DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301) 796-3334 Fax:(301) 847-8738 Industry Information: www.fda.gov/oc/industry	03/16/2012 - 03/20/2012
	FEI NUMBER 3004422881

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jurgen KP Gerhardt, CEO and Owner

FIRM NAME	STREET ADDRESS
C.A.T. Gmbh and Co. KG	Heerweg 10
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tubingen D-72070, Germany	Contract Testing Laboratory

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 OBSERVED:

OBSERVATION 1

The establishment of test procedures and laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically, USP <621> Chromatography states that system suitability tests are an integral part of gas and liquid chromatographic methods which verify that the system is adequate for the intended analysis. It states that replicate injections of standard solutions are compared to ascertain whether precision requirements are met. Additionally, it states that system suitability ascertains final operating system effectiveness, and that additional injections of standard solutions are required at appropriate times to demonstrate system suitability throughout the chromatography run.

Using chromatographic methods, your firm analyzed residual solvents and/or the optical purity of (b) (4) on of multiple lots of the Active Pharmaceutical Ingredient (API) for the drug product (b) (4) including lots (b) (4)

However, your firm did not establish system suitability through multiple consecutive injections of the appropriate standard solutions. According to the CEO and Owner, your firm currently performs system suitability by analyzing (b) (4) injection of the appropriate standard solutions (b) (4) Additionally, your firm did not confirm the effectiveness of the final operating system through injecting standard solutions at appropriate intervals and after the final API sample injection.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Elizabeth L. L. Edwards, Investigator	03/20/2012