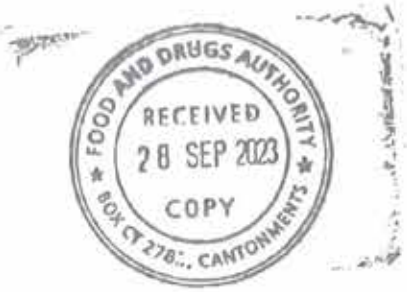
HILLS PHARMACEUTICALS LTD

GPS: GA - 217 - 2446
Tel.233-(0) 302-239398, 2253048
Email: info@hillspharmagh.com

P. O. Box AD 785 Adabraka, Accra
No. 17 Fadama Street, South Industrial Area
www.hillspharmagh.com

28th September, 2023



THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
HEAD OFFICE
P. O. BOX CT 2783
CANTONMENTS - ACCRA

Dear Madam,

IMMEDIATE PRODUCT RECALL BELTOCIN AND VERMETOCIN (OXYTOCIN) INJECTIONS 10IU/ML

A publication with the above heading was brought to our attention yesterday 27th of September, 2023. We are importers of Beltocin.

We would like to inform you that we immediately started the process of recalling all batches of the product and will furnish you with an update and details either under your direction and or when the process is complete.

We will be grateful if we can be furnished with the COA or COAs which confirmed the quality issue if possible. This will enable the manufacturer conduct an investigation into the quality issue that has necessitated the recall.

We will also be grateful for any further direction to aid the manufacturer, the Authority and Hills Pharmaceuticals Ltd. to get to the bottom of this quality issue.

Hills Pharmaceuticals Ltd. remains committed to product safety, quality and efficacy and will be grateful for your assistance and direction to achieve this.

We count on your usual cooperation.
Thank you.

Yours faithfully,

ERIC K. TAKYI
0249812328

Akgai
28/9/23

FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority

Head Office
Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana
(+233)-302-233200/235100
(+233)-551-112223/4/5 (Hotline)
Email: fda@fda.gov.gh
Digital Address: GA-237-7316

FDA/TOD/ENF/INT/QMU/23/0092

13th November 2023

The Director
Hills Pharmaceuticals Limited
No.17 Fadama street, south Industrial Area
Tel: 0302239398/03022253048

Dear Sir,

RE: IMMEDIATE PRODUCT RECALL BELTOCIN AND VERNETOCIN (OXYTOCIN) INJECTION 10IU/ML

This is in response to your letter dated 28th September 2023 requesting the Food and Drugs Authority (FDA) to furnish your company with the Certificates of Analysis (CoA's) which resulted to the recall of Beltocin Injection 10iu/ml.

Please find attached the certificates of analysis of the products.

Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER

1471

FDA

Certificate No.: PCM-23/09/0356

CENTRE FOR LABORATORY SERVICES AND RESEARCH
CERTIFICATE OF ANALYSIS

Sample Information

Testing Laboratory: Drug Laboratory Department		Testing Unit: Drug Physicochemical Unit	
Sample ID:	FDA/SD23/D0263	Client Ref No.:	LD/27/03/001
Sample Name: Beltecin Oxytocin Injection BP 10 unit/10 ml		Generic Name:	Oxytocin Injection
Formulation:	Solution for Injection	Environmental Condition (If applicable) Temp./Humidity:	Satisfactory
Composition: Each ml contains Oxytocin BP 10IU		Batch No: GH-HH-48	Condition of Sample: Satisfactory
Mfg. Date:	08 - 2022	Exp. Date:	07 - 2023
Manufactured for:	Belco Pharma	Manufacturer's Address	515, M.I.E., Bahadurgarh-124507 (Haryana)
Submitted/Source	Enforcement Directorate	Method of Analysis (Test Reference):	IP 2023
Sample receipt date:	26 - 04 - 2023	Testing Date:	27 - 04 - 2023
Date of Completion of Test:	25 - 08 - 2023	Report Date:	06 - 09 - 2023

