



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  
10903 New Hampshire Avenue  
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June 6, 2008

Mr. Rashesh Gogri  
Director  
AARTI Industries Ltd.  
71, Udyog Kshetra, 2<sup>nd</sup> Floor  
Mulund Goregaon Link Road  
Mulund (W), Mumbai-400 080  
India

Dear Mr. Gogri:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your pharmaceutical manufacturing facility in Thane, India on March 24-28, 2008, by FDA Investigator Stephen Brown. Based on the inspection, 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 L. Jones  
Compliance Officer  
International Compliance Team

Enclosure: