API GOOD MANUFACTURING PRACTICE INTERIM UPDATE REPORT

Please complete one API Interim Update Report per site.

The Chapters and Annexes of the EU GMP Guide can be obtained from
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-4/index_en.htm

Section 1

Please identify your site details:

Site name	
Full address of site **Including Post Code (Zip Code)**	
Contact name for this report	
Telephone no.	
Fax.	
Mobile	
Email	
Date of Last Inspection	

Please return this completed report electronically to your inspector's email address and please copy: gmpinspectorate@mhra.gsi.gov.uk

PLEASE NOTE THIS FORM IS FOR USE BY **ACTIVE PHARMACEUTICAL INGREDIENT** MANUFACTURERS ONLY.

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Section 2 Site Changes

Please provide information on site changes that the MHRA should be aware of. See guidance document on MHRA web site for further information. *Please include information on any mitigating action taken where appropriate.*

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Section 3

DECLARATION

To the best of my knowledge and belief the particulars I have given in this form are truthful and complete.
The signatories shall take all reasonable precautions and exercise all due diligence, to ensure that any information he/she provides to MHRA, is not false or misleading in any material particular, in accordance with relevant UK Regulations which make it an offence to provide false and misleading information.

Site Based Person completing this report:

Signed: _____ Date: _____

Name: _____ Position: _____

(BLOCK CAPITALS)

Person Accountable for the Site Approving this Report:

Signed: _____ Date: _____

Name: _____ Position: _____

(BLOCK CAPITALS) (see note below #)

 # This signatory is expected to be the person responsible for the business e.g. Chief Executive Officer, Site Director, Managing Director or equivalent (this is not likely to be the QP or QA Manager/Pharmacist although may be in small companies/facilities). This signatory is responsible for confirming the accuracy of the changes reported and confirming that no other relevant information has been withheld.

Justification for suitability of person responsible to sign on behalf of the company where the role is not listed or equivalent to the above.