	TITLE	SOP No.	EP-INS-003
	Procedure for Planning and Preparation of GMP Inspection for issue of "Written Confirmation" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC	Effective Date	
		Review Date	
		Supersedes	NA
Division Name		Revision No.	00
Export Division		Page No.	1 of 5

Prepared By		Checked By		Approved By		Authorized By	
Name		Name		Name		Name	
Designation		Designation		Designation		Designation	
Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

Control Status

1.0 Purpose

To lay down a procedure for planning and preparation of GMP inspection for issue of "Written Confirmation" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC.

2.0 Scope

This document is applicable for planning and preparation of inspections for issue of "Written Confirmation" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC by the inspectors of CDSCO.

3.0 Responsibility

3.1 The Drugs Inspectors/ADC(I)/DDC(I) of Zones/ Sub Zones shall be responsible for planning and preparation of inspection.

3.2 The Head of concerned zone/Export Division shall be responsible for overall compliance of the SOP.

4.0 Accountability

Zonal/Sub Zonal Division Head and DCG (I)

5.0 Procedure

5.1 Inspection Team

5.1.1 Composition of the team

One or two inspectors from CDSCO and One QC expert from CDTL/RDTL/CDL of which one trained & qualified Inspector shall be designated as the team leader.

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Division Name		Revision No.	00
Export Division		Page No.	2 of 5

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5.1.2 **Responsibility of the Inspection Team**

The responsibility of the Inspection Team shall be as follows:

- To conduct a GMP inspection
- To agree on the inspection's scope
- To discuss and resolve, where possible, any major problems which may occur during the inspection process
- To ensure that all inspectors play an active role in the inspection process
- To make decisions on inspection findings by way of consensus however, where this is not possible, the Team Leader makes the final decision
- To prepare an inspection report

5.1.3 **Responsibility of the Team Leader**

The Team Leader shall be responsible to organize, coordinate, lead during all stages of the inspection and act as spokesperson.

5.2 **Preparing for Inspection**

5.2.1 After receiving application of the firm by the deputed inspection team member (s), a review should be made relating to the firm to be visited from the documents available in the office file. This shall include review of following documents:-

5.2.1.1 Covering letter

5.2.1.2 Authorization letter

5.2.1.3 Copy of GMP certificate issued as per WHO GMP, USFDA, EDQM, etc. if any

5.2.1.4 Copy of Manufacturing License issued by SLA

5.2.1.5 List of all APIs approved by SLA.

	TITLE	SOP No.	EP-INS-003
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		Review Date	
		Supersedes	NA
Division Name		Revision No.	00
Export Division		Page No.	3 of 5

Prepared By		Checked By		Approved By		Authorized By	
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5.2.1.6 List of Products applied for issue of "Written Confirmation" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC

5.2.1.7 List of SOPs and STPs

5.2.1.8 Master Formula Record and batch Manufacturing Record

5.2.1.9 Summary of Stability data (3 batches) Accelerated/ Real time (as prescribed)

5.2.1.10 List of Equipment and Instruments

5.2.1.11 List of Technical staff, their qualification, experience and their approval by SLA.

5.2.1.12 Manufacturing Layout Plan as approved by SLA

5.2.1.13 Validation Master Plan

5.2.1.14 Summary of Process validation data for 3 batches of each product.

5.2.1.15 Schematic Diagram of Water System specifying circulation loop and Material of Construction.

5.2.1.16 Schematic Diagram of HVAC System specifying terminal filter configuration

5.2.1.17 Export data of last 3 years

5.2.1.18 Summary of Annual Product review.

5.2.1.19 Summary of Market Complaint Review

5.2.1.20 Summary data of Impurity profiling

5.2.1.21 Summary data of OVI

5.2.1.22 Summary data of Analytical Method Validation

5.2.1.23 Schematic Diagram of ETP

5.2.1.24 Site Master File (as specified under WHO TRS 823)

5.2.1.25 Good Distribution Practices followed by the firm.

5.2.1.26 NSQ reports

	TITLE	SOP No.	EP-INS-003
	Procedure for Planning and Preparation of GMP Inspection for issue of "Written Confirmation" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC	Effective Date	
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Division Name		Revision No.	00
Export Division		Page No.	4 of 5

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5.2.1.27 Non Conformances pointed out in previous inspection reports.

5.2.2 Any data or information not submitted by the applicant shall be communicated to the firm.

5.2.3 If all the documents are in place, a day wise inspection plan (2-4) days depending on the scope of inspection (Size of the facility, products etc.,) shall be prepared.

5.2.4 The inspection plan may be communicated to the firm at least 7 days before the inspection.

5.2.5 The checklist for inspection shall be given to the firm for filling the self appraisal by the manufacturer at least 7 days before inspection.

6.0 Annexure / Format

Nil

7.0 References

Doc. No.	Title
1	WHO TRS 823
2	GMP requirements as per Directives No. 2001/83/EC latest amended vide Directive 2011/62/EU

8.0 Abbreviation

Acronym	Full Form
QA	Quality Assurance
DI	Drug Inspector
CDSCO	Central Drugs Standard Control Organization
DCG(I)	Drugs Controller General, India
DDC (I)	Deputy Drug Controller, India
ADC (I)	Assistant Drug Controller, India
SOP	Standard Operating Procedure
INS	Inspection
GMP	Good Manufacturing Practices
WHO	World Health Organization

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Division Name		Revision No.	00
Export Division		Page No.	5 of 5

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MFR	Manufacturing Formula Record
BMR	Batch Manufacturing Record
QC	Quality Control
CDTL	Central Drug Testing Laboratory
USFDA	United States Food & Drug Administration
EDQM	European Drug Quality Management
NSQ	Not of Standard Quality
IPQC	In-process Quality Control
RDTL	Regional Drug Testing Laboratory
CDL	Central Drug Laboratory
API	Active Pharmaceutical Ingredient
SLA	State Licensing Authority
STP	Standard Testing Procedure
HVAC	Heating Ventilation and Air Conditioning
TRS	Technical report Series

9.0 Revision History

Revision No.	Reason(s) for Revision
00	Created New