	TITLE	SOP No.	INC-WCC-001
Division Name: International Cell, CDSCO(HQ)	Procedure for review and processing of online 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 at Zonal/Subzonal offices of CDSCO	Effective Date	27/03/2026
		Review Date	26/03/2029
		Supersedes	00
		Revision No.	01
		Page No.	1 of 5

Prepared By		Checked By		Approved By		Authorized By	
Name	K. Bhavani	Name	Sidharth Malhotra	Name	Shiv Kumar	Name	Dr. R. Chandrashekar
Designation	Drugs Inspector	Designation	ADC (I)	Designation	DDC(I)	Designation	JDC(I)
Sign		Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

Control Status

CONTROLLED COPY

1.0 Background

1.1 European Union has mandated through directives No. 2001/83/EC dated 08th June, 2011 that every consignment of Active Pharmaceutical Ingredient (API) from Non-EU/non-listed countries must be supported by a "Written Confirmation" Certificate (WCC) issued by the Competent Authority of that Country, stating that the consignment conforms to the standards of Good Manufacturing Practices (GMP) as laid down in the EU guidelines or equivalent thereof Purpose.

1.2 CDSCO issues Written Confirmation Certificate on the basis of recommendation received from the concerned CDSCO zonal/sub-zonal office and the standards shall be applicable for issue of "Written Confirmation Certificate" 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 Purpose

To lay down a procedure for review and processing of online application made through SUGAM portal (https://cdscoonline.gov.in) at Zonal/Sub-Zonal offices 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.

3.0 Scope

This document is applicable to online applications made through SUGAM portal (https://cdscoonline.gov.in) 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.

	TITLE	SOP No.	INC-WCC-001
Division Name: International Cell, CDSCO(HQ)	Procedure for review and processing of online 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 at Zonal/Subzonal offices of CDSCO	Effective Date	27/03/2026
		Review Date	26/03/2029
		Supersedes	00
		Revision No.	01
		Page No.	2 of 5

Prepared By		Checked By		Approved By		Authorized By	
Name	K.Bhavani	Name	Siddhartha Kalita	Name	Shiv Kumar	Name	Dr. L. Chandrashekar
Designation	Drugs Inspector	Designation	ADC (2)	Designation	DDC(I)	Designation	JDC(I)
Sign		Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

4.0 Responsibility:

4.1 The RO/NO/DDA at Zonal/Sub-Zonal offices of CDSCO shall verify the completeness of online application submitted through SUGAM portal (https://cdscoonline.gov.in)

4.2 Concerned Head of Zonal/Sub-Zonal offices shall be responsible for the implementation and regular monitoring of compliance of this SOP.

5.0 Accountability

Concerned Head of Zonal/Sub-Zonal offices of CDSCO.

6.0 Procedure

6.1 Application for issuance/renewal/endorsement of "Written Confirmation" for active substances exported to EU for medicinal products for human use, in accordance with Article 46b (2) (b) of Directive 2001/83/EC shall be submitted by manufacturer through online mode via SUGAM portal (https://cdscoonline.gov.in).

6.2 Upon receipt of the online application, the concerned Nodal Officer of the Zonal/Sub-Zonal Office shall allocate the application to their Reviewing Officer.

6.3 The Reviewing Officer shall verify whether documents against each checklist points are correctly and legibly uploaded by the applicant. Adequacy of documents may not be required to be verified at Zonal/sub-zonal level.

6.4 For the applications made for the Grant/Renewal/Endorsement, no site inspection shall be required, provided the firm has been inspected within two years by the zonal/sub-zonal office to verify the compliance to the requirements of GMP as required as per Directives No. 2001/83/EC latest amended vide Directive 2011/62/EU or WHO Good Manufacturing Practices (GMP) for active

Division Name: International Cell, CDSCO(HQ)	TITLE: Procedure for review and processing of online 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 at Zonal/Subzonal offices of CDSCO	SOP No.	INC-WCC-001
		Effective Date	27/03/2026
		Review Date	26/03/2029
		Supersedes	00
		Revision No.	01
		Page No.	3 of 5

Prepared By		Checked By		Approved By		Authorized By	
Name	K.Bhavani	Name	Sidhartha Mallick	Name	Shiv Kumar	Name	Dr. R. Chandrashekar
Designation	Drugs Inspector	Designation	ADC (I)	Designation	DDC(I)	Designation	JC(I)
Sign	Bhavs	Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

as per Annex 2- WHO Technical report Series(TRS), No. 957, 2010 or Good Manufacturing Practice guide for Active Pharmaceutical Ingredients ICH Harmonised Triplicate Guideline stated as per ICH Q7, for the category of drug substances applied.

