**WARNING LETTER**

# Wilson Medicine Company

**MARCS-CMS 557206 — SEP 10, 2018**

**Product:**

Drugs
Pharmaceutical Quality

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**Recipient:**

Mr. Vineet Thakkar

Wilson Medicine Company

Wilson Medicine Company

Plot No 24, MBD Ind Est, Nandore Road
B/H P.M. Electro Auto
Nandore, Palghar East, Thane 401404
India

**Issuing Office:**

Center for Drug Evaluation and Research

United States

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**Via UPS**
**Return Receipt Requested**

**Warning Letter 320-18-75**

September 11, 2018

Mr. Vineet Thakkar
Partner
Wilson Medicine Company
Plot No 24, MBD Ind Est, Nandore Road
B/H P.M. Electro Auto
Nandore, Palghar East, Thane 401404
India

Dear Mr. Thakkar:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Wilson Medicine Company at Plot 24, S 361-364 Nandore, Palghar East, Maharashtra from February 26 to March 1, 2018.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your March 16, 2018, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

**1. Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).**

You failed to conduct process performance qualification for your **(b)(4)** and **(b)(4)** over-the-counter (OTC) drug products. You did not demonstrate that your manufacturing processes are reproducible and controlled to consistently yield drugs of uniform character and quality. You also have not conducted equipment qualification.

In your response, you stated that you will prepare protocols for your manufacturing process validation and equipment qualification.

Your response is inadequate because you failed to provide a detailed process performance qualification protocol and an overall program for assuring ongoing maintenance of a validated process.

In response to this letter, provide your validation and equipment qualification protocols, and reports with timelines for completion for all drug products distributed to the U.S. market. Also include a detailed summary of your approach for routinely monitoring intra- and inter-batch variation to ensure an ongoing state of control.

See FDA's guidance document, *Process Validation: General Principles and Practices*, for approaches that FDA considers appropriate elements of process validation, at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070336.pdf (/media/71021/download).

**2. Your firm failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of its test methods (21 CFR 211.165(e)).**

Analytical test methods that you used to determine acceptability of your drug products prior to release for distribution are not validated (or verified, for USP compendial methods.) These methods include, but are not limited to, assay, limit of nonvolatile residue, limit of preservative, and specific gravity.

Your response acknowledges that you lack adequate validation and verification studies. Although you committed to prepare an analytical method validation protocol by May 20, 2018, you did not specify a timeframe to complete method validation/verification or provide an interim plan of action.

See United States Pharmacopeia (USP), General Chapter <1225>, *Validation of Compendial Procedures* and USP, General Chapter <1226>, *Verification of Compendial Procedures* for typical performance characteristics that should be considered for validation and verification of analytical test methods.

In response to this letter, provide:

- An independent assessment of all test methods used by your firm to ensure they have appropriate instructions, method suitability criteria, and appropriate validation (or verification, for USP compendial methods) to determine whether they are fit for purpose.
- Your plan of action to complete validation (or verification, for USP compendial methods) for all analytical test methods used in association with products shipped to the United States.
- A comprehensive independent review of your entire laboratory system, and a corrective action and preventive action (CAPA) plan that ensures full remediation of the laboratory operation. For example, the review of your laboratory system should include, but not be limited to, the suitability of all laboratory equipment, a fully remediated calibration program, staff competencies, supervisory oversight, data systems, and other elements of laboratory control.
- A summary of test results obtained from testing retain samples of all drug products within expiry. You should test all appropriate quality attributes including, but not limited to, identity, strength, and purity of active ingredients and finished drug products. If your testing for any previously released batch yields any out-of-specification results, indicate the corrective actions you will take, including notifying customers and initiating recalls.

**3. Your firm failed to establish and follow written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).**

You have not conducted cleaning validation studies to demonstrate that your cleaning procedures for non-dedicated production equipment are adequate to prevent potential cross-contamination between the drug products manufactured at your facility.

In your response, you stated that you will prepare a cleaning validation protocol for your manufacturing equipment. However, you failed to provide a timeframe to complete your cleaning validation, and your plan to ensure that equipment is adequately cleaned in the interim.

In response to this letter, provide:

- Your updated cleaning validationprotocol and subsequent reportfor all equipment used in the manufacture of your drugs, including results to show whether results meet established acceptance criteria. Also include updated procedures for equipment cleaning and maintenance, and details on how you will effectively train employees.
- A risk assessment to determine the effect of inadequate cleaning practices on product quality for drug products within expiry and distributed to the U.S. market.
- Your proposed market action plan, which may include customer notifications, additional testing, and enhanced complaint monitoring for drug products within expiry and distributed to the U.S. market at risk for potential cross-contamination.
- Your plan of action for ensuring adequate cleaning in the interim, before completing your planned validation studies, including, but not limited to, cleaning verification sampling with appropriate acceptance criteria.
- A comprehensive, independent review of your facility to identify factors that present potential risks of cross-contamination of products manufactured at your facility. Include an assessment of the suitability of your facility design to prevent cross-contamination, with an evaluation of your equipment, materials, personnel, and waste flows. Include a detailed CAPA plan with systemic remediation and timelines of improvements to your cross-contamination control strategy.

**CGMP Consultant Recommended**

Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant, qualified as set forth in 21 CFR 211.34, to evaluate your operations and assist your firm in meeting CGMP requirements. We also recommend that the qualified third party perform a comprehensive audit of your entire operation for CGMP compliance, and evaluate the completion and effectiveness of any CAPA you have implemented.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all violations and ensuring ongoing CGMP compliance.

**Conclusion**

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in FDA continuing to refuse admission of articles manufactured at Wilson Medicine Company at Plot 24, S 361-364 Nandore, Palghar East, Maharashtra, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov) or mail your reply to:

Christina Alemu-Cruickshank
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4212
10903 New Hampshire Avenue
Silver Spring, MD 20993

USA

Please identify your response with FEI 3004974700.

Sincerely,
/S/
Francis Godwin
Acting Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

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