OBSERVATION I

The specificity of test methods has not been established. Specifically,

A. Your firm fail in perform the stress (forced degradation) studies for the USP non-compendia optical purity test by HPLC analytical test method during the test method validation. The validation number 20.000, dated 06/26/2002 does not contain the specificity/selectivity studies necessary to demonstrate the suitability and adequacy of the analytical test method and specifications, S - 08 - USP/13, used for the release and stability testing of this Active Pharmaceutical Ingredient (API). In addition, the current HPLC chromatographic purity test profile was found different than that obtained during the method validation. The retention time for the main peak changed from about minutes in the validation test minutes during the routine testing.

B. The data supporting validation activities performed by your firm to demonstrate the suitability and adequacy of the analytical method used for the release and stability testing of USP Active Pharmaceutical Ingredient (API) was found to be inadequate and incomplete. Data and documents presented by your firm supporting the validations number: 20.000, AMV - 001 - 10 for the non-compendia Related Substances analytical test method and specification, S - 08 - USP/07, does not contain the specificity/selectivity studies necessary to determine if the method is a stability indicating method for the testing of the API. Validation documents showed that the Validation of the methods does not contain complete forced degradation studies. Degradation of the main peak was not achieved. In addition, the routine analytical test method specification, S - 08 - USP/07, failed to contain the precision standard system suitability (RSD) that the injection of the sample solution.

Nevertheless, the validation of the test methods were approved by QCU.
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRIBUT OFFICE ADDRESS AND PHONE NUMBER
Food and Drug Administration, CDER/OC/OMP/QDIDQ HFD-325  
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ATTN: Mr. Conception Cruz  
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION  
02/13/2017 - 02/17/2017,  
02/20/2017 - 02/21/2017

FEIN NUMBER  
3005447965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Rahul P. Pradhan, Director, Location Head - CTO-5

FIRM NAME  
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STREET ADDRESS  
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CITY, STATE AND ZIP CODE  
Nalgonda Dist., Telangana, India

TYPE OF ESTABLISHMENT INSPECTED  
Manufacturer

OBSERVATION 2

Procedures describing the calibration of instruments are deficiently written or followed. Specifically,

a) The calibration of the Gas Chromatographic (GC) instruments was incomplete. The review of the [D] Operational Calibration for the Agilent GC/Headspace (GC/HS) QC- 206, conducted by the outside contractor and [a] in-house calibration, did not include the HS oven temperature, noise and drift, signal to noise and detector accuracy tests as part of the GC/HS calibration. The GC instruments were used for the Residual Solvents test determination for released of the API's and raw materials.

b) The micro balance, QC- 465, was used outside its calibration range (usage range: 10 mg to 2 g) for the testing of USP Active Pharmaceutical Ingredient (API) during released and stability studies. The firm performed and documented the weight of mg, mg, mg, mg, mg and mg for the standards of the related substance test for USP, batch number using the balance number QC-465 that was certified for weights in the range of 10 mg to 2 g. In addition, the linearity of this balance was performed with three points starting with 10 mg and the accuracy with 10 mg that do not support the use of the balance below 10 mg.

OBSERVATION 3

Records maintained of any modification of an established method employed in testing do not include the reason for the modification, the data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method. Specifically,

Your firm failed to follow the USP monograph identification test method for the Ultraviolet Absorption <197U> that defined how to perform the test and calculate the results for API's. For , it was noted that the absorbance readings were obtained at a maximum wavelength other than nm as prescribed by the USP test monograph. During the review of batch it was observed that the absorbance was determined at approximately nm instead of the exact wavelength of nm as established by the USP test monograph.
Also, the final calculations were performed with the absorbance readings instead of absorptivity as prescribed by the USP monograph. These modifications to the USP test method and calculations formulas were not validated or the equivalencies demonstrated.