Remarks

1. The test result is based on the tests carried out on the samples submitted to the laboratory by the customer.
2. This certificate is traceable to record number CLSR/WKS/PCM/23/222a-d

Analyst: -	[illegible]	Sign: -	Date: - [illegible]
HOL: -	[illegible]	Sign: -	Date: - 06/09/2023
HQA: -	[illegible]	Sign: -	Date: - 07/09/23

"This test is accredited under the laboratory's ISO/IEC 17025 accreditation issued by ANAB. Refer to certificate and scope of accreditation AT -1870"
"Test not accredited for ISO/IEC 17025:2017

Head Office
Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana
(+233) 302-233200/235100
(+233) 501-122230/4/5 (Hotline)
Email: fda@fdaghana.gov.gh
Digital Address: GA-237-7316

Certificate No.: PCM-23/09/0373

CENTRE FOR LABORATORY SERVICES AND RESEARCH

CERTIFICATE OF ANALYSIS

Sample Information

Testing Laboratory: Drug Laboratory Department		Testing Unit: Drug Physicochemical Unit	
Sample ID:	FDA LSD23 DG0248	Client Ref No.:	ED/23/04-001
Sample Name: Beltocin Oxytocin Injection BP		Generic Name:	Oxytocin Injection
Formulation:	Solution for Injection	Environmental Condition (If applicable) Temp./Humidity:	Satisfactory
Composition: Each ml contains Oxytocin (Synthetic) BP 10 Oxytocin units eq. to Oxytocin peptide 16.66mcg		Batch No:GH-B3-48	Condition of Sample: Satisfactory
Mfg. Date:	08 - 2022	Exp. Date:	07 - 2024
Manufacturer:	Beleo Pharma	Manufacturer's Address	515, M.I.E., Bahadurgarh – 124507 (Haryana)
Submitted/Source	Enforcement Directorate	Method of Analysis (Test Reference):	BP 2023, USPNF 2023 ISSUE 2
Sample receipt date:	26 - 04 - 2023	Testing Date:	29 - 04 - 2023
Date of Completion of Test:	15 - 09 - 2023	Report Date:	15 - 09 - 2023

Test Parameter	Specification	Result	Compliance Statement
*DESCRIPTION	Not Available	Colourless free flowing liquid	Not Applicable
IDENTIFICATION[HPLC] Oxytocin	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay	The retention time of the major peak of the sample solution corresponded to that of the standard solution as obtained in the Assay	Passed
*VISIBLE PARTICLES	Essentially free from visible particulates	Solution was free from visible particulates	Passed
EXTRACTABLE VOLUME/ml	Label Claim: 1.0	1.0	Passed
pH	3.5 – 4.5	4.1	Passed
ASSAY%[HPLC] Oxytocin	90.0 – 110.0	115.1	Failed
STERILITY Anaerobic Bacteria Aerobic Bacteria & Fungi	No growth; Clear solution No growth; Clear solution	No growth; Clear solution No growth; Clear solution Refer to report number MBP-23/08/1073	Passed

"This test is accredited under the laboratory's ISO/IEC 17025 accreditation issued by ANAB. Refer to certificate and scope of accreditation AT -1870"

** Test not accredited for ISO/IEC 17025-2017*

Certificate No.: PCM-23/09/0373

CENTRE FOR LABORATORY SERVICES AND RESEARCH

CERTIFICATE OF ANALYSIS

Sample Information			
Testing Laboratory: Drug Laboratory Department		Testing Unit: Drug Physicochemical Unit	
Sample ID:	FDA/LSD23/DG0248	Client Ref No.:	ED/23/04-001
Sample Name: Bellocin Oxytocin Injection BP (LL 79688 DX)		Generic Name:	Oxytocin Injection
Formulation:	Solution for Injection	Environmental Condition (If applicable) Temp./Humidity:	Satisfactory
Composition: Each ml contains Oxytocin (Synthetic) BP 10 Oxytocin units eq. to Oxytocin peptide 16.66mcg		Batch No:GH-B3-48	Condition of Sample: Satisfactory
Mfg. Date:	08 - 2022	Exp. Date:	07 - 2024
Manufacturer:	Belco Pharma	Manufacturer's Address	515, M.I.E., Bahadurgarh – 124507 (Haryana)
Submitted/Source :	Enforcement Directorate	Method of Analysis (Test Reference):	BP 2023, USPNF 2023 ISSUE 2
Sample receipt date:	26 - 04 - 2023	Testing Date:	29 - 04 - 2023
Date of Completion of Test:	15 - 09 - 2023	Report Date:	15 - 09 - 2023

