DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration, CDER OC/OMPQ/ICT 10903 New Hampshire Avenue Bldg. 51, Room 4234, Silver Spring, MD 20993 Phone: 301-796-3206 Fax: 301-847-8738 Email: CDERICT @ fda.hhs.gov Industry Information: www.fda.gov/oc/industry	May 9 thru May 13, 2016
	FEI NUMBER 3004117486

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO Mr. Chenggang Zheng, General Manager

FIRM NAME	STREET ADDRESS
Hubei Gedian Humanwell Pharmaceutical Co., Ltd.	No. 25 Jiuxian Road, Gedian Economic Development Zone
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ezhou 436070, Hubei, China	Human API and API intermediate manufacturer

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
Failure to adequately calibrate the (b) (4) located at (b) (4) # (b) (4) according to actual operating condition.

OBSERVATION# 2
Failure to conduct (b) (4) cleaning at both Sampling Room# 1 and 2 according to your SOP# MM-019(04), entitled, "Sampling Room and Sampling Booth Management Procedures", effective November 23, 2015.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Alice S. Tsao, CSO	05/13/2016