DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	7/14/2025-7/18/2025
	FEI NUMBER 3032144832

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Samuel (N.M.I.) Miron, CEO

FIRM NAME	STREET ADDRESS
GenoGenix , LLC	2840 Nw 2nd Ave Ste 204 **and Ste 205**
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boca Raton, FL 33431-6692	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the process.

Specifically,

A) On 07/16/2025, we observed three lots of sterile intact injectable drugs with visible contaminants and within expiry which were all released and distributed:

	Vials examined	Contaminants Observed
L-Glutamine 25 mg/ mL 30 mL vial Lot# GG042225-025 Mfg. (b) (4) EXP. 10/21/2025	(b) (4) vials	• (b) (4) vials with numerous particulates • At least five vials with numerous fibrous filaments and spherical clumps floating or adhering to the inner wall and lower stoppers.
Alpha Lipoic Acid 25 mg/ mL 30 mL vial Lot# GG050525-004 Mfg. (b) (4) EXP. 11/01/2025	47 vials	• 20 vials with one to three particulates
Glutathione Preserved 200 mg/ mL 30 mL vial Lot # ~~G071125-002~~ **GG071125-002** Mfg. (b) (4) EXP. 10/10/2025	30 vials	• 5 vials with numerous particulates

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Sarah M. Gauna, Investigator

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7/18/2025

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B) On July 14, 2025, during aseptic filling in ISO 5 Biological Safety Cabinets (BSCs) (#GG-0075), we observed your sterile technician:

- Blocking first air to the opened sterile vials with their gloved hands and sleeved wrists while filling the sterile bulk solution into sterile vials.
- Rubbing their gloved hands vigorously for about 1 minute over the open vials.
- Manually reaching into a bag of stoppers and stoppering vials with gloved hands.
- ~~Transferring a beaker stored in the ISO 8 area to the ISO 5 work area without sanitizing the outer surfaces.~~
- Transferring a beaker stored in the ISO 8 area to the ISO 5 work area without sanitizing the inner surfaces, which had been directly touched by gloved hands.
- Placing components within the ISO 5 work area that had the potential to block the movement of first air to critical in-process operations.
- Performing sterile operation in the ISO 5 hood with exposed skin on their face.
- Moving the tubing for filling out and back into the ISO 5 hood without sanitizing the tubing.

On (b) (4), your firm manufactured the following respectively in ISO 5 BSC (b) (4) (b) (4)

- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vials Lot # GG071425-002, Mfg. (b) (4), EXP. 10/13/2025
- Bacteriostatic Water ~~Sterile Waster for Injection USP,~~ 0.9% Benzyl Alcohol 30 mL Multi-Dose Vials, Lot # GG071425-004, Mfg. (b) (4), EXP. 07/13/2027
- Bacteriostatic Water ~~Sterile Waster for Injection USP,~~ 0.9% Benzyl Alcohol 10mL and 30 mL Multi-Dose Vials, Lot # GG071425-005, Mfg. (b) (4), EXP. 07/13/2027

C. Your firm has not performed media fills for any drug products since you started manufacturing and releasing sterile drugs from August 2024 to July 2025.

D. Your firm has not performed gowning qualifications for any compounding technicians that manufactured sterile drugs from August 2024 to July 2025.

E. Your firm has not performed any personnel monitoring for any compounding technicians that manufactured sterile drugs from August 2024 to July 2025.

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F. Your firm has not performed (b) (4) testing for any non-sterile bulk solutions aseptically filtered through the (b) (4) after each batch manufactured in your ISO 5 Biological Safety Cabinets (BSCs).

G. Your firm has not performed smoke studies in any of your (b) (4) ISO 5 BSCs (Equipment ID# (b) (4) (b) (4)) ~~or~~ (b) (4) ISO 7 clean rooms since you started manufacturing and releasing sterile drugs from August 2024 to July 2025.

