DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/31/2025-4/8/2025*
	FEI NUMBER 3011742679

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Glen G. Gong, CEO

FIRM NAME	STREET ADDRESS
Microvascular Tissue, Inc	6199 Cornerstone Ct E Ste 109
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92121-4740	TYPE ESTABLISHMENT INSPECTED Biological product manufacturer/distributor

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 WE OBSERVED:

OBSERVATION 1

Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

Specifically, you did not investigate complaint (ID CM 2022-02) received June 21st, 2022 that reported a patient had "pain" and "minor swelling" in their knee after receiving an injection of your product mVASC- lot (b)(4).

Furthermore, you did not follow your written procedures entitled "Complaint Handling" Document Number [redacted] SOP-8001 which states: "For all complaints, the evaluation shall include an assessment of whether there is potential for harm to a patient or end user of the device. Should such a case arise, appropriate customer notification and failure investigation shall commence without delay".

Since commercial distribution began in (b)(4), you have distributed approximately (b)(4) of mVASC (a product described by your Instructions For Use (IFU) as extracellular matrix derived from hypodermis skin).

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, since your commercial operations began beginning in (b)(4) you have not validated

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Garrad R Poole, Investigator Richard T Riggie, Investigator	X Garrad R Poole Investigator signed by GARRAD R. POOLE - S Date Signed: 04-08-2025 13:27:17	4/8/2025

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the following processes:

1. You did not validate the [redacted] using [redacted] with the addition of [redacted].
2. You did not validate determining [redacted] and viability as outlined in your batch records [redacted]" DOC. NO. [redacted] which are further processed into your mVASC product.
3. You have not performed a process validation since moving the "isolation of [redacted]" to a [redacted]. You have manufactured [redacted] batches of mVASC at this [redacted] and [redacted] of the batches have been commercially distributed.

Since commercial distribution began in [redacted], you have distributed approximately [redacted] of mVASC (a product described by your Instructions For Use (IFU) as extracellular matrix derived from hypodermis skin).

OBSERVATION 3

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, you have not specified any identity test to be performed on components used to manufacture mVASC product.

You have established acceptance criteria based off the certificate of analysis for the following, but you have not established criteria for a specific test to verify the identity of the components:

a.
b.
c. (b)(4)

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	Garrad R Poole, Investigator Richard T Riggie, Investigator X Garrad R Poole Investigator Signed by: GARRAD R. POOLE - S Date Signed: 04-08-2025 13:27 T	4/8/2025

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d.
e. (b)(4) .

Since commercial distribution began in (b)(4), you have distributed approximately [redacted] of mVASC (a product described by your Instructions For Use (IFU) as extracellular matrix derived from hypodermis skin).

OBSERVATION 4

There is a failure to thoroughly review 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, your (b)(4) document number (b)(4), does not address evaluating batches that fail to meet specifications. Of the [redacted] batches produced [redacted] have failed for reasons to include (b)(4) (b)(4) bioburden.

Additionally, you did not investigate into the reason of failure for lot (b)(4) that failed for [redacted] (b)(4).

Since commercial distribution began in (b)(4), you have distributed approximately (b)(4) of mVASC (a product described by your Instructions For Use (IFU) as extracellular matrix derived from hypodermis skin).

*DATES OF INSPECTION

3/31/2025(Mon), 4/01/2025(Tue), 4/02/2025(Wed), 4/03/2025(Thu), 4/04/2025(Fri), 4/07/2025(Mon), 4/08/2025(Tue)

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X Richard T Riggie
Investigator
Signed By: Richard T. Riggie -S
Date Signed: 04-08-2025 13:27:48

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EMPLOYEE(S) SIGNATURE
Garrad R Poole, Investigator
Richard T Riggie, Investigator

X Garrad R Poole
Investigator
Signed By: GARRAD R. POOLE -S
Date Signed: 04-08-2025 13:27:11

DATE ISSUED
4/8/2025

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 4 of 4 PAGES

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."