pes	253	253	253	<u>fr</u>
3	P0100345	Plastic Cap (Blue Color) (EVER BRIGHT)	Diameter: 3.5mm	H029210401	pes	253	253	253	<u>fr</u>
4	C0100026	RHEOLOGICAL ADDITIVE (SUBBENT MP)	-	H080210801	gm	800	800	800	<u>fr</u>
5	C0100048	Sodium Hypochlorite, 10% Available Chlorine	0	C023210701	ml	200	200	200	<u>fr</u>
6	C0100024	Pure Dry Vacuum Salt (2kg)	-	C021210601	gm	20	20	20	<u>fr</u>
7		STOCK SOLUTION	10#	619/8073206	ltr	20	20	20	<u>fr</u>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100666	Hydrocyn Aqua Aerosol Gel Spray Label 50gram-PP Top White (W)105mm X (H)8.5mm Roll/1000	L091210201	254					<u>fr</u>
2			#N/A						
3			#N/A						
4			#N/A						
5			#N/A						
6			#N/A						
7			#N/A						

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	QTY ISSUED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H		H164220201	5	5	<u>monal</u>
2	P0100681	100ml nesting short and Long-		H079200402	5	5	<u>monal</u>
3			#N/A				
4			#N/A				
5			#N/A				
6			#N/A				
7			#N/A				

ISSUED BY (MM) :	<u>Parul</u>	VERIFIED BY (PR) :	<u>Parul</u>
Signature :	<u>Muthu</u>	Signature :	<u>Muthu</u>
Name :	JOVIN	Date :	28/05/2022

Title: PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL SPRAY (BOV)

Document type:
FORM

	Doc Id: QC-PC011-01	Issue Date: 15/11/2021	Page: 1(1)
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Description <i>Hydrocyn aqua Gel spray</i> (BOV) 50g	Reference No. <i>HW42E 800</i>	Date of Inspection <i>20.05.22</i>
Lot No. <i>B20406</i>	Sample Size <i>50g x 1 pieces</i>	

Packing Integrity (Visual Inspection)			Chemical Testing			Test Disposition
Correct and Legible Printing of Label	Free from Contamination / Deformed / Damaged	Ability to Dispense	pH (9.00 – 10.50)	FAC (100 – 200 ppm)	Instrument No.: <i>Q6-78</i> Calibration due date: <i>09/06/2023</i>	PASS / FAIL
			<i>✓</i>	<i>9.64</i>	<i>comply</i>	<i>Pass</i>

✓ = Pass ✗ = Fail

REMARKS: *N/A*

CONCLUSION:
 RELEASE
 ON-HOLD



Inspected By : <i>Wan Wan</i>	Approved By : <i>E. Janice</i>
Name : <i>Wan Wan</i>	Name : <i>MKT/AR</i>
Date : <i>20.05.22</i>	Date : <i>20.05.22</i>

Rework Instruction No. : R1-PM12-22204						
Reference Code	BW42E800	Lot No.	B20406	Lot Quantity (pes)	258	Quantity Affected (pes)
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	Change Bactiguard Woundcare, Gel Spray (BOV) 50g label to Hydrocyn Aqua Gel Spray (BOV), 50g label					
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	Eva, Amanu, Yati, Lind, Farah					
Required Tools	N/A					
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)	
1) Segregate the affected bottles	<i>AJ</i> 20/05/22	All the bottles were verified			Wah 20-5-22	
2) Remove the old labels	<i>AJ</i> 20/05/22	All the labels were removed from the bottles			Wah 20-5-22	
3) Replace with new labels	<i>AJ</i> 20/05/22	New labels were replaced			Wah 20-5-22	
4) Replace white caps with blue caps	<i>AJ</i> 20/05/22	New caps were replaced			Wah 20-5-22	
5) Re-print again the Expiry date and Lot number at correct position	<i>AJ</i> 20/05/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			Wah 20-5-22	
6) Proceed to Final Control Process	<i>AJ</i> 20/05/22	Verified in Final Control process and complies with all the specifications			Wah 20-5-22	
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>AJ</i>	Acknowledge By : <i>Martin</i>			Approved By : <i>Shaamim</i>		
Name : MUHD. ARIFUDDIN	Name : MARTINI BINTI GHAZALI			Name : Shaamim Zainul		
Date: 20-05-2022	Date: 25/05/2022			Date : 28/05/2022		

