DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5454 Fax: (410) 779-5707 Industry Information: www.fda.gov/oc/industry	05/02/2016, 05/04/2016, 05/06/2016
	FEI NUMBER 3012283530

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Neil P. McGarvey, Owner and Pharmacist

FIRM NAME	STREET ADDRESS
Arnold Professional Pharmacy	1460 Ritchie Highway, Suite 103
CITY, STATE AND ZIP CODE Arnold, MD 21012	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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

Testing and release of drug products for distribution do not include appropriate laboratory determination of satisfactory conformance to final specifications and identity and strength of each active ingredient prior to release.

Specifically, the firm does not test batches of produced non-sterile drugs to ensure consistency and potency before products are released. The firm compounds (b) (4) drugs/~~week~~ day NPM

OBSERVATION 2

Records of the calibration checks of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically, the firm does not have any documentation demonstrating the calibration and service for the (b) (4) balance, (b) (4) machines, (b) (4) thermometer and (b) (4). Further, there is no record of calibration of thermometers for the refrigerator, where compounded Lansoprazole 15 mg/5 ml for pediatric populations is stored.

OBSERVATION 3

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 or establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at

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	Jai P. Singh	Tajah L. Blackburn, Investigator Jai P. Singh, Investigator	05/06/2016

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appropriate intervals.

Specifically, the firm relies solely on the Certificate of Analysis provided with each raw ingredient as no additional tests are conducted upon receipt.

OBSERVATION 4
Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the firm does not consistently perform in-process checks on produced non-sterile drugs to reduce variability. The in-process checks is based on the (b) (4) .

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