

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857		06/24/2019 - 06/28/2019
Industry Information: www.fda.gov/oc/industry		FEI NUMBER
		3004117486
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED		
TO: Zheng Chenggang, General Manager		
FIRM NAME	STREET ADDRESS	
Hubei Gedian Humanwell Pharmaceutical Co., Ltd.	No. 25 Juxian Road, Gedian Economic Development District	
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED	
Ezhou, Hubei, China 436070	API Manufacturer	

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

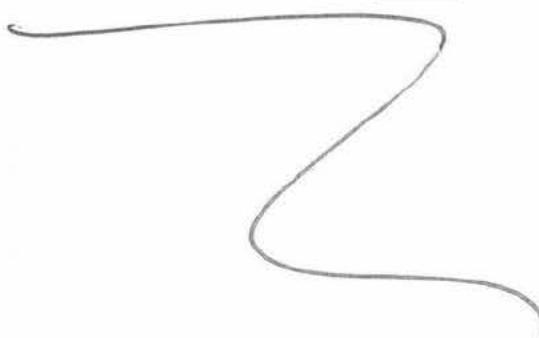
Observation # 1

The preventive maintenance of the (b) (4) tanks is inadequate.

Specifically,

A. On June 24, 2019, (b) (4) tanks (b) (4) were observed to have loose plastic tape pieces attached to the seal inside the (b) (4) tanks. Your Workshop Director stated that the tape pieces were used to hold the seal of the tank in place during the maintenance process. The last maintenance for these (b) (4) tanks occurred on August 14, 2018. The seal is replaced on an (b) (4) basis.

B. On June 24, 2019, the (b) (4) tank (b) (4) was observed to have old and worn out seal. The seal is made of (b) (4). The last maintenance for this (b) (4) tank occurred on August 13, 2018. The seal is replaced on an (b) (4) basis.


Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Uttaniti Limchumroon, Investigator	DATE ISSUED 06/28/2019
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