**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<br>Rockville, MD 20857 email: orapharminternationa483responses@fda.hhs.gov | 11/14-18/2022 |
| | FEI NUMBER<br>3002806677 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Ching Peng (Patrick) Wei, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Chunghwa Chemical Synthesis & Biotech Co., Ltd. | 1, Tung-Hsing St., Shu-Lin District |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| New Taipei City 23850, Taiwan | API Manufacturer |

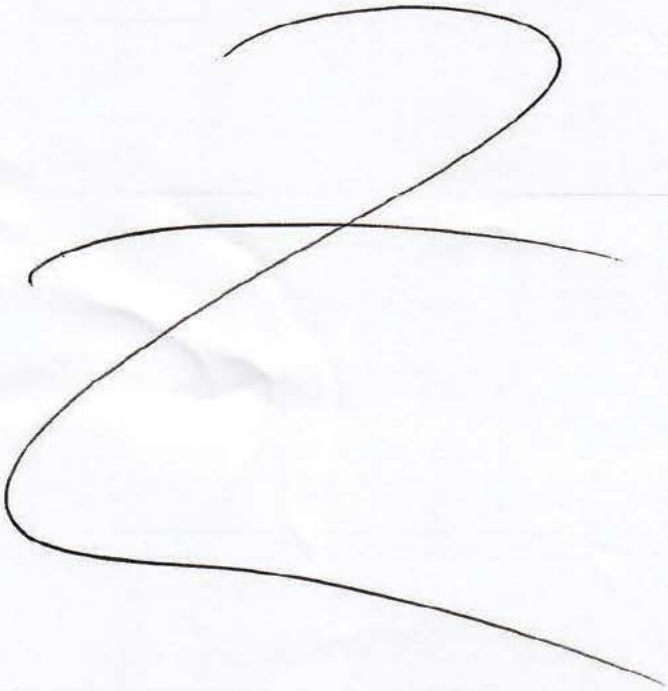
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO 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:

1) The 2021 (b) (4) Report of (b) (4) Water System (b) (4) does not discuss, explain, or propose corrections for the continual finding of Total Aerobic Microbial Count results higher than the feed water results for samples taken after the (b) (4) after the (b) (4) micron filter, and after the (b) (4) despite the fact that these samples have average values above (b) (4) CFU/mL and the point after the (b) (4) has an average result of too numerous to count. (b) (4) is used to supply water for equipment cleaning and production for the majority of the active pharmaceutical ingredients produced on site, including (b) (4) (b) (4)

2) There has been no requirement to review electronic raw data in the chromatography system for any active pharmaceutical ingredient batches released to date.

3) The retest date for (b) (4) the key starting material for the active pharmaceutical ingredient (b) (4) was extended by (b) (4) for (b) (4) batches of (b) (4) (b) (4) in the warehouse without further testing.



| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE *(Print or Type)* | DATE ISSUED |
|---|---|---|---|
| | Wenning Chan | **Matthew B. Casale, Investigator**<br>**Wen Ning Chan, Investigator** | **11/18/2022** |