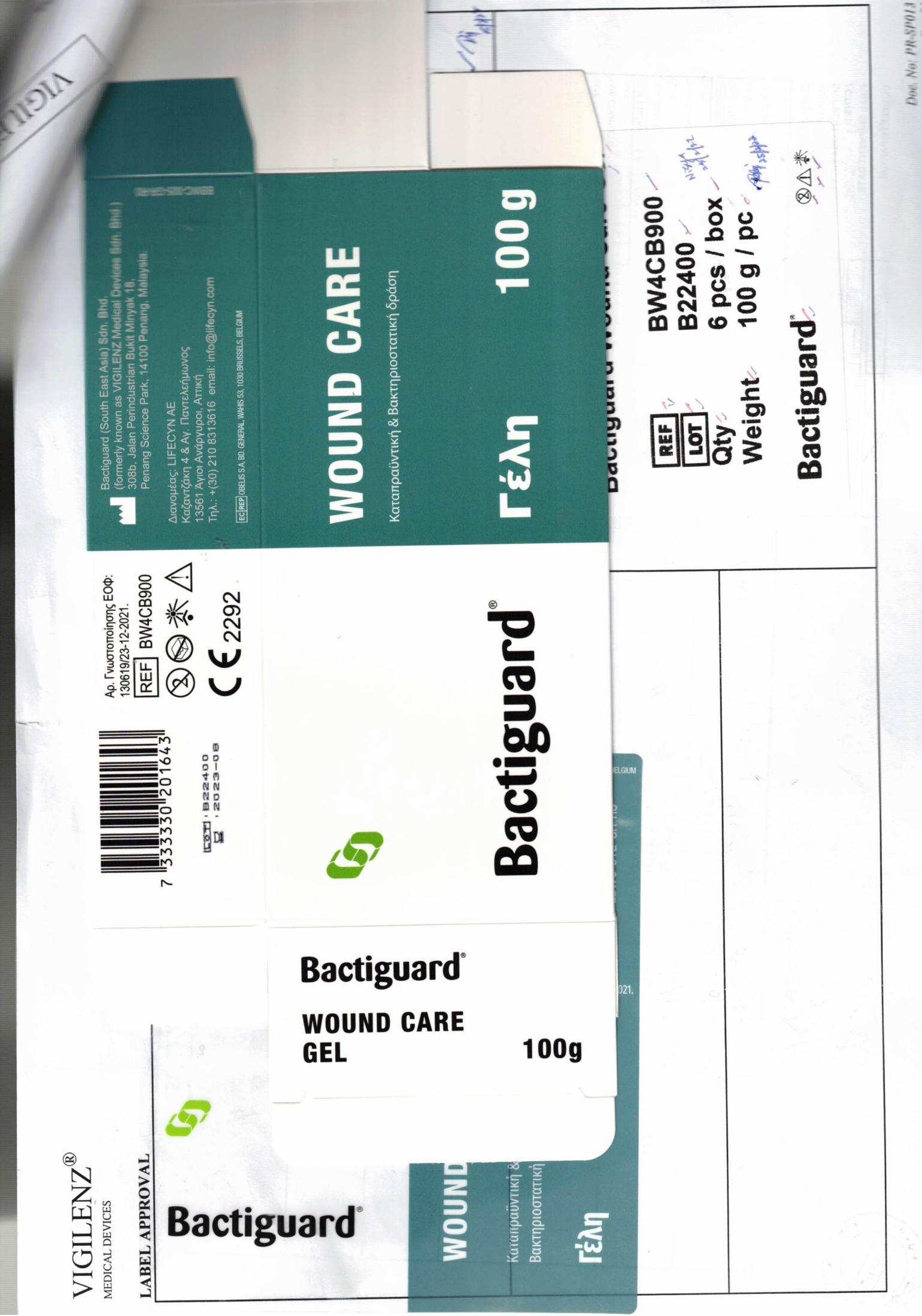


SHOP PACKET - HYDROCYN AQUA GEL

SHOP PACKET - HYDROCYN AQUA GEL						
REF :	BWA4CB900	ODR. QTY :	30	ISSUED DATE	24-Feb-22	6.0.
ITEM CODE :	BW010010	PACK SIZE :	6/BOX	LOT NO	B22400	
CUSTOMER	Bactiguard AB (LIFECYN)	MFG. DATE	3-Feb-22			
ORD. NO	B140	EXP. DATE:	2023-08			
RESULTS			RESULTS			
PROCESS	START QTY TUBE	OUTPUT TUBE	REJECT TUBE	OPERATOR	IPQC APPROVAL	APPROVAL
HYDROCYN AQUA GEL PREPARATION	100 PM 2/3-02-22 1:08 PM 2/3-02-22	39	N/i	Fawad (1051)	Reshi 108pm 23/02/22	1/1
DATE : TIME COMPLETE :	2/3-02-22			Dewi (1126)	Reshi 1:15PM 23/02/22	
CHECK : pH / VISCOSITY / FAC	PR-HR001 QC-HR003					
LABELLING GEL TUBE	2:00 PM 2/3-02-22 2:15 PM 2/3-02-22	39	N/i	Reshi (1126)	Reshi 2:30PM 24/02/22	5/5
DATE : TIME START :	2/3-02-22					
DATE : TIME COMPLETE :	2/3-02-22					
GEL FILLING	2:15 PM 2/4-02-22 2:30 PM 2/4-02-22	39	N/i	Reshi (1126)	Reshi 3:00PM 24/02/22	5/5
DATE : TIME START :	2/4-02-22					
DATE : TIME COMPLETE :	2/4-02-22					
