DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
San Juan District Office HAFE4 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787)729-8500 Fax:(787)729-6809 Industry Information: www.fda.gov/oc/industry	08/29/2018 – 08/31/2018
	FEI NUMBER 2000019494

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: YIN Yi feng, GENERAL MANAGER

FIRM NAME	STREET ADDRESS
JIANGSU TOHOPE PHARMACEUTICAL CO., LTD.	188, WUYISHAN ROAD, SOUTH EAST ECONOMIC DEVELOPMENT ZONE
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
CHANGSHU CITY, JIANGSU, CHINA 215533	DIETARY SUPPLEMENT

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

YOUR QUALITY CONTROL PERSONNEL DID NOT PERFORM REQUIRED OPERATIONS FOR INSTRUMENTS.

Specifically, on 08/30/2018, I observed your pH meter, (b) (4), (b) (4) Log Book without the required entries of calibration from 07/05/2018 – 08/30/2018. This instrument was used to adjust the pH Buffer solution in the testing of the following finished product of Alpha Lipoic Acid manufactured at your firm:

(b) (4)

DATES OF INSPECTION
08/29/2018 (WED)
08/30/2018 (THU)
08/31/2018 (FRI)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Jose E. Perez-Soto	Jose E. Perez-Soto, Investigator	08/31/2018

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

EAttch 1 Jiangsu Tohope Pharmaceutical Form FDA 483
FEI #: 2000019494
Insp. Dates: 08/29-31/2018
CSO JEP

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."