

Page 1 of 2
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

US FDA CDRH Bryan Benesch
White Oak Building 66, Room 3540
10903 New Hampshire Ave.
Silver Spring, MD 20993 301-796-5819
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

10/21 - 24/2019

FEI NUMBER

30065113362

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Vikas Narang, Director

FIRM NAME

GPC MEDICAL LIMITED

STREET ADDRESS

Plot No. 1540, HSIDC, RAI Industrial Area

CITY, STATE AND ZIP CODE

Sonepat, Haryana, India 110018

TYPE OF ESTABLISHMENT INSPECTED

Device Manufacturer

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.

The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Process Control Procedures that describe any process controls necessary to ensure conformance to the specifications have not been adequately established. For example:

The Procedure for (b)(4) does not identify the temperature that the process is operated at. The (b)(4) Cleaning process validation was performed at a temperature of (b)(4). During a walk through of the manufacturing facility on Tuesday October 22, I observed the (b)(4) Cleaning process operating at a temperature of (b)(4). Also, the procedure for the (b)(4) cleaning does not provide sufficient detail for how parts will be rinsed after (b)(4) cleaning such as volume of water used and rinsing time.

The Procedure for (b)(4) identifies that the (b)(4) consists of equal parts of (b)(4). The Validation of the (b)(4) process used an (b)(4) containing (b)(4).

2. Procedures for acceptance of in-process product have not been adequately established. Specifically, during a walk through of the Manufacturing Production area I observed the Machining of 4.0MM Canulated Cancellous Screw/LOT (b)(4). The First Piece Approval document indicated that the thread length of the piece was 7mm and three pieces were measured and were reported as 7.0mm, 7.1mm and 7.1mm. The screw length is 20mm and the thread length should be 8mm. Re-measurement determined that the screw thread length was actually 8mm.

3. Procedures for Corrective and Preventive Action have not been adequately established. CAPA procedure/QSP/12 identifies product non conformance (receiving and finished product) as a Quality Data source for CAPA. The firm log book of product non conformance is not analyzed to identify recurring non conformance for Corrective actions. There have been no CAPA actions for product non conformance in the last three years.

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EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Stephen D. Eich, Investigator

DATE ISSUED

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4. A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated. Specifically, the process validation for (b)(4) cleaning did not demonstrate that the acceptance criteria for (b)(4) was satisfied. The testing after (b)(4) cleaning only reported a (b)(4) (b)(4) and the acceptance criteria established that there would be no (b)(4) difference to "neat" water. Also (b)(4) cleaning validation did not define or describe that the product will be rinsed after (b)(4) cleaning in the enzymatic reagent. Further the chemicals of the enzymatic reagent were not tested for as part of the residual testing.

5. Schedules for maintenance of equipment have not been adequately established. Specifically, the Reverse Osmosis water system is reportedly serviced by (b)(4). There are no service reports of these activities. The firm has not evaluated the water quality of the RO water used for the (b)(4) cleaning since 2017.

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