H. Your firm has not qualified any compounding technician for visual inspection.

From approximately August 2024 to July 2025 your firm released approximately (b) (4) units of sterile injectable vials, (b) (4) vials, ~~nasal sprays,~~ and non-sterile products such as capsules**, and nasal sprays**.
Examples of sterile products released include but are not limited to:
Aseptically compounded ~~by firm~~:

- L-Glutamine 25mg/mL 30mL Multi-Dose Vial
- Alpha Lipoic Acid 25mg/mL 30mL Multi-Dose Vial
- Glutathione Preserved 200mg/mL 30mL Multi-Dose Vial
- Bacteriostatic Water 10mL and 30mL vials Multi-Dose Vial
- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vial
- ~~Oxytocin 100iU/ Methylene Blue 1%/mL 15mL Nasal Spray~~

Repackaged or Relabeled ~~by firm~~:

- Semaglutide **20** ~~25~~mg/10mL (b) (4)
- Tirzepatide 60mg/10mL vial (b) (4)
- Retatrutide 60mg/10mL vial (b) (4)
- Thymosin Alpha 1 (TA1) 10mg/3mL vial (b) (4)
- **BPC 157 15 mg Thymosin Beta-4 15 mg/ 10mL vial** (b) (4)
- **Mitochondrial Powerhouse PEG-MOTS-c FG 40mg, PEG-SS31 FG 40mg, NAD+ 500 mg, MSC Exosomes** (b) (4) **/ 10mL vial** (b) (4)

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OBSERVATION 2
The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically, your firm has manufactured and released drug products without quality unit (QU) oversight.

A. Your QU has not established control over:
   - The release specifications of finished drug products, including the review and approval for release and distribution.
   - Recall, reject, and quarantine of drug products and active pharmaceutical ingredients (APIs) held, manufactured, labeled, and/or repackaged at this facility.
   - Drug products reprocessed and repackaged at this facility.
   - Changes to drug formulations, components, and manufacturing steps. Labels and information listed on the drug product labels.
   - Employee training and qualifications for cGMP manufacturing

B. Your QU has not implemented sterility assurance programs for injectable drug products manufactured at this facility, these includes:
   - **Contamination control strategie**s-e.g.,
     - Environmental monitoring is not established.
     - Cleaning validations is not established.
     - Cleaning records are inconsistently recorded or not recorded.
   - **Aseptic process validations – e.g.,**
     - Media fill is not established.
     - Aseptic technician qualification is not established.
     - Personnel monitoring is not established.
     - Post aseptic (b) (4) testing is not established.
     - Process validation **is not established**.

~~C.~~ **Sterility Data** - e.g,
   - Finished product testing is not established.
   - Stability program is not established.
   - Container closure integrity testing

~~D.~~ **C.** Your QU has not established the following procedures, examples include:

- Established master batch record and production batch records
- Review and release of drug products
- Investigations
- Change Controls
- Corrective and Preventive actions
- Recalls
- Quarantine, Reprocess, Reject
- Adverse Events and Complaints
- Incoming and Release Testing
- Inventory Management
- Equipment Validation and Qualifications
- Product Retains
- Stability Study Programs
- Document Control and Retention
- Data Integrity
- Training Program
- Aseptic Processes

From approximately August 2024 to July 2025 your firm released approximately (b) (4) units of sterile injectable vials, (b) (4) vials~~, nasal sprays,~~ and non-sterile products such as capsules **and Nasal Sprays**. Examples of sterile products released include but are not limited to:
Aseptically compounded:

- L-Glutamine 25mg/mL 30mL Multi-Dose Vial
- Alpha Lipoic Acid 25mg/mL 30mL Multi-Dose Vial
- Glutathione Preserved 200mg/mL 30mL Multi-Dose Vial
- Bacteriostatic Water 10mL and 30mL vials Multi-Dose Vial
- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vial

Repackaged or Relabeled~~:~~

- Semaglutide 25mg/10mL (b) (4)
- Tirzepatide 60mg/10mL vial (b) (4)
- Retatrutide 60mg/10mL vial (b) (4)
- Thymosin Alpha 1 (TA1) 10mg/3mL vial (b) (4)

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Compounded:

- Oxytocin 100iU/ Methylene Blue 1%/mL 15mL Nasal Spray
- Rapamycin 2.5mg Capsules

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A) Your firm failed to initiate an investigation after a power outage on July 12, 2025, which interrupted the power supplies to your cleanrooms and refrigerators used for product storage. On (b) (4), your firm recommenced sterile manufacturing without performing any sterility impact assessment and determination on the length of the power outage. The following lots were manufactured on (b) (4):

- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vials Lot # GG071425-002, Mfg. (b) (4), EXP. 10/13/2025
- Bacteriostatic Water ~~Sterile Waster for Injection USP,~~ 0.9% Benzyl Alcohol 30 mL Multi-Dose Vials, Lot # GG071425-004, Mfg. (b) (4), EXP. 07/13/2027
- Bacteriostatic Water ~~Sterile Waster for Injection USP,~~ 0.9% Benzyl Alcohol 10mL and 30 mL Multi-Dose Vials, Lot # GG071425-005, Mfg. (b) (4), EXP. 07/13/2027

B) Your firm lacks appropriate complaint investigation and root-cause determination, e.g.,
Your firm initiated complaint investigation QA018-F001 into NAD+ lot GG121624-023 after receiving a notification from a health provider that ~~four~~ **three** patients had developed adverse symptoms (e.g., low blood pressure, uncontrollable shaking, shivers, and body aches) shortly after or while receiving NAD+ infusion. According to the complaint report, these ~~four~~ **three** patients received NAD+ Lot# GG121624-023 from the same vial and were directed to the emergency room. As part of your investigation, your firm sent three vials to a testing laboratory for endotoxin and sterility testing and received the following results.

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	Sample Condition	Test Completion Date	Endotoxin Result
NAD 200mg/mL Lot# GG121624-023	Intact vial	01/23/2025	3360 EU/mL "---"
NAD 200mg/mL Lot# GG121624-023	Opened vial	01/23/2025	9410 EU/mL "---"
NAD 100mg/mL Lot# ~~GG121624-023~~ **GG020425-010**	Intact vial	02/11/2025	254 EU/mL "---"

From your investigation, you determined the root-cause of these adverse reactions were attributed to the presence of (b) (4) as a pH adjuster for the NAD lot GG121624-023 formulation. Your firm concluded this investigation without any evaluation of these endotoxin testing results and impact to patient safety.

~~D)~~ **C)** Your firm released reprocessed material from a batch of that had been calculated to be super potent in the initially released portion without performing testing to verify the reprocessed material met specifications. After recalling half of the batch due to superpotency, **you released** ~~releasing~~ the remaining reprocessed portion without testing fails to ensure the product meets established quality standards. ~~and presents a significant risk of distributing adulterated product.~~

- Original batch record was identified as Magnesium Chloride 200mg/mL **Lot # GG043025-001, Mfg.** (b) (4) **, EXP. 10/29/2025**
- Reprocessed batch was provided, Magnesium Chloride 200mg/mL
  Lot # GG050225-001, Mfg. (b) (4) , EXP. 11/01/2025
  ~~Lot # GG043025-001, Mfg.~~ (b) (4) ~~, EXP. 10/29/2025~~

~~E)~~ **D)** Your firm has out of specification (OOS) endotoxin and potency test results but failed to initiate corrective and preventive actions (CAPA) or investigations for most of these OOS results. Your firm did not adequately identify root causes or implement corrective and preventive actions including but not limited to the following products:

