PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 013-3
1 Annex
25 September 2007

STANDARD OPERATING PROCEDURE

PIC/S INSPECTION REPORT FORMAT

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1. DOCUMENT HISTORY

Adoption by Committee	8 October 2002
Entry into Force	1 November 2002

2. INTRODUCTION

2.1 The PIC/S Inspection Report provides a summary of the GMP inspection activities undertaken, observations made during the inspection, deficiencies noted during the inspection, any product samples taken, assessment of the Site Master File, the inspector's summary and conclusions.

2.2 The format for the PIC/S Inspection Report is attached at Annex 1 of this SOP.

2.3 The format of PIC/S Inspection Report is consistent with the format used for the preparation of an EC Inspection Report, but modified for use by non-EC members of PIC/S. An alternative format that contains equivalent information may be used.

2.4 This SOP replaces documents PH 8/92 and PH 6/91 which were previously used for the preparation of PIC inspection reports.

3. PURPOSE

3.1 This document provides guidance on the format to be used for the preparation of PIC/S inspection reports.

3.2 The format used for PIC/S inspection reports is consistent with the format for EC inspection reports.

4. SCOPE

4.1 This SOP is for use by non-EC members of PIC/S. However, alternative formats (e.g used by EU Members) that contain equivalent information may be used.

5. REVISION HISTORY

Date	Version Number	Reasons for revision
1 July 2004	PI 013-2	Change in the Editor's co-ordinates
25 September 2007	PI 013-3	Change in the Editor's co-ordinates

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ANNEX: PIC/S INSPECTION REPORT

PIC/S INSPECTION REPORT

GMP Inspector's Information

Inspected site(s):	*Name and full address of the Inspected site*	
Activities carried out by company	*Manufacture of Active Ingredient* *Manufacture of Finished Medicinal Product* *Manufacture of Intermediate or bulk* *Packaging* *Importing* *Laboratory Testing* *Batch Control and Batch Release* *Other* _____	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Inspection date(s):	*Date(s), month, year*	
Inspector(s):	*Name of the inspector(s),* *Name of expert / assessor (if applicable)* *Name of the Competent Authority(ies).*	
References:	*Reference Number of Marketing and / or Manufacturing Authorisations* *Inspection reference number(s).(If applicable)*	
Introduction:	*Short description of the company and the activities of the company.* *<u>For inspections in non-PIC/S countries</u> it should be stated whether the Competent Authority of the country, where the inspection took place, was informed of the inspection and whether the Competent Authority took part in the inspection.* *Date of previous inspection* *Names of Inspectors involved in previous inspection* *Major changes since the previous inspections*	
Brief report of the inspection activities undertaken:		
Scope of Inspection:	*Short description of the inspection (Product related inspection and/or General GMP inspection). The reason for the inspection should be specified (e.g. new marketing application, routine, investigation of product defect)*	
Inspected area(s):	*Each inspected area should be specified.*	
Personnel met during the inspection:	*The names and titles of key personnel met, should be specified (listed in annex)*	

Inspectors Team's findings and observations relevant to the inspection; and deficiencies:	*Relevant headings from the PIC/S GMP Guide.* *New headings may be introduced as relevant.* *This section can link the findings to the deficiencies and used to explain classification.*
Headings to be used	Quality Management Personnel Premises and Equipment Documentation Production Quality Control Contract Manufacture and Analysis Complaints and Product Recall Self Inspection
Distribution and Shipment	e.g. Compliance with Good Distribution Practice
Questions raised relating to the assessment of a marketing application	e.g. Pre- authorisation Inspections
Other specific issues identified	e.g. Relevant future changes announced by company
Site Master File (SMF)	Assessment of SMF if any; date of SMF
Miscellaneous: Samples taken Distribution of Report	
Annexes attached:	*List of any annexes attached*
List of Deficiencies classified into critical, major and others:	*All deficiencies should be listed and the relevant reference to the PIC/S GMP Guide and other relevant PIC/S Guidelines should be mentioned.* *All deficiencies found should be listed even if corrective action has taken place straight away.* *If the deficiencies are related to the assessment of the marketing application, this should be clearly stated.* *The company should be asked to inform the Inspectorate about the progress of the corrected actions and a proposed time schedule for corrections.*

Recommendations	*To the Committee requesting the Inspection or to the Competent / Enforcement Authority for the site inspected*
Summary and conclusions:	*The Inspection Team should state if the Company operates in accordance with the PIC/S GMP Guide and mention any other item to alert requesting authority.*
Name(s) **Signatures(s)** **Organisation(s)** **Date:**	*The Inspection Report should be signed and dated by the Inspector(s)/Assessors who participated in the Inspection.*

DEFINITION OF DEFICIENCIES
TO BE USED IN PIC/S INSPECTION REPORT

1. **CRITICAL DEFICIENCY**

A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.

2. **MAJOR DEFICIENCY**

A non-critical deficiency:

which has produced or may produce a product, which does not comply with its marketing authorisation;

or

which indicates a major deviation from PIC/S Good Manufacturing Practice;

or

(within PIC/S) which indicates a major deviation from the terms of the manufacturing authorisation;

or

which indicates a failure to carry out satisfactory procedures for release of batches or (within PIC/S) a failure of the authorised person to fulfil his/her required duties;

or

a combination of several “other” deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.

3. **OTHER DEFICIENCY**

A deficiency which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice.

(A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical)