

SHOP PACKET - HYDROCYN AQUA GEL (AEROSOL SPRAY)

REFERENCE	HW42E800	ODR. QTY	250	RS: 2(RS) + 1(QC TEST)	ISSUED DATE	8-Feb-21
ITEM CODE	H0100029	PACK SIZE	50/BOX	LOT NO.	B10802	
ITEM DESCRIPTION	Hydrocyn Wound Gel (Aerosol) 50g	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	8-Feb-21	
PREPARED BY	NAME : SITI NORSHAFIQAH DATE : 08/02/2021	ODR. NO	B085	EXP. DATE	2022-08	
		VERIFIED BY	NAME : MUNIRAJA DATE : 08/02/2021	INT. ORDER	IO/VMD/050221/01	

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
HYDROCYN AQUA GEL PREPARATION						
TIME START : 10:30 AM DATE : 10-02-21 TIME COMPLETE : 10:38 AM DATE : 10-02-21	253	253	nil	Kyi (890)	Dewi 10:38AM 10/02/2021	1/
CLAMPING AND PRESSURE FILLING						
TIME START : 3:15 PM DATE : 18-02-21 TIME COMPLETE : 4:00 PM DATE : 18-02-21	253	253	nil	Kyi (890)	Dewi 4:00PM 18/02/2021	NA
GEL FILLING						
TIME START : 4:00 PM DATE : 18-02-21 TIME COMPLETE : 5:00 PM DATE : 18-02-21	253	253	nil	Kyi (890)	Dewi 5:00PM 18/02/2021	NA
CAPPING						
TIME START : 11:00 AM DATE : 19-02-21 TIME COMPLETE : 11:50 AM DATE : 19-02-21	253	253	nil	Kyi (890) Nisya (980)	Roshni 11:50 AM 19/02/2021	NA
LABELLING						
TIME START : 3:00 PM DATE : 19-02-21 TIME COMPLETE : 3:55 PM DATE : 19-02-21	253	253	nil	Nisya (980)	Roshni 3:55PM 19/02/2021	NA
PRINT LOT NUMBER & EXPIRY DATE						
TIME START : 3:00 PM DATE : 19-02-21 TIME COMPLETE : 3:55 PM DATE : 19-02-21	253	253	nil	Kyi (890)	Roshni 3:55PM 19/02/2021	NA
TEST AEROSOL MIST SPRAY						
TIME START : 11:00 AM DATE : 19-02-21 TIME COMPLETE : 11:50 AM DATE : 19-02-21	253	253	nil	Kyi (890) Nisya (980)	Roshni 11:50 AM 19/02/2021	NA
FINAL CONTROL						
TIME START : 3:00 PM DATE : 19-02-21 TIME COMPLETE : 3:55 PM DATE : 19-02-21	253	253	nil	Kyi (890)	Roshni 3:55PM 19/02/2021	NA
CARTON PACK	S-12					
TIME START : 12:20 PM DATE : 22-02-21 TIME COMPLETE : 12:40 PM DATE : 22-02-21	46tn20bh	46tn20bh	Nil	Kyuc887 Zurichi (378)	INV# 22/02/2021	SCM - Sunif 22/02/2021 (22-617)

QUANTITY PRODUCED : 253 PCS
 QUANTITY FOR QC / RETAIN SAMPLE : 2+1 PCS
 SHIPMENT QUANTITY PCS / CTNS : 220 PCS
 FINAL SHIPMENT DATE :

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 COMPLETE/PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : Muniraja Date : 22/02/2021	Name : M. Lugman Date : 05/03/2021	Name : A. Dewi Roshni Designation : IPQC Supervisor Date : 23/02/2021
Remarks: -20 pcs taken for validation (PQ1).	Stamp :	

*The attachments pending for approval.

*This lot under validation (PQ1)

VIGILENZ®

HYDROCYN aqua® GEL - RECORDS OF PREPARATION

Doc. No.	P-1
Rev.	04

Date : 10/02/2021
Batch No. : 61B10022110

	Equipment ID	
	QC-56	HSM-01
Purified Water (L)	3.0 - 3.1	20.0 - 20.1
Lithium Magnesium Sodium Silicate (g)	120 ± 1	800 ± 1
Sodium Hypochlorite (ml)	30.0 ± 0.05	200.0 ± 0.1
PDV Salt (g)	3.0 ± 0.1	20.0 ± 0.1

Reference / Lot No.	HU012E800/1310802
Order Qty.	252

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.: QC-78	Instrument No.: N/A	Instrument No.: QC-96		
GB10022110	G10	9.46	comply	9366	✓	PASS
			N/A			

B. Filling Process

↓

Weight Specification: 50g : 55–65g

53.0g–60.0g

10.6.0g–117.0g

 100g : 105–115g

18/02/2021

Sampling / Frequency	Weight of Sample (g)						Leak Test	Test Disposition (PASS / FAIL)
	1	2	3	4	5	Average		
5/5	50.1g	56.7g	55.8g	52.7g	51.8g	54.4g	✓	PASS
1/5	55g	55.6g	56.2g	55.2g	55.5g	55.5g	✓	PASS
2/5	54.5g	53.8g	54.1g	54.1g	54.7g	54.2g	✓	PASS
3/5	53.9g	54.1g	54.6g	54.4g	54.5g	54.3g	✓	PASS
4/5	54.2g	54.7g	54.6g	54.1g	54.7g	54.5g	✓	PASS
5/5	54.9g	55.2g	54.8g	54.2g	54.1g	54.6g	✓	PASS
				N/A				

C. Capping Process

Sampling / Frequency	Actuators are properly fixed onto the canister	Functionality of actuator	Caps are properly fixed onto the canister	Test Disposition (PASS / FAIL)
5/5	✓	✓	✓	PASS
1/5	✓	✓	✓	PASS
2/5	✓	✓	✓	PASS
3/5	✓	✓	✓	PASS
4/5	✓	✓	✓	PASS
5/5	✓	✓	✓	PASS
		NA		

D. Labelling & Printing Process

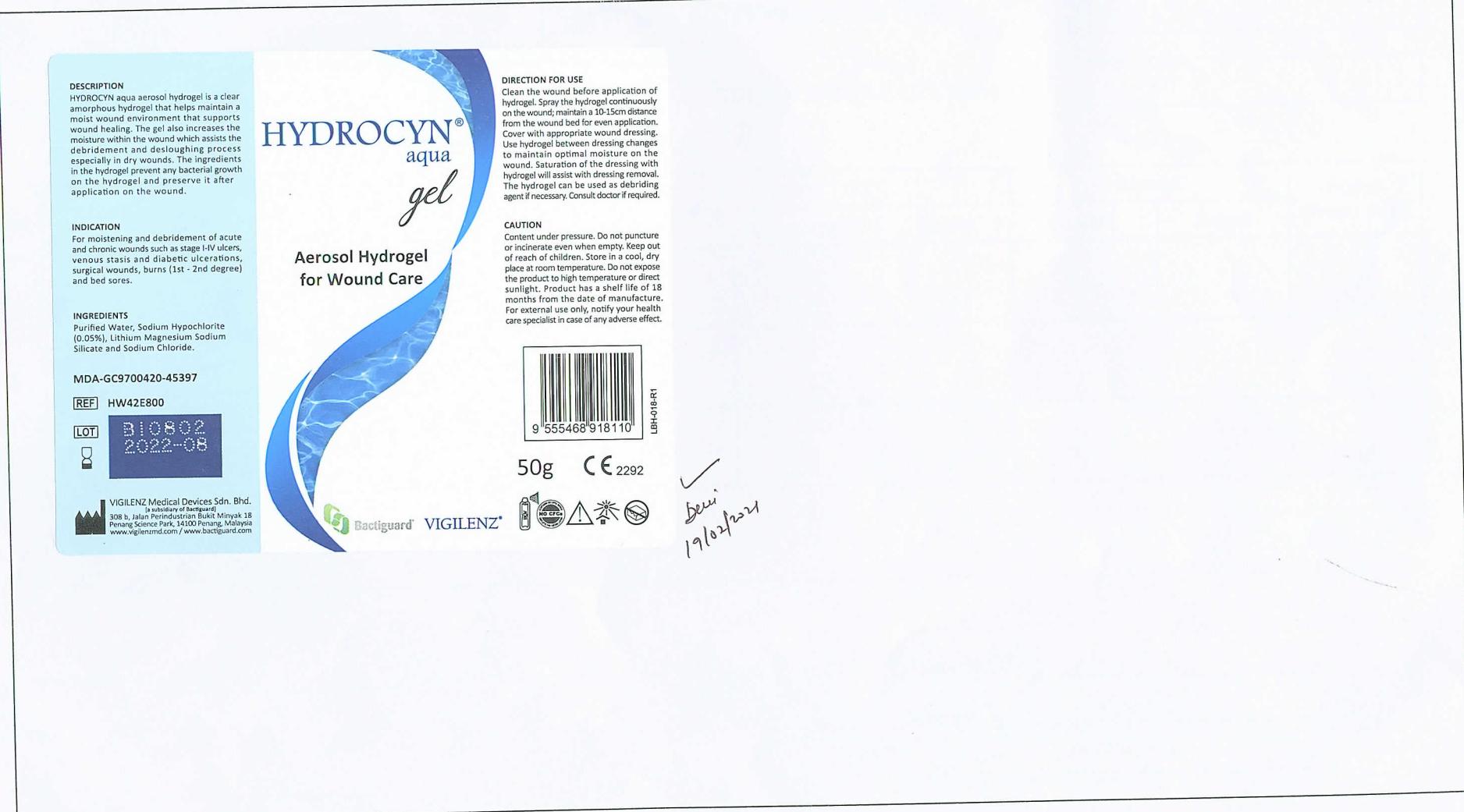
Sampling / Frequency	Print Information must be Clear / Legible and Conforms to Specifications as Stated in Approved Artwork	Ref No., Lot No. & Expiry Date Corresponds to Shop Packet and Approved Artwork	Correct Label Position	Correct Printing Position	Test Disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	PASS
1/5	✓	✓	✓	✓	PASS
2/5	✓	✓	✓	✓	PASS
3/5	✓	✓	✓	✓	PASS
4/5	✓	✓	✓	✓	PASS
5/5	✓	✓	✓	✓	PASS
		NA			

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QC IN-PROCESS INSPECTION RECORD – HYDROCYN AQUA GEL (BOV)

Doc. No	QC-IP006
Rev.	00

E. Attachment (Label)



F. Conclusion

Overall in-process inspection: PASS / FAIL

Inspected by : Roshni
Name : Roshni
Date : 19/02/2021

VIGILENZ®

FINAL CONTROL TEST REPORT – HYDROCYN aqua GEL (BOV)

Doc. No. QC-FC009

Rev. 00

REF : HW42E800

QTY PRODUCED (pcs) : 252

LOT NO : B10802

RETAIN SAMPLE QTY (pcs) : 2

No.	Inspection Criteria	Sampling Details	Sample size	AQL		Results		Status (Pass / Fail)
				Accept	Reject	Accept	Reject	
1.	Legible and correct printing of label.	S3, 0.15	8	0	1	8	0	PASS
2.	Free from contamination, deformed or damage on packaging.	S3, 0.15	8	0	1	8	0	PASS
3.	Proper crimping and capping.	S3, 0.15	8	0	1	8	0	PASS

REMARKS : N/A

Inspected By : Roshni

Name : ROSHNI

Date : 19/02/2021

Approved By : Jyoti

Name : Jyoti

Date : 19/02/2021

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

AR

Doc. No.

Rev.

06

DATE :	09/02/2021
REF :	HW42E800
LOT NO. :	B10802

SHOP PACKET QTY (pcs) :	250	RS	
CUSTOMER :	VMD (MALAYSIA)		
LO NO. :	IO/VMD/050221/01		

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)			RECEIVED BY
						REQUIRED	ISSUED	CONSUMPTION	
1	P0100656	45 X 150mm, Aluminium can (KOSMETEK)	BOV : 100ml : Capacity: 150ml Size of can: 45X150mm	A010200401	pcs	253	253	253	Rajayana (740)
2	P0100344	Plastic Actuator (EVER BRIGHT)	0.46mm (Orifice)	H08350601	pcs	253	253	253	Rajayana (740)
3	P0100345	Plastic Cap (Blue Color) (EVER BRIGHT)	Diameter: 35mm	H02950601R	pcs	253	253	253	Rajayana (740)
4	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080200901	gm	800	800	800	Rajayana (740)
5	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023201001	ml	200	200	200	Rajayana (740)
6	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021201201	gm	20	20	20	Rajayana (740)
7		STOCK SOLUTION		GIB10022110	ltr	20	20	20	Rajayana (740)

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100666	Hydrocyn Aqua Aerosol Gel Spray Label 50gram-PP Top White (W)105mm X (H)85mm Roll/1000	L090210201	254	Rajayana (740)
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	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H	H164200501	5	Anil
2	P0100681	100ml nesting short and Long-	H079200402	5	Anil
3		#N/A			

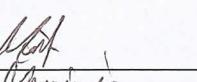
(4) SPECIAL REQUIREMENT

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	N/A
2		#N/A			

ISSUED BY (MM) :


FIRDAUS
09/02/2021

VERIFIED BY (PR) :