BACTERIAL ENDOTOXIN TEST	NMT 35.7 Eu/u	< 35.7 Eu/u Refer to report number MBP-23/08/1073	Passed

Conclusion: The sample conforms to test for Identification, Visible Particles, pH but failed Assay as per the acceptance criteria in the British Pharmacopoeia. The Extractable volume is as per the manufacturer's label claim. The sample also conforms to test for Sterility and Bacterial Endotoxin as per the United States Pharmacopeia.

Opinions/Interpretations: Not Applicable

Remark

1. The test result is based on the tests carried out on the samples submitted to the laboratory by the customer.
2. This certificate is traceable to record number CLSR/WKS/PCM/23/240a-d

Analyst: -	*GILBERT M. TETEVI*	Sign: -		Date: -	15-09-2023
HOL: -	*PATRICK OWUSU-DANSO*	Sign: -		Date: -	15/09/2023
HQA: -	*JOSEPH OFOSU SIAW*	Sign: -		Date: -	18/9/23

"This test is accredited under the laboratory's ISO/IEC 17025 accreditation issued by ANAB. Refer to certificate and scope of accreditation AT-1870"

** Test not accredited for ISO/IEC 17025-2017*

Certificate No.: PCM-23/09/0375

CENTRE FOR LABORATORY SERVICES AND RESEARCH

CERTIFICATE OF ANALYSIS

Sample Information			
Testing Laboratory: Drug Laboratory Department		Testing Unit: Drug Physicochemical Unit	
Sample ID:	FDA/LSD23/DG0258	Client Ref No.:	ED/23/04-001
Sample Name: Beltocin Oxytocin (Oxytocin Injection) (ASIL – OX 008)		Generic Name:	Oxytocin Injection
Formulation:	Solution for Injection	Environmental Condition (If applicable) Temp./Humidity:	Satisfactory
Composition: Each ml contains Oxytocin (Synthetic) BP 10 Oxytocin units		Batch No: GH-B3-48	Condition of Sample: Satisfactory
Mfg. Date:	08 - 2022	Exp. Date:	07 - 2024
Manufacturer:	Belco Pharma	Manufacturer's Address	S15, M.I.E. Bahadurgah - 124507 Haryana - India
Submitted/Source	Enforcement Directorate	Method of Analysis (Test Reference):	BP 2023, USPNF 2023 ISSUE 2
Sample receipt date:	26 - 04 - 2023	Testing Date:	28 - 04 - 2023
Date of Completion of Test:	15 - 09 - 2023	Report Date:	15 - 09 - 2023

BACTERIAL ENDOTOXIN TEST	NMT 35.7 Eu/u	< 35.7 Eu/u Refer to report number MBP-23/08/1062	Passed

Conclusion: The sample conforms to test for Identification, Visible Particles and pH but failed Assay as per the acceptance criteria in the British Pharmacopoeia. The Extractable volume is as per the sample's label claim. The sample also conforms to test for Sterility and Bacterial Endotoxin as per the United States Pharmacopeia

Opinions/Interpretations: Not Applicable

Remark

1. The test result is based on the tests carried out on the samples submitted to the laboratory by the customer.
2. This certificate is traceable to record number CLSR/WKS/PCM/23/216a-e

Analyst: -	GILBERT M. TETEVI	Sign: -		Date: -	15 - 09 - 2023
HOL: -	PATRICK OWUSU-DANSO	for Sign: -		Date: -	18/09/2023
HQA: -	JOSEPH OFOSU SIAW	Sign: -		Date: -	18/9/23

