GOOD MANUFACTURING PRACTICE COMPLIANCE & INTERIM UPDATE REPORT

Please complete one Compliance Report per site or clearly cross refer where information for more than one site is recorded on a single form, e.g. where a small satellite site is used but reported information is not distinguished from the main 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			
Licence holder where different from above			
Licence number (s) and type (not applicable to non UK sites)			
Site number (on licenses)			
Full address of site **Including Post Code (Zip Code)**			
Contact name for this report			
Telephone no.			
Fax.			
Mobile			
Email			
Compliance Report? **Tick box (√)**		**Interim Update?** **Tick box (√)**	

Please return this completed report electronically to your inspector's email address no less than five working days prior to your inspection – see detailed instructions on page 3.

For Interim Updates only please copy: gmpinspectorate@mhra.gsi.gov.uk

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Section 2 Changes since the last submitted Compliance/ Interim Update Report (or last inspection)

Please provide information on site changes that the MHRA should be aware of in conducting a GMP compliance risk assessment of the site. Please add additional numbered pages where required but do not attach reports or procedures. *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 the licensing authority, 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.

When complete please return this form to the inspector by one of the following methods:
- Complete electronically and e mail to inspector with a scanned copy of the signature page.
- Complete a hard copy then scan as a single file and e mail to the inspector
- If no scanning facilities are available e mail all pages except the signature page to the inspector prior to the inspection and provide a signed page to the inspector at the inspection.

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Appendix Anticipated Changes (Not Required if Submitting an Interim Update)

Please advise any changes that are anticipated to happen within a period up to two years. It is expected that these may not be confirmed changes and that information reported will be the best available at the time. A confirmation of actual changes should be submitted on an interim update report to the inspector once these are definite.