Munirah
09/02/2021

VIGILENZ®

PRODUCT RELEASE TEST REPORT - HYDROCYN aqua GEL
(BOV)

ART

Doc. No. QC-PC011
Rev 00

Description	Hydrocyn Wound Gel (Aerosol) 50g	Reference No.	HW40E800	Date of Inspection	22/02/2021
		Lot No.	B10802	Sample Size	1pc x 50g

Packing Integrity					Visual Inspection (Gel)	Chemical Testing		Test Disposition
Correct and Legible Printing of Label	Proper Crimping Capping	Ability to Dispense	Free from Contamination / Deformed / Damaged	No leakage	Free from Contamination / Particles / Foreign matter	pH (9.00 – 10.50)	FAC (100 – 200 ppm)	PASS / FAIL
						Instrument No.: 0C-78	Instrument No.: N/D	
✓	✓	✓	✓	✓	✓	9.73	comply	PASS

✓ = Pass X = Fail

REMARKS : N/ACONCLUSION: RELEASE ON-HOLDInspected By : RoshniName : ROSHNIDate : 22/02/2021Approved By : DeeName : A. DeoDate : 22/02/2021

GILENZ®

**PRODUCT TRANSFER SLIP –
ETO STERILIZATION & HYDROCYN ITEMS**

Doc No.	PR-TS003
Rev	00

Date	19/02/2021			Lot No	B10802	
Product Detail	Aerosol (Rel)			Customer		
Reference No.	HW42E800				VMD	
Order Qty	220	Retain Sample Qty	3	Sterilization	ETO (Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>)	
Final Packaging Process						
Process	Input Qty	Output Qty	Rejects	Operator	QC Approval	Remarks
OVERWRAPPING			N/A			
	TIME START :	TIME COMPLETE :				
	DATE :	DATE :				
CARTON PACK	4ctn 20bh	4ctn 20bh	N/A	Kyu (887) Zurchi (376)		Scm! - Sunif 22/02/2021 (220 bh)
	TIME START : 12:20pm	TIME COMPLETE : 12:40pm				
	DATE : 22.02.2021	DATE : 22.02.2021				
OQC Inspection	Inspected by: JINURS			Date: 22/02/2021	Status: <input type="checkbox"/>	Release <input type="checkbox"/> Onhold <input type="checkbox"/>
Remarks	N/A					

DATE : 19-02-21	PRINT LOT NUMBER & EXPIRY DATE	253	253	nil	Kyi (890)	Roshni 3:55 PM 19/02/2021	NA
TIME START : 3:00 pm							
DATE : 19-02-21							
TIME COMPLETE : 3:55 pm							
DATE : 19-02-21		253	253	nil	Kyi (890) nisya (980)	Roshni 11:50 AM 19/02/2021	NA
TEST AEROSOL MIST SPRAY							
TIME START : 11:00 AM							
DATE : 19-02-21							
TIME COMPLETE : 11:50 AM		253	253	nil	Kyi (890)	Roshni 5:50 PM 19/02/2021	NA
DATE : 19-02-21							
FINAL CONTROL							
TIME START : 3:00 pm							
DATE : 19-02-21		253	253	nil	Kyi (890)	Roshni 5:50 PM 19/02/2021	NA
TIME COMPLETE : 3:55 pm							
DATE : 19-02-21							
CARTON PACK	5-12						
TIME START : 12:20 PM		4ctn 20bh	4ctn 20bh	N/A	Kyu (887) Zurchi (376)	JINURS 22/02/2021	Scm! - Sunif 22/02/2021 (220 bh)
DATE : 22-02-21							
TIME COMPLETE : 12:40 PM							
DATE : 22-02-21							

QUANTITY PRODUCED :	253 PCS
QUANTITY FOR QC / RETAIN SAMPLE :	2+1 PCS
SHIPMENT QUANTITY PCS / CTNS :	220 PCS
FINAL SHIPMENT DATE :	_____
COMPLETE/PARTIAL :	COMPLETE <input checked="" type="checkbox"/> PARTIAL <input type="checkbox"/>

Checked by (PR), Signature : Name : M. Munirya Date : 22/02/2021	Approved by (QA), Signature : Name : M. Luqman Date : 05/03/2021	Released by (QC), Signature : Name : A. Darsini Designation : IPEC Supervisor Date : 23/02/2021
Remarks: -20 per taken for validation (PQI).	Stamp : VMD RELEASED QC	

*The attachments pending for approval.

*This lot under validation (PQI)