"This test is accredited under the laboratory's ISO/IEC 17025 accreditation issued by ANAB. Refer to certificate and scope of accreditation AT -1870"

* Test not accredited for ISO/IEC 17025-2017

HILLS PHARMACEUTICALS LTD

GPS: GA - 217 - 2446
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Email: info@hillspharmagh.com

P. O. BOX AD 785 ADABRAKA, Accra -Ghana
No. 17 Fadama Street, South Industrial Area
www.hillspharmagh.com

2nd January, 2023

THE CHIEF EXECUTIVE
FOOD AND DRUG AUTHORITY
HEAD OFFICE
P. O. BOX CT 2783
ACCRA

Dear Madam,

APPLICATION FOR SAFE DISPOSAL OF BELTOCIN OXYTOCIN INJECTION BP AND PAYMENT OF DISPOSAL FEES

This letter is in response to your letters dated 15th December, 2024 with your reference number FDA/TOD/OPS/SDU/23/0008. We thank you for the content therein.

By this letter we here by apply for safe disposal of our Beltocin Oxytocin Injection BP and also makes payment of Two Thousand, Two Hundred and Eighty Two Ghana Cedis GH¢2,282.00 as Disposal Fees as directed.

Attached to this letter are copies of your said letter and Bill/Invoice issued to us.
Counting on your usual cooperation.

Thank you.

Yours faithfully,

ERIC K. TAKYI
0249812328

Afrigu!
2/1/24

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/OPS/FOR - 04	
		Page 1 of 1	Ver. No.: 01
	DET/OPS/23/	Effective Date: 17/04/2023	

TITLE: NOTICE OF DETENTION/SEIZURE FORM

In Pursuance of the general provisions of Part Seven of the Public Health Act, 2012 (Act 851) and the powers conferred on me by Section 135 (1d) & (5b) of this Act,

I, ...Isaac Adom..... an authorized officer of the Food and Drugs Authority (FDA), hereby detain/seize the underlisted articles:

Product Description	Quantity	Batch Code	Reason(s) for Detention/Seizure
1. Bettocin Oxytocin Inj. BP.	1ampoule	GH-B3-48	Failed quality testing

Consent:

I, ...George Asong..... of

....Hills Pharmaceuticals Ltd.....

Tel: 0266164457 Fax: .....E-mail: georgeasong@hillspharm.com

owner/agent of goods, in agreement with Part Seven, Section 136 (2) of the Public Health Act, 2012, Act, consent to the above as provided for in section 135 (1d) & (5b).

Signature: ..... Date: ....22-09-2023....

(Owner of Article/Representative)

Signature: ..... Date: 22/09/23

(FDA Official)

FDA Officer's Remarks: Detained products should not be sold or moved until further regulatory clearances from the FDA

FDA	FOOD AND DRUGS AUTHORITY DET/OPS/23/	DOC. TYPE: FORM DOC NO.: FDA/OPS/FOR - 04 Page 1 of 1 | Ver. No.: 00 Effective Date: 17/04/2023

TITLE: NOTICE OF DETENTION/SEIZURE FORM

In Pursuance of the general provisions of Part Seven of the Public Health Act, 2012 (Act 851) and the powers conferred on me by Section 135 (1d) & (5b) of this Act,

I, Isaac Adom an authorized officer of the Food and Drugs Authority (FDA), hereby detain/seize the underlisted articles:

Product Description	Quantity	Batch Code	Reason(s) for Detention/Seizure
① Beltocin Oxytocin Inj. BP	114,078 amps	GH-B3-52 -53 -50 -49 -48 -51	Products failed Quality testing

Consent:

I, George Anaana of Hills Pharmaceuticals Ltd

Tel: 0266164451 Fax: — E-mail: .....

owner/agent of goods, in agreement with Part Seven, Section 136 (2) of the Public Health Act, 2012, Act, consent to the above as provided for in section 135 (1d) & (5b).

