



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality  
International Compliance Team  
Room # 4219  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
301-796-3194

September 17, 2008

Mr. Hasmukh Ghandi  
Director – Commercial  
Megafine Pharma (P) Ltd.  
No. 201 Village Lakhmapur, Dindori  
Nashik, Maharashtra  
India

Dear Mr. Ghandi,

This letter is regarding the inspection of your active pharmaceutical ingredient manufacturing facility in Nashik, India, by FDA Investigator Tara Gooen and Chemist Guo Shen, during the period of March 5-7, 2008. A FDA-483, Notice of Inspectional Observations was issued to you at the conclusion of that inspection.

We have reviewed your written response to the FDA-483 observations, dated April 3, 2008. We have also reviewed your July 7, 2008 response to our request for additional information. Based on the corrections described in the responses, **we are classifying your facility as acceptable.** It remains your responsibility to assure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.

Since the Agency is working to make its regulatory process and activities more transparent to the regulated industry, enclosed is a copy of the Establishment Inspection Report (EIR) for the above inspection. The enclosed copy contains only the narrative portion of the report. However, you may request additional information under the Freedom of Information Act.

If you have any questions concerning this letter, you may contact me at the above address or telephone numbers.

Sincerely,

Carole Jones  
Compliance Officer  
International Compliance Team