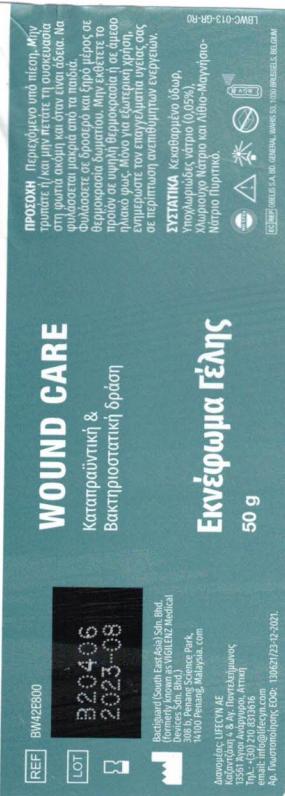
REWORK INSTRUCTION

DESCRIPTION: Change Label

BEFORE



Bactiguard®



WOUND CARE

Καταπράσινη &
Βακτηριοστατική δράση

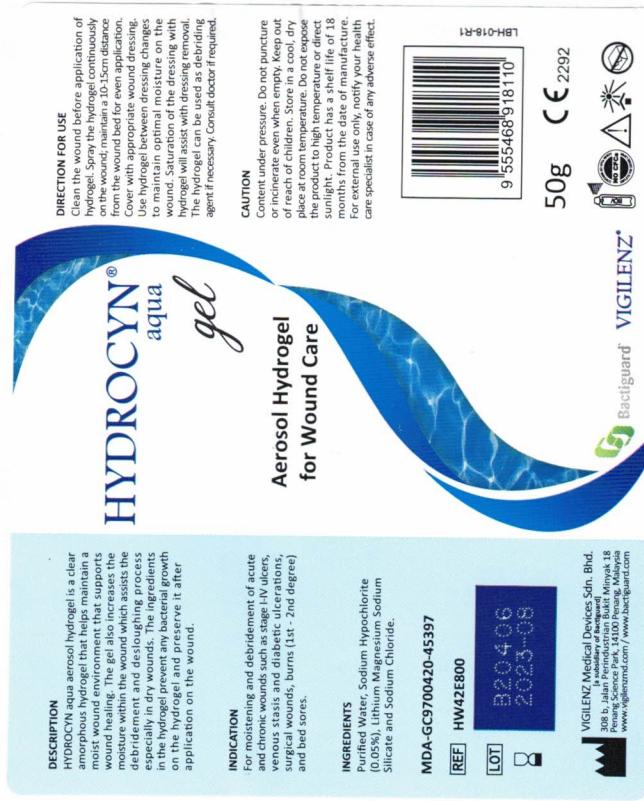
Επιχειρηματική Στρατηγική
59

REWORK INSTRUCTION

DESCRIPTION: Change Label

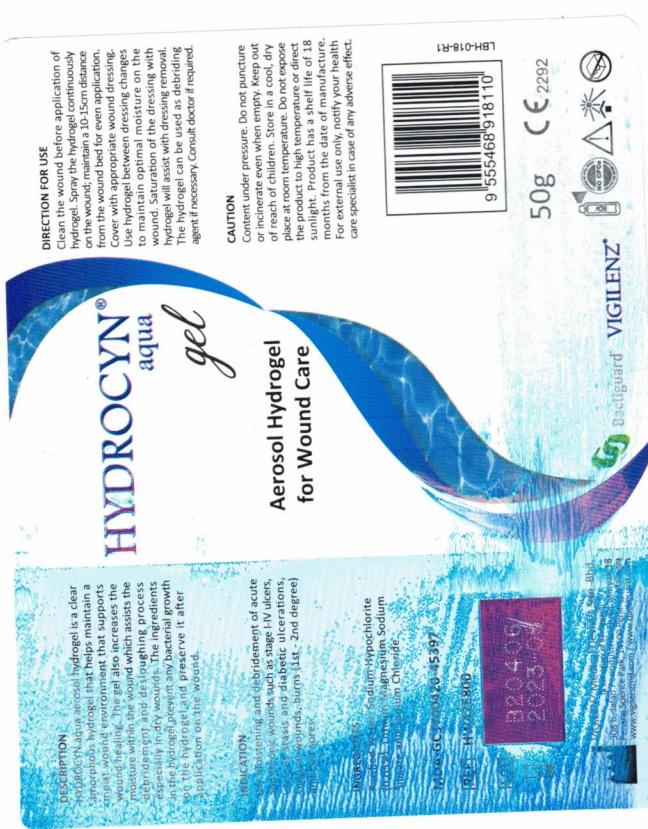
AFTER

SAMPLE
NOT FOR SALE



REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



DESCRIPTION

HYDROCYN aqua aerosol hydrogel is a clear, aqueous hydrogel that helps maintain an intact wound environment that supports the growth of healthy tissue. The gel which coats the wound surface, retains moisture within the wound, which assists the debriding and whitening process, especially in necrotic areas. The ingredients effectively remove any bacterial growth from the hydrogel and preserve it after application on the wound.

INDICATION

Debriding and whitening of acute and chronic wounds such as Stage IV ulcers, pressure sores, diabetic ulcerations, surgical wounds, burns (1st - 2nd degree).

INGREDIENTS

Aerosol Hydrogel: Sodium Hypochlorite (0.05%), Lotion: Magnesium Sodium Sulphate, Ammonium Chloride.

MANUFACTURER

PEE-HOON LTD.

EXPIRY DATE

2023/09/20

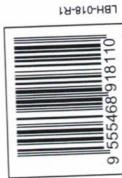
BEST GUARDED VIGILENZ

DIRECTION FOR USE

Clear the wound before application of hydrogel. Spray the hydrogel continuously on the wound, retain a 10-15cm distance from the nozzle and hold for even application. Cover with appropriate wound dressing. Use hydrogel between dressing changes to maintain optimal moisture on the wound. Saturation of the dressing removal with hydrogel will assist with dressing removal. The hydrogel can be used as debriding agent if necessary. Consult doctor if required.

CAUTION

Content under pressure. Do not puncture or incinerate even when empty. Keep out of reach of children. Store in a dry place at room temperature. Do not expose the product to high temperature or direct sunlight. Once opened it has a shelf life of 18 months from the date of manufacture. For external use only. Notify your health care specialist in case of any adverse effect.



50g C € 2292