Signature: ..... Date: 24-11-2023

(Owner of Article/Representative)

Signature: ..... Date: 24-11-2023

(FDA Official)

FDA Officer's Remarks: All detained products (Beltocin Oxytocin Inj BP) should not be sold/distributed until further regulatory directives from the FDA

PHARMACY COUNCIL
GHANA
P. O. Box 10344, Accra-North. Tel: (0302) 680150, 681928 Fax: (233) 681931 Website: www.pcghana.org Email: info@pcghana.org

PC/ADM/294/2023

30 NOVEMBER, 2023

THE MANAGING DIRECTOR
HILLS PHARMACY
ACCRA

RECALL OF BELTOCIN AND VERNETOCIN (OXYCIN) INJECTIONS 10IU/ML

Pharmacy Council has received a complaint from the Food and Drugs Authority on your role in the importation of Beltocin and Vernetocin Injections (Oxytocin 10iu/ml) which has to be recalled because of the following:

1. Laboratory analyses for both Beltocin and Vernetocin (Oxytocin) injections 10iu/ml) have been inconsistent with several batches failing to meet approved quality standards.
2. Importing substandard oxytocin that could result in prolonged labour and post-partum haemorrhage which can negatively affect the mother and/or baby.

The Food and Drugs Authority has accordingly ordered for immediate recall of all batches of Beltocin and Vernetocin Injections (Oxytocin 10iu/ml) imported by your company.

You are by this letter to explain your role in this importation to the Registrar within **25 days** of receipt of this letter.

Thank you.

DR. DANIEL AMANINING DANQUAH
DEPUTY REGISTRAR – OPERATIONS
for: REGISTRAR

cc: THE CHIEF EXECUTIVE OFFICER
FDA – ACCRA

26533

Greater Accra Reg. Office — P.o. Box AN 10344, Accra-North, Ghana — Tel: (233) (0302) 681929, 680150 — Fax: (233) (0302) 681931
Eastern Regional Office — P.o. Box KF 2228, Koforidua. — Tel: (03420) 23205 — Fax: (233) (03420) 24699
Volta Regional Office — P.o. Box HP 1266, HO. — Tel: (03620) 26324 — Fax: (233) (03620) 26324
Central Regional Office — P.o Box CC 1339, Cape Coast — Tel: (03321) 33233 — Fax: (233) (03320) 33233
Western Regional Office — P.o. Box 1216, Takoradi — Tel: (03120) 46391 — Fax: (233) (03120) 46391
Ashanti Regional Office — P.o. Box KS 778, Kumasi — Tel: (03220) 31636, 41455 — Fax: (233) (03320) 31636
Brong Ahafo Reg. Office — P.o. Box 744, Sunyani. — Tel: (03520) 26551, 26490 — Fax: (233) (03520) 26551
Northern Reg. Office — P.o. Box TL 1777, Tamale — Tel: (03720) 23061 — Fax: (233) (03720) 23061
Upper East Reg. Office — P.o. Box BG 869, Bolgatanga — Tel: (03820) 29208 — Fax: (233) (03820) 29208
Upper West Reg. Office — P.o. Box 179, Wa — Tel: (03920) 22842 — Fax: (233) (03920) 22842

FDA/OPS/SD/24/0204

7th February 2024

CERTIFICATE OF SAFE DISPOSAL

The products described below were destroyed in the normal course of operations in pursuant of policies, regulations and procedures under the Public Health Act, 2012, Act 851

Applicant Name/Business Address
Hills Pharmaceuticals Limited
P O Box AD 785
Adabraka Accra

Description of product Disposed.
As per the attached list

Method of Disposal
The products were destroyed by crushing

Site of disposal
At Adipa Waste Management Centre, Nsawam

Date of Disposal
11th January 2024

Product disposal supervised by
Regulatory Officers of the Food and Drugs Authority

Product disposal witnessed by
Representatives from the Hills Pharmaceuticals Limited and Nsawam-Adoagyiri Municipal Assembly

