DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	February 24 to February 27, 2025
	FEI NUMBER 3020871572

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Liangdeng Nie, General Manager

FIRM NAME	STREET ADDRESS
Anhui Poly Pharm. Co., Ltd.	No. 58 Xiahong Rd. Hi-Tech Industrial Development Zone
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Anqing, Anhui CN 246000	API 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

In-process materials are not tested for quality by the quality control unit after storage for long periods.

Specifically,

In the bulk hold time studies that your firm performed for the following API products, you did not include a study that assessed the bulk intermediate API (b) (4) study samples and then placement of the finished API on stability:

(b) (4)

The allowable bulk hold time for (b) (4) API intermediates (b) (4) is (b) (4)

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	Josh Renzo N. Ramilo -S Digitally signed by Josh Renzo N. Ramilo -S Date: 2025.02.26 21:34:42 -05'00'	Josh Renzo Ramilo, Investigator	02/27/2025