DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
Food and Drug Administration CDER/OC/OMPQ/DIDQ Attn: Alicia Mozzachio White Oak Bldg. 51, Room 4234	10903 New Hampshire Ave. Silver Spring, MD 20993 Tel: 301-796-3206	9/1-5/2014
Industry Information: www.fda.gov/oc/industry		FEI NUMBER 3002807309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Akira Kobayashi, Director/Managing Executive Officer

FIRM NAME	STREET ADDRESS
Ishihara Sangyo Kaisha, Ltd.	1, Ishihara-cho
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Yokkaichi, Mie prefecture, 510-0842, Japan	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) Validation of the production process and testing methods used in the manufacture of (b) (4) [redacted] and (b) (4) [redacted] intended for use as active pharmaceutical ingredients in (b) (4) [redacted] products have not been demonstrated.

2) The two additional pages issued for the batch record of (b) (4) [redacted] 2011 batch (b) (4) [redacted] step (b) (4) [redacted] were not signed and dated when issued, nor is there any documentation that the page that was modified from the master production instruction was reviewed and approved by the quality unit.

3) The written procedures for auditing suppliers of raw materials used in the manufacture of active pharmaceutical ingredients do not include an explanation of the requirements a supplier must meet in order to be considered acceptable.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	[signature]	Matthew Casale, Investigator	9/5/14

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