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
		DOC NO.: FDA/OPS/FOR - 11
		Page 1 of 2 | Ver. No.: 01
		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Note: This form should be completed for **ONLY** one batch of the recalled product

Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No.		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	BELTOUM INJECTION	
Batch No. GH-BJ-53	Mfg Date: 07/2023	Exp. Date: 06/2026
Reason for Recall:		

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	**Official Use** Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
GOPENS PHARMACY	6400 Amps	0	6400 Amps	6400 Amps	
MARY THERESA	500 Amps	100 Amps	400 Amps	400 Amps	
CATHOLIC HOSPITAL					
Total Quantity	(G) 6400	(H) 100	(E) 6850	(F) 6800	

** refers to quantities recalled from lower levels of distribution where applicable*

TITLE: RECALL SUMMARY REPORT

Stock not distributed by importer/manufacturer (D)	56300
Quantity available in Warehouse after Recall (D+F)	67564
Justification for any deviations observed during reconciliation	N/A
Batch Disposition Safe Disposal Initiated: Yes [✓] No [ ]	Quantity: 67564

Recall Summary: (including action taken if the product was still available for sale or use)

RECALL SUCCESSFULLY DONE AND AWAITING FDA DIRECTIVE

Responsible Person / QA (Sign./Date): PATIENCE GEORGE 24-11-2023

Part C: Recall Evaluation (FDA USE ONLY)

Recall effectiveness (based on the number of Outlets notified/reached).

Level A: 100% [✓]
Level B: Between 100% and 10% [ ]
Level C: Less than 10% [ ]

Were products found during post-recall verification **Yes** [ ] **No** [ ]

General Remarks by HOD: 67564 empowers of affected/ Locations were recalled and safely disposed.

FDA Officer (Sign./Date): 01/02/2024

x refers to quantities recalled from lower levels of distribution where applicable*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
		DOC NO.: FDA/OPS/FOR - 11
		Page 1 of 2 | Ver. No.: 01
		Effective Date: 17/04/2023
TITLE: RECALL SUMMARY REPORT		

Note: This form should be completed for **ONLY** one batch of the recalled product

Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	BLEOMH INJECTION	
Batch No. HH-133-52	Mfg Date: 07/2023	Exp. Date: 07/2025
Reason for Recall:	SUB STANDARD PRODUCT	

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	**Official Use** Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
EASTERN REGIONAL HOSPITAL	9000 AMPS	1085 AMPS	7915 AMPS	7915 AMPS	
BAPTOR CATHOLIC HOSPITAL	2000 AMPS	559 AMPS	1441 AMPS	1441 AMPS	
NJANJAMA GOVT HOSPITAL	3000 AMPS	200 AMPS	2800 AMPS	2800 AMPS	
MUA GOVT HOSPITAL	800 AMPS	280 AMPS	520 AMPS	520 AMPS	
Total Quantity	(G) 14800	(H) 2124	(E) 12676	(F) 12676	

x refers to quantities recalled from lower levels of distribution where applicable*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
		DOC NO.: FDA/OPS/FOR - 11
		Page 2 of 2 | Ver. No.: 01
		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Stock not distributed by importer/manufacturer (D)	4100
Quantity available in Warehouse after Recall (D+F)	36225
Justification for any deviations observed during reconciliation	N/A
Batch Disposition Safe Disposal Initiated: Yes [✓] No [ ]	Quantity: 36225

Recall Summary: (including action taken if the product was still available for sale or use)

PRODUCT RECALLED SUCCESSFULLY AND AWAITING FDA DIRECTIVE

Responsible Person / QA (Sign./Date): AMSONG GEORGE 24/11/2023

Part C: Recall Evaluation (FDA USE ONLY)

Recall effectiveness (based on the number of Outlets notified/reached):

Level A: 100% [✓]
Level B: Between 100% and 10% [ ]
Level C: Less than 10% [ ]

Were products found during post-recall verification **Yes [ ] No [ ]**

General Remarks by HOD: 36225 Comprises of the effected batch were recalled and safely disposed

FDA Officer (Sign./Date): 05/12/2024

* refers to quantities recalled from lower levels of distribution where applicable.

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
		DOC NO.: FDA/OPS/FOR - 11
		Page 1 of 2 | Ver. No.: 01
		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Note: This form should be completed for **ONLY** one batch of the recalled product

Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No.		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	BELOCIN INJECTION	
Batch No. GH-B3-57	Mfg Date: 03/2023	Exp. Date: 02/2025
Reason for Recall:	SUB STANDARD PRODUCT	

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	**Official Use** Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
PORTECOST HOSPITAL THYOLA	500 AMPS	350 AMPS	200 AMPS	200 AMPS	
Total Quantity	(G) 500	(H) 350	(E) 200	(F) 200	

** refers to quantities recalled from lower levels of distribution where applicable*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
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		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Stock not distributed by importer/manufacturer (D)	499
Quantity available in Warehouse after Recall (D+F)	8776
Justification for any deviations observed during reconciliation	N/A
Batch Disposition Safe Disposal Initiated: Yes [✓] No [ ]	Quantity: 8776

Recall Summary: (including action taken if the product was still available for sale or use)

RECALL SUCCESSFULLY DONE AND WAITING FOR FDA DIRECTIVE

Responsible Person / QA (Sign /Date): AMSONG CLEMENCE 24-11-2023

Part C: Recall Evaluation (FDA USE ONLY)

Recall effectiveness (based on the number of Outlets notified/reached):

Level A: 100% [✓]
Level B: Between 100% and 10% [ ]
Level C: Less than 10% [ ]

Were products found during post-recall verification **Yes** [ ] **No** [ ]

General Remarks by HOD: 8776 ampoules of the affected batch were recalled and safely disposed.

FDA Officer (Sign./Date): 05/12/2024

** refers to quantities recalled from lower levels of distribution where applicable*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
		DOC NO.: FDA/OPS/FOR - 11
		Page 1 of 2 | Ver. No.: 01
		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Note: This form should be completed for **ONLY** one batch of the recalled product
Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No:		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	BELDUM INJECTION	
Batch No. GH-B3-50	Mfg Date: 03/2023	Exp. Date: 04/2025
Reason for Recall:	SUB STANDARD PRODUCT	

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	Official Use Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
EFRA HUSPITA					
REGIONAL HOSPITAL	4500 Amps	3500 Amps	1000 Amps	1000 Amps	
ADJAFUA PHARMACY	500 Amps	300 Amps	200 Amps	200 Amps	
Total Quantity	(G) 5000	(H) 3800	(E) 1200	(F) 1200	

** refers to quantities recalled from lower levels of distribution where applicable*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
		DOC NO.: FDA/OPS/FOR - 11
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		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Note: This form should be completed for **ONLY** one batch of the recalled product

Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No.		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	GELTOCIN INJECTION	
Batch No. GH-B3-50	Mfg Date: 03/2023	Exp. Date: 04/2025
Reason for Recall:	SUB STANDARD PRODUCT	

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase Invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	Official Use Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
GREATER ACCRA REGIONAL HOSPITAL	4000 Amps	1689 Amps	2311 Amps	2311 Amps	
EFFEDUA REGIONAL HOSPITAL	8600 Amps	7300 Amps	1300 Amps	1300 Amps	
AKLAJI GOVT HOSPITAL	1000 Amps	800 Amps	200 Amps	200 Amps	
KINTUS PHARMACY	3000 Amps	1340 Amps	1660 Amps	1660 Amps	
TAMALE MUN. HOSPITAL	7000 Amps	1394 Amps	1606 Amps	1606 Amps	
Total Quantity	(G) 19600	(H) 12523	(E) 7077	(F) 7477	

x refers to quantities recalled from lower levels of distribution where applicable*

TITLE: RECALL SUMMARY REPORT

Stock not distributed by importer/manufacturer (D)	0
Quantity available in Warehouse after Recall (D+F)	1012
Justification for any deviations observed during reconciliation:	N/A
Batch Disposition Safe Disposal Initiated: Yes [✓] No [ ]	Quantity: 1012

Recall Summary: (including action taken if the product was still available for sale or use)

PRODUCT WAS SUCCESFULLY RECALLED AND WAITING FOR FDA DIRECTIVE

Responsible Person / QA (Sign./Date): ANSUMAN GEORGE 24-1-2023

Part C: Recall Evaluation (FDA USE ONLY)

Recall effectiveness (based on the number of Outlets notified/reached):

Level A: 100% [✓]
Level B: Between 100% and 10% [ ]
Level C: Less than 10% [ ]

Were products found during post-recall verification **Yes [ ] No [ ]**

General Remarks by HOD: 1012 ampoules of the affected batch were recalled and safely disposed.

FDA Officer (Sign./Date): 05/02/2024

x refers to quantities recalled from lower levels of distribution where applicable.*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
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	TITLE: RECALL SUMMARY REPORT	

Note: This form should be completed for **ONLY** one batch of the recalled product

Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No.		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	BELADUM INJECTION	
Batch No. GH-83-49	Mfg Date: 08/2022	Exp. Date: 07/2024
Reason for Recall:	SUB STANDARD PRODUCT	

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	**Official Use** Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
MADUBIE GOVT HOSPITAL	2000 AMPS	1238 AMPS	762 AMPS	762 AMPS	
PONEGOS HOSPITAL TAYLOR	1000 AMPS	750 AMPS	250 AMPS	250 AMPS	
Total Quantity	(G) 3000	(H) 1988	(E) 1012	(F) 1012	

X refers to quantities recalled from lower levels of distribution where applicable*

FDA	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM
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		Effective Date: 17/04/2023
	TITLE: RECALL SUMMARY REPORT	

Note: This form should be completed for **ONLY** one batch of the recalled product
Part A: To be filled by Recalling Firm (Manufacturer / Importer / Local Agent / Wholesaler)

Recall Ref No.		Date: 24-11-2023
Name of Recalling Firm:	HILLS PHARMACEUTICALS LTD	
Product Name:	BELTOUM INJECTION	
Batch No. GH-B3-48	Mfg Date: 08/2022	Exp. Date: 07/2024
Reason for Recall	SUB STANDARD PRODUCT	

Recall Reconciliation

Name of Customer / Distribution or Retail Outlet	Qty. Issued with Purchase invoice (A)	Quantity Sold Out by Distributor (B)	Quantity Undistributed / Available Stock (C) = (A)-(B)	Quantity Received from Distribution Outlet in response to recall (C+X*)	**Official Use** Verification at Recall Outlets (Distributor/Retail)
e.g. Distributor/Retail 1	*100*	*75*	*25*	*25+X*	
ALUKLA PHARMACY	3000 AMPS	2700 AMPS	300 AMPS	300 AMPS	
Total Quantity	(G) 3000	(H) 2700	(E) 300	(F) 300	

x refers to quantities recalled from lower levels of distribution where applicable*

TITLE: RECALL SUMMARY REPORT

Stock not distributed by importer/manufacturer (D)	1
Quantity available in Warehouse after Recall (D+F)	301
Justification for any deviations observed during reconciliation	N/A
Batch Disposition Safe Disposal Initiated: Yes [✓] No [ ]	Quantity: 301

Recall Summary: (including action taken if the product was still available for sale or use)

PRODUCT WAS SUCCESSFULLY RECALLED AND HARMING FDA DIRECTIVE

Responsible Person / QA (Sign./Date): GEORGE ANSOMG 24-11-2023

Part C: Recall Evaluation (FDA USE ONLY)

Recall effectiveness (based on the number of Outlets notified/reached):

Level A: 100% [✓]
Level B: Between 100% and 10% [ ]
Level C: Less than 10% [ ]

Were products found during post-recall verification **Yes [ ] No [ ]**

General Remarks by HOD: 301 samples of the affected batch were recalled and disposed.

FDA Officer (Sign./Date): 05/12/2024

"x" refers to quantities recalled from lower levels of distribution where applicable