

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  12420 Parklawn Drive, Room 2032 Rockville, MD 20857  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/24/2019 - 06/28/2019
	FEI NUMBER 3004117486

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Zheng Chenggang, General Manager**

FIRM NAME Hubei Gedian Humanwell Pharmaceutical Co., Ltd.	STREET ADDRESS No. 25 Juxian Road, Gedian Economic Development District
CITY, STATE AND ZIP CODE Ezhou, Hubei, China 436070	TYPE OF ESTABLISHMENT INSPECTED 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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