6.5 In case, the firm does not fulfill the criteria of para 6.4, the Zonal/Sub-zonal Head shall depute an officer(s) to conduct an onsite Inspection to verify compliance with Good Manufacturing Practices as stated in para 6.4 above.

6.6 If deficiencies are identified in inspection, the same shall be communicated to the applicant for submission of compliance. The concerned Zonal/Sub-Zonal office shall be responsible for verification of compliance after receipt of the compliance report from the applicant.

6.7 Based on the nature and severity of the deficiencies reported, if required, appropriate regulatory action shall be initiated, as detailed below:-

6.7.1 Based on the reply received from the applicant, and if deemed necessary, suitable regulatory action may be recommended to the State Licensing Authority (SLA).

6.7.2 Shall inform the Head Quarter for the findings of the inspection and update further on the action taken, so as that the Written Confirmation issued for active substances exported to the European Union for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC, may be suspended or cancelled.

6.8 Where the applicant submits compliance to the deficiencies and informs the concerned Zonal/Sub-Zonal Office, the compliance report shall be scrutinized. Based on the adequacy of the compliance, a further inspection may be conducted, if required.

Division Name	TITLE	SOP No.	INC-WCC-001
International Cell, CDSCO(HQ)	Procedure for review and processing of online 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 at Zonal/Subzonal offices of CDSCO	Effective Date	27/03/2021
		Review Date	26/03/2029
		Supersedes	00
		Revision No.	01
		Page No.	4 of 5

Prepared By		Checked By		Approved By		Authorized By	
Name	K. Bhavani	Name	Siddhartha Malik	Name	Shiv Kumar	Name	Dr. A. Chandrashekar
Designation	Drugs Inspector	Designation	ADC(I/C)	Designation	DDC(I)	Designation	JC(I)
Sign	Bhavi	Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

6.9 Upon receipt of the compliance report, the concerned Zonal/Sub-Zonal Office shall verify the completeness and adequacy of the compliance either through causing an on-site inspection or by desktop review by officer. A compliance verification report shall be prepared, clearly indicating the status of each observations for their complete compliance and providing clear recommendations by the compliance verification officer.

6.10 Applications with partial or open compliance to the observations made during inspections shall not be considered for the recommendation of Written Confirmation by the zonal/sub-zonal head.

6.11 The inspection report, compliance verification report, and clear recommendation letter of the Head of the Zonal/Sub-Zonal Office of CDSCO, along with the list of drug substances to be considered for Written Confirmation, shall be uploaded in the relevant dropdown section of the corresponding SUGAM online application. The Zonal/Sub-zonal offices shall ensure that all the applications are forwarded to Head Quarter within three weeks of the receipt of complete application.

7.0 References

Doc. No.	Title
1	GMP requirements as per Directives No. 2001/83/EC latest amended vide Directive 2011/62/EU
2	WHO Good Manufacturing Practices (GMP) for active pharmaceutical ingredients stated as per Annex 2- WHO Technical report Series(TRS), No. 957, 2010
3	Good Manufacturing Practice guide for Active Pharmaceutical Ingredients stated as per ICH Q7 of ICH Harmonised Triplicate Guideline

	TITLE	SOP No.	INC-WCC-001
Division Name: International Cell, CDSCO(HQ)	Procedure for review and processing of online 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 at Zonal/Subzonal offices of CDSCO	Effective Date	27/03/2026
		Review Date	26/03/2029
		Supersedes	00
		Revision No.	01
		Page No.	5 of 5

Prepared By		Checked By		Approved By		Authorized By	
Name	K.Bhavani	Name	Siddhartha Mallick	Name	Shiv Kumar	Name	Dr. A. Chandrashekar
Designation	Drugs Inspector	Designation	ADC (I)	Designation	DDC(I)	Designation	JDC(I)
Sign		Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

8.0 Abbreviation

Acronym	Full Form
RO	Reviewing Officer
NO	Nodal Officer
DDA	Deputy Decision Authority
SOP	Standard Operating Procedure
INS	Inspection
EU	European Union

9.0 Revision History

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