	TITLE	SOP No.	EP-INS-002
	Requirement for submission of application 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 4

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 requirement for submission of application 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 requirement for submission of application 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 to the office of CDSCO.

3.0 Responsibility

3.1 The Drugs Inspectors, Export Division, CDSCO(HQ) shall be responsible for checking the complete receipt of documents upon the receipt of application 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.

3.2 The Head of concerned Zone/Sub Zone/Export Division CDSCO (HQ) shall be responsible for overall compliance of the SOP.

4.0 Accountability

Division Head, Head of concerned Zone/Sub Zone/Export Division CDSCO (HQ) and DCG (I).

5.0 Procedure

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5.1 Application shall be submitted to the DCGI as well as to the Head of concerned Zonal/Sub Zonal office of CDSCO 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 Following documents shall be submitted by the applicant along with application 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 Covering Letter – The covering letter is an important part of the application and should clearly specify the intent of the application (whether the application is being submitted for the first time, whether the application is for re-issue or is for the additional products to an existing Written Confirmation) the list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory alongwith the name and address of the firm.

5.2.2 An Authorization letter in original issued by the Director/Company Secretary/Partner of the firm revealing the name & designation of the person authorized to sign (along with the name and address of the firm) on behalf of the firm should be submitted at the time of submission of the application Duly self attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.

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

5.2.4 Copy of Manufacturing License issued by SLA

5.2.5 List of all APIs approved by SLA.

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5.2.6 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

5.2.7 List of SOPs and STPs

5.2.8 Master Formula Record and batch Manufacturing Record

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

5.2.10 List of Equipment and Instruments

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

5.2.12 Manufacturing Layout Plan as approved by SLA

5.2.13 Validation Master Plan

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

5.2.15 Schematic Diagram of Water System specifying circulation loop and MOC.

5.2.16 Schematic Diagram of HVAC System specifying terminal filter configuration

5.2.17 Export data of last 3 years

5.2.18 Good Distribution Practices followed by the firm.

5.2.19 Summary of Annual Product review.

5.2.20 Summary of Market Complaint Review

5.2.21 Summary data of Impurity profiling

5.2.22 Summary data of OVI

5.2.23 Summary data of Analytical Method Validation

5.2.24 Schematic Diagram of ETP

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

6.0 Annexure / Format

Annexure/Format No.	Title

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Annexure 1	WHO TRS 823

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
IPQC	In-process Quality Control
SLA	State Licensing Authority
OVI	Organic Volatile Impurities
ETP	Effluent Treatment Plant
TRS	Technical Report Series
HVAC	Heating Ventilation and Air Conditioning
MOC	Material of Construction

9.0 Revision History

Revision No.	Reason(s) for Revision
00	Implementation of New Format