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TYPE ESTABLISHMENT INSPECTED
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Endotoxin Result (Specification)	Test Completed Date	Product	Lot Number	Root Cause
6.62 EU/mL "Fail"	06/06/2025	NAD+ 100mg/mL	GG060225- 005	Not determined, no investigation, no CAPA
5.08 EU/mL "Fail"	06/14/2025	NAD+ 100mg/mL	GG052225- 001	Not determined, no investigation, no CAPA
10.8 EU/mL "Fail"	07/10/2025	NAD+ 100mg/mL	GG061225- 004	Not determined, no investigation, no CAPA
Potency Result (specification)	**Test Completed Date**	**Product**	**Lot Number**	**Root Cause**
84.4%	03/12/2025	Tirzepatide 40mg/vial	VI7920240918- 40	Not determined, no investigation, no CAPA
87.5%	03/31/2025	Tirzepatide 100mg/vial	VI7920250306- 100	Not determined, no investigation, no CAPA
65.3% (b) (4)	05/12/2025	B12 Methylcobalamin	GG042425-031	Not determined, no investigation, no CAPA
84.5% (b) (4)	06/03/2025	NAD+200mg/mL	GG042525-005	Not determined, no investigation, no CAPA
59.4% (b) (4)	06/04/2025	Zinc Sulfate 10mg/mL	GG051725-002	Not determined, no investigation, no CAPA
43.1%; 58% (b) (4)	06/09/2025	B Complex ~~100/2/100/2/2 mg/ml Dexpanthenol 2mg/ml;~~	GG051525-005	Not determined, no investigation, no CAPA

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OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A) Your firm has not performed any environmental monitoring during aseptic operation since you started manufacturing and releasing sterile drug products from August 2024 to July 2025.

B) Your firm has not performed personnel monitoring during aseptic operations since you started manufacturing and releasing sterile drug products from August 2024 to July 2025.

C) Your firm does not perform continuous pressure differential monitoring in your ISO 7 cleanrooms. You only perform pressure differential at the (b) (4) of your production day. Pressure differentials monitored (b) (4) production began around 06/12/2025.

D) Your firm had a power outage sometimes during July 12, 2025, however, your firm has not determined the length of the outage, nor taken appropriate steps to mitigate the issue, for example but not limited to performing any environmental monitoring following cleaning.

E) Your firm has no cleaning records from August 2024 to July 2025, e.g.,

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	Manufacturing Date	Cleanroom Cleaning Record [Yes/No]
NAD 200 mg/ mL Lot # GG121624-023	(b) (4) **Unknown*** **	No
L-Glutamine 25 mg/ mL 30 mL vial, Lot# GG042225-025 EXP. 10/21/2025	(b) (4)	No
Alpha Lipoic Acid 25 mg/ mL 30 mL vial, Lot# GG050525-004 EXP. 11/01/2025	(b) (4)	No
Glutathione Preserved 200 mg/ mL 30 mL vial, Lot# G071125-002 EXP. 10/10/2025	(b) (4)	No

***** Firm stated there is no manufacturing batch record for Lot /# GG121624-023**

From approximately August 2024 to July 2025 your firm released approximately (b) (4) units of sterile injectable vials, (b) (4) vials, and non-sterile products such as nasal sprays and capsules. Examples of products released include but are not limited to:

- L-Glutamine 25mg/mL 30mL Multi-Dose Vial
- Alpha Lipoic Acid 25mg/mL 30mL Multi-Dose Vial
- Glutathione Preserved 200mg/mL 30mL Multi-Dose Vial
- Bacteriostatic Water 10mL and 30mL vials Multi-Dose Vial
- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vial
- Semaglutide 25mg/10mL (b) (4)
- Tirzepatide 60mg/10mL vial (b) (4)
- Retarutide 60mg/10mL vial (b) (4)
- Thymosin Alpha 1 (TA1) 10mg/3mL vial (b) (4)
- Oxytocin 100iU/ Methylene Blue 1%/mL 15mL Nasal Spray
- Rapamycin 2.5mg Capsules

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OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, closures, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

~~A)~~ Your firm failed to consistently conduct required testing on manufactured lots prior to May 2025. The absence of systematic lot testing compromises batch release procedures and prevents verification that each lot conforms to established specifications before distribution. Lots without documented release testing include:

- NAD 200mg/ml Lot # GG121624-023
- L-Glutamine 25 mg/ mL 30 mL vial Lot# GG042225-025, Mfg. (b) (4), EXP. 10/21/2025
- MSC Exosomes Reconstitution Solution 20% MSC Exosomes. (b) (4) exosomes per vial, 8mL in a 10mL Multi-Dose Vial Lot # GG052825-019, Mfg. (b) (4), EXP. 11/12/2025
- Alpha Lipoic Acid 25mg/mL 30mL vial Lot# GG050525-004, Mfg. (b) (4), EXP. 11/01/2025

OBSERVATION 6

Reprocessing procedures lack the steps to be taken to ensure that reprocessed batches will conform with all established standards, specifications, and characteristics.

Specifically,

Your firm did not complete an investigation for released reprocessed material from a batch of that had been calculated to be super potent in the initially released portion. Your firm did not perform product testing to verify the reprocessed material met specifications. After recalling half of the batch due to

superpotency, **you released** ~~releasing~~ the remaining reprocessed portion without testing fails to ensure the product meets established quality standards. ~~and presents a significant risk of distributing adulterated product.~~

- Original batch record was identified as Magnesium Chloride 200mg/mL Lot # GG043025-001, Mfg. (b) (4) , EXP. 10/29/2025
- Reprocessed batch was provided, Magnesium Chloride 200mg/mL Lot # GG050225-001, Mfg. (b) (4) , EXP. 11/01/2025

OBSERVATION 7
Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

A) Your "Ceiling Cassette" located in the ISO 7 cleanrooms circulate air without HEPA filtration. The absence of HEPA filtration on this unit compromises the cleanroom's ability to control airborne particulate contamination and maintain the designed cleanliness levels necessary for aseptic manufacturing operations. Additionally, your ISO 7 cleanrooms lacks air return capability while the adjacent ISO 8 room has a ceiling-mounted air return.

B) The door frame between your ISO 7 cleanroom and ISO 7 "area" room appears to be constructed of wood-like material. Wood is porous and cannot be adequately cleaned and disinfected to maintain the controlled environment standards required for cleanroom operations.

C) Your cleanroom sliding glass doors have visible gaps that could compromise the integrity of the controlled environment. These openings create pathways for uncontrolled air movement and potential contamination transfer. Additionally, when the sliding door is open your ISO 7 cleanrooms do not maintain positive pressure and there is no alarm to notify a drop of pressure.

D) Your (b) (4) between the ISO 8 room and ISO 7 "area" room lacks an interlocking mechanism to prevent both doors from being opened simultaneously.

E) Each of your cleanrooms have a "Ceiling Cassette" which supplies cooled air through side vents that are not easily cleanable. Additionally, on July 14, 2025, we observed dust-like accumulation on air intake for these units.

F) The sliding glass door tracks to ISO 7 and ISO 8 cleanrooms have difficult to clean surfaces, e.g., the wall-mounted tracks contain grooved channels that create crevices and recessed areas that are difficult to clean.

G) The caulking to the ISO 7 cleanroom ceiling tiles, wall seams, and door frames are not constructed of smooth and easily cleanable surfaces.

H) Your material (b) (4) (b) (4) between the ISO 7 and ISO 8 cleanrooms have adhesive residue with visible debris and fibers adhered to the surface.

From approximately August 2024 to July 2025 your firm released approximately (b) (4) units of sterile injectable vials, (b) (4) vials, nasal sprays, and non-sterile products such as capsules. Examples of sterile products **manufactured and** released include but are not limited to:
Aseptically compounded:

- L-Glutamine 25mg/mL 30mL Multi-Dose Vial
- Alpha Lipoic Acid 25mg/mL 30mL Multi-Dose Vial
- Glutathione Preserved 200mg/mL 30mL Multi-Dose Vial
- Bacteriostatic Water 10mL and 30mL vials Multi-Dose Vial
- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vial
- ~~Oxytocin 100iU/ Methylene Blue 1%/mL 15mL Nasal Spray~~

Repackaged or Relabeled:

- Semaglutide 25mg/10mL (b) (4)
- Tirzepatide 60mg/10mL vial (b) (4)
- Retatrutide 60mg/10mL vial (b) (4)
- Thymosin Alpha 1 (TA1) 10mg/3mL vial (b) (4)

OBSERVATION 8
Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity

test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically,

A. Your firm has not:
- Performed at least one specific identity test on each incoming component as required and you lack confirmatory testing procedures for incoming components.
- Established the reliability of supplier analyses through appropriate validation of supplier test results at defined intervals.
- Established process for testing active pharmaceutical ingredients (APIs) upon receipt.

From approximately August 2024 to July 2025 your firm released approximately (b) (4) units of sterile injectable vials, (b) (4) vials, ~~nasal sprays,~~ and non-sterile products such as capsules **and nasal sprays**. Examples of sterile products **manufactured and** released include but are not limited to:
- L-Glutamine 25mg/mL 30mL Multi-Dose Vial
- Alpha Lipoic Acid 25mg/mL 30mL Multi-Dose Vial
- Glutathione Preserved 200mg/mL 30mL Multi-Dose Vial
- Bacteriostatic Water 10mL and 30mL vials Multi-Dose Vial
- Ascorbic Acid (Vitamin C) Preservative Free 500mg/mL 30mL Multi-Dose Vial
- ~~Oxytocin 100iU/ Methylene Blue 1%/mL 15mL Nasal Spray~~

B. Your firm receives finished (b) (4) drug products and relabels them for distribution without performing required identity testing or establishing supplier reliability. Specifically, your received products including:
- Semaglutide 20mg
- Tirzepatide 20mg
- Retatrutide 60mg
- Thymosin Alpha-1 10mg

Your firm then relabels and releases these products without confirmatory testing. Additionally, the certificates of analysis lack manufacturer identification, and your receiving records do not document supplier addresses. This practice fails to ensure product identity and quality before relabeling and distribution.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/14/2025-7/18/2025
	FEI NUMBER 3032144832

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samuel (N.M.I.) Miron, CEO

FIRM NAME	STREET ADDRESS
GenoGenix , LLC	2840 Nw 2nd Ave Ste 204 **and Ste 205**
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33431-6692	TYPE ESTABLISHMENT INSPECTED **Outsourcing Facility**

OBSERVATION 9
Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically,

A) Your firm has not provided complete distribution records. When requested during the inspection, you were unable to provide distribution records containing the required elements including name, strength, dosage form, recipient name and address, date, quantity shipped, and lot number for drug products distributed from January 2024 to July 2025. This failure compromises your ability to conduct effective recalls and maintain proper traceability of distributed products.

B) Your firm only started documenting and using draft batch records in May 2025, e.g., you do not have batch records for the following:
- L-Glutamine 25 mg/ mL 30 mL vial Lot# GG042225-025, Mfg. (b) (4), EXP. 10/21/2025. Additionally, during a visual examination of this lot on July 16, 2025, we observed contaminants in all (b) (4) vials of this lot held in your inventory.
- MSC Exosomes Reconstitution Solution 20% MSC Exosomes. (b) (4) exosomes per vial, 8mL in a 10mL Multi-Dose Vial Lot # GG052825-019, Mfg. (b) (4), EXP. 11/12/2025
- NAD 200mg/ml Lot # GG121624-023

OBSERVATION 10
Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

A. On July 14, 2025, we observed five pre-printed and unsecured labels stored in the finished product refrigerator. The following information is listed on the label "Rapamycin 2.5 mg Capsules" "(b) (4) Capsules" (b) (4) "For Research Purposes Only" "Manufactured for (b) (4)" "Made in the USA" "LOT: GG070225-001" "MFG: (b) (4)" "EXP: 07/01/2026"

B. Your batch record for Glutathione Preserved 200mg/mL in 30mL vials Lot # GG071125-002, Mfg. (b) (4), EXP. 10/01/2025 has (b) (4) of (b) (4) listed as a component of the batch. The product is labeled as Glutathione Preserved 200mg/mL 30mL Multi-Dose Vial and does not include the (b) (4) listed on the batch record. This product was compounded on (b) (4)

Bei Y. He, Investigator
Sarah M. Gauna, Investigator

Bei Y. He -S Digitally signed by Bei Y. He -S Date: 2025.07.31 15:38:28 -04'00'

DATE ISSUED
7/18/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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and released for distribution the same day. Product shipping records show this lot was distributed starting 7/14/2025.

OBSERVATION 11

Control procedures are not established which of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

Your firm does not perform 100% visual inspection for particulate matter on sterile drug products packaged in amber vials, nor does your firm perform Acceptable Quality Level (AQL) testing. For example:

- Batch Record Document Number (b) (4) for Alpha Lipoic Acid 25 mg/mL, Lot Number GG050525-004, manufactured on (b) (4) with expiration date 10/01/2025,
  - Step 5.2 states: "Perform Visual Inspection on all finished product bottles/vials. For amber vials or opaque or translucent vials/containers, inspect for container integrity. For clear vials or containers, inspect for container integrity and product particulates.
  - Step 5.2.3 indicated that all vials passed 100% visual inspection; however, your actual practice does not include particulate inspection for amber vials.
- Batch Record Document Number (b) (4) for Glutathione Preserved 200 mg/mL in 30 mL vials, Lot Number GG071125-002, manufactured on (b) (4) with expiration date 10/10/2025,
  - Step 8.2 states: "Perform Visual Inspection on all finished product bottles/vials. For amber vials or opaque or translucent vials/containers, inspect for container integrity. For clear vials or containers, inspect for container integrity and product particulates."
  - Step 8.2.3 indicated that all vials passed 100% visual inspection; however, your actual practice does not include particulate inspection for amber vials.
- L-Glutamine 25 mg/ mL 30 mL vial Lot# GG042225-025, EXP. 10/21/2025, manufactured on (b) (4).
  - While your firm asserts that "a basic visual inspection" is performed, you do not have documentation to demonstrate that this lot was inspected prior to release.
  - Furthermore, on July 17, 2025, we visually inspected all (b) (4) vials of this lot on hand and observed contaminants in all (b) (4) vials.

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OBSERVATION 12
Employees engaged in the manufacture, processing, packing and holding of a drug product lack the education, training and experience required to perform their assigned functions.

Specifically,

Your firm failed to provide documentation of training or relevant experience for all your technicians involved in sterile processing operations.

OBSERVATION 13
The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

~~A~~. The labels for some of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

- The established name of the drug;
  Examples of your drug product labels that do not contain this information, include but are not limited to: Rapamycin 2.5mg caps, Clear Mind 150 (NAD+ 150mg/mL) Nasal Spray **and** LIPO (MIC) + B Multidose Vial

- The dosage form;
  Examples of your drug product labels that do not contain this information, include but are not limited to:, LIPO (MIC) + B Multidose Vial **and** B-Complex Multidose Vial

- A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.
  Examples of your drug product labels that do not contain this information, include but are not limited to: Rapamycin 2.5mg caps **and** Clear Mind 150 Nasal Spray

Bei Y. He, Investigator
Sarah M. Gauna, Investigator

Bei Y. He -S Digitally signed by Bei Y. He -S Date: 2025.07.31 15:39:23 -04'00'

DATE ISSUED 7/18/2025

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OBSERVATION 14

The container of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

~~A~~. The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

- Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA– 1088; Examples of your container labels that do not contain this information:
    - Immune Defense Nasal Spray
- Directions for use, including, as appropriate, dosage and administration. Examples of your container labels that do not contain this information:
    - Immune Defense Nasal Spray

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OBSERVATION 15

Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because they (a) are not used to compound drug products that appear on the drug shortage list in effect under section 506E of the Act and (b) do not appear on a list developed by FDA of bulk drug substances for which there is a clinical need.

Specifically,

You produce and distribute drug products containing bulk drug substances that are ineligible for use in human drug compounding, including but not limited to:(b) (4)
(b) (4).

OBSERVATION 16

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

Your outsourcing facility did not submit a report to FDA identifying all the drugs compounded during the previous six-month period. Specifically, you did not submit the required initial product report or the required biannual product report for June 2025.

***DATES OF INSPECTION**

07/14/2025 (Mon), 07/15/2025 (Tue), 07/16/2025 (Wed), 07/17/2025 (Thu), 07/18/2025 (Fri),

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."