

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 8/21/2018-9/5/2018*
	FEI NUMBER 3012283530

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Neil P. McGarvey, Pharmacist

FIRM NAME Arnold Professional Pharmacy	STREET ADDRESS 1460 Ritchie Hwy Ste 103
CITY, STATE, ZIP CODE, COUNTRY Arnold, MD 21012-2704	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products

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 OBSERVED:
OBSERVATION 1**

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, your firm used **(b) (4)** water in the production of a released and distributed drug product. **(b) (4)** water was used in the production of Rx # **(b) (6)**, Amlodipine 1mg/mL, for a pediatric population.

***DATES OF INSPECTION**

8/21/2018(Tue), 8/23/2018(Thu), 8/28/2018(Tue), 9/05/2018(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sena G Dissmeyer, Investigator	Sena G Dissmeyer Investigator Signed By Sena G. Dissmeyer -S Date Signed 09-05-2018 09:19:00 X _____	DATE ISSUED 9/5/2018