SEALING AND CUTTING GEL TUBE	2:15 PM 2/4-02-22 3:00 PM 2/4-02-22	39	N/i	Reshi (1126)	Reshi 3:00PM 24/02/22	5/5
DATE : TIME START :	2/4-02-22					
DATE : TIME COMPLETE :	2/4-02-22					
LOT NUMBER AND EXPIRY DATE PRINTING	2:15 PM 2/5-02-22 3:00 PM 2/5-02-22	33	N/i	Reshi (1126)	Reshi 10:15 AM 25/02/22	5/5
DATE : TIME START :	2/5-02-22					
DATE : TIME COMPLETE :	2/5-02-22					
BOX PACKING & FINAL CONTROL	10:00 AM 2/5-02-22 10:15 AM 2/5-02-22	33	N/i	Reshi (1126)	Reshi 10:15 AM 25/02/22	Refer P102
DATE : TIME START :	2/5-02-22					
DATE : TIME COMPLETE :	2/5-02-22					
CARTON PACKING	11:20 AM 2/5-02-22 11:20 AM 2/5-02-22	5 box	Hil	FAGI (1054)	Wurin 25/02/22	Log 25/02/2022
DATE : TIME COMPLETE :	2/5-02-22					
DATE : TIME COMPLETE :	2/5-02-22					
COMPLETE						
QUANTITY PRODUCED	39 pcs					
QUANTITY FOR QC RETAIN SAMPLE	3 RST 6 pcs					
SHIPMENT QUANTITY PCS	72 pcs					
/ CTNS :						
FINAL SHIPMENT DATE	PABTAL					



VIGILENZ®

MEDICAL DEVICES

LABEL APPROVAL

Bactiguard®



Αρ. Γωντοπόρος ΕΟΦ:
130619/23-12-2021.

REF BW4CB900



€ 2292

ΕΛΛΑΣ · Ε222400
· 20223-08

WOUND CARE

Καταπραϋντική & Βακτηριοστατική δράση



Bactiguard®

WOUND CARE
GEL

100g

WOUND

Καταπραϋντική &
Βακτηριοστατική

Γέλη

Bactiguard®

100 g

BW4CB900

B22400

6 pcs / box

Weight
100 g / pc

Bactiguard®



Doc. No. PR-SP013

ENZ[®]

HYDROCYN aqua® GEL - RECORDS OF PREPARATION

HYDROCYN aqua® GEL - RECORDS OF PREPARATION	Doc. No. Rev.	PR-HR001 (04)
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	Equipment ID
Purified Water (L)	QC-56
Lithium Magnesium Sodium Silicate (g)	HSM-01
Sodium Hypochlorite (ml)	3.0 ± 3.1
PDV Salt (g)	120 ± 1
	800 ± 1
	30.0 ± 0.05
	200.0 ± 0.5
	3.0 ± 0.1
	20.0 ± 0.1

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard	Page: 1(3)
Document type: FORM	Doc id: QC-IP004-01	Issue Date: 15/11/2021	

Reference / Lot No.	<u>BWYEB900 / BWYB90</u>
Order Qty.	30

A. Before Filling

B. Tube Labelling

B. Tube Labelling		Test disposition (PASS / FAIL)	
Sampling / Frequency	Printed label is clear and legible	Reference no. corresponds to Shop Packet and approved artwork	Correct positioning of labelling
4/5	✓	✓	pass
1/5	✓	✓	pass
2/5	✓	✓	pass
3/5	✓	✓	pass
4/5	✓	✓	pass
5/5	✓	✓	pass

Product Type:	Hydrocyn aqua GEL
Doc id:	QC-IP004-01

E. Printing on Primary Packaging

Sampling / Frequency	Print information must be clear / legible and conforms to specifications as stated in approved artwork	Lot no. and expiry date are corresponding to Shop Packet and approved artwork	Correct position of printing	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

F. Primary Packaging

Sampling / Frequency	Product is properly pack in primary packaging	Ref. no., lot no. and expiry date on primary box is correct and legible	Special requirement printing is clear and legible	Presence of secure stickers on both opening sides of the primary box	Presence of hologram sticker on the primary box	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

G. Conclusion

Overall in – process inspection: (PASS / FAIL)

Inspected By : Raj
 Name : Positive
 Date : 15/11/20

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021
		Page: 2(3)

C. Filling Process

Sampling / Frequency	Weight of Sample					Test disposition (PASS / FAIL)
	1	2	3	4	5	
5/5	103.91 g	103.83 g	103.21 g	103.75 g	104.12 g	103.7 g pass
1/5	103.63 g	103.15 g	103.39 g	103.57 g	103.73 g	103.5 g pass
2/5	103.73 g	103.21 g	103.71 g	103.57 g	104.41 g	103.7 g pass
3/5	104.21 g	103.94 g	103.16 g	103.47 g	104.12 g	103.8 g pass
4/5	104.15 g	104.21 g	103.73 g	103.36 g	103.51 g	103.7 g pass
5/5	103.36 g	104.36 g	103.15 g	103.35 g	103.35 g	103.5 g pass

D. Sealing and Cutting

Sampling / Frequency	Sealing is intact	No sharp edge and not slanted after sealing and cutting	Lot no. and expiry date on tube is correct as in Shop Packet and legible	Seal Width Specification: (15g : 4-6mm) (30g/ 50g/ 100g : 6-8mm)	Leak Test	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	Pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

VIGILENZ®

FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

REF :	<input type="text" value="B04103900"/>	Doc. No.	QC-FC006
Rev.	<input type="text" value="03"/>	Rev.	03

REF : QTY PRODUCED (pcs) : LOT NO : RETAIN SAMPLE QTY (pcs) :

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	39	0	1	34	0	pass
2	Availability of Hologram and Secure Sticker.	S3,0.15	39	0	1	34	0	pass
3	Free from contamination, deformed or damaged on packaging.	S3,0.15	39	0	1	34	0	pass
4	Proper sealing and no leakage.	S3,0.15	39	0	1	34	0	pass
5	Correct quantity in secondary box packaging.	S3,0.15	39	0	1	34	0	pass

Remarks : Inspected By :
Name :
Date : Approved By :
Name :
Date :

RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001
Rev. 06

14/01/2022	SHOP PACKET QTY (pes)	:	30
BW4CB900	CUSTOMER :	:	BACTIGUARD AB (JIFECYN)
B22400	LO NO. :	:	IO/CYN/06/05/01

SHOP PACKET QTY (pes) :
CUSTOMER :
LO NO. :

NO.	SYSTEM CODE	ITEM DESCRIPTION 1		DESCRIPTION 2	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 1							
1	P0100727	100g Tubes with D40 White Color Screw-on Cap	Diameter 40 x 135 mm, White Colour Tube + neck, 5mm Tube Orifice with Aluminium Foil Seal, Open End	H11G210501	pcs	39	39	39	39	1. Tony
2	P0100804	White Nozzle Cap	0	H12G210701		78	78	78	78	2. Tony
3	C0100026	RHEOLOGICAL ADDITIVE (SUPPLEMENT MP)	-	H080210801	gm	800	800	800	800	3. Tony
4	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	200	200	4. Tony
5	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	20	20	5. Tony
6	N/A	STOCK SOLUTION	N/A		ltr	20	20	20	20	6. Tony

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1		LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO	ITEM DESCRIPTION 1		LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 1					ITEM DESCRIPTION 1	ITEM DESCRIPTION 1			
1	P0100896	LBWC-012-GR-RO (100G - Gel Tube- GREECE), VIGILLENZ0132, 10MM X 125MM, IN ROLL, TRANSPARENT PE, 4C + WHITE	LBE542101	40	1. Tony	1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LR150/M/LR150 (IBC FLUTE)	LR150/M/LR150 (IBC FLUTE)	H114210801/2	1	6. Tony
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22210801	79	1. Tony	2	P0100767	V0047-0154; POF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m; 1 rolls/carton	#N/A	P092210801	1	7. Tony
3	P0100806	LDPE ZIPPER BAG; Size: 0.05mm x 2" (opening) x 3" (L) USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	40	1. Tony	3						
4	P0100911	V09-BX034-00 BWC GEL INNER BOX 100G - GREECE 310GSM 1 SIDE ART CARD; 77 X 39 X 166MM; CYK, 5483C; GLOSS LAMINATION	BGR3220202	40	1. Tony							
5	P0100790	V09-BX024-00 Hydrogen Gel 100g (outer box) 300gsm 1 Side Art Card; 237 x 84 x 168mm	PH02210701	3	1. Tony	1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)	N/A			
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210801	3	1. Tony	2						
7		#N/A										

(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1		ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
		ITEM DESCRIPTION 1	ITEM DESCRIPTION 1	ITEM DESCRIPTION 1			
1				Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LR150/M/LR150 (IBC FLUTE)	H114210801/2	1	6. Tony
2				V0047-0154; POF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m; 1 rolls/carton	P092210801	1	7. Tony
3				#N/A			
4							
5							
6							
7							

ISSUED BY (MM) :

Name : FIRDAUS

VERIFIED BY (PR) :

Name : J. COOL

Signature : 

PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL		Doc No.	QC-PC008
		Rev.	02

Description	Bactiguard wound care , Gel Tube 100 g	Reference No.	BW4CB900	Date of Inspection	24 / 02 / 2022
Lot No.	B22400	Sample Size	1 Pcs x 100g		

Release Criteria:

Packing Integrity			Visual Inspection		Chemical Testing		Test Disposition
Correct and legible printing of label	Proper sealing	Ability to dispense	Free from contamination/ deformed/ damaged	No leakage	Free from contamination / particles / foreign matters	pH (9.00 – 10.50)	FAC (100 – 200 ppm) PASS / FAIL
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	9.81	comply <i>pass</i>

✓ = Pass, X = Fail

Remarks: N/A

- CONCLUSIONS: RELEASE
 ON-HOLD

Inspected By : Wahid
Name : wahid
Date : 24/02/22

Approved By : Martin
Name : Martin
Date : 24/02/22

