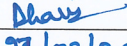
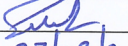
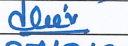
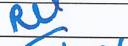
 CDSCO CENTRAL DRUGS STANDARD CONTROL ORGANIZATION MINISTRY OF HEALTH AND FAMILY WELFARE, GOVT. OF INDIA	TITLE		SOP No.	INC-WCC-002	
	Procedure for review and processing of online application for issue of "Written Confirmation" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC at International Cell, Head Quarter of CDSCO		Effective Date	27/03/2026	
Division Name			Review Date	26/03/2029	
International Cell, CDSCO(HQ)			Supersedes	00	
			Revision No.	01	
			Page No.	1 of 4	
Prepared By		Checked By		Approved By	
Name	K. Bhavani	Name	Sidhalkrishna Mahalingam	Name	Shiv Kumar
Designation	Drugs Inspector	Designation	ADC (I)	Designation	DDC (I)
Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026
				Authorized By	
				Name	Dr. R. Chandrasekhar
				Designation	DDC (I)
				Sign	
				Date	27/03/26

Control Status
CONTROLLED COPY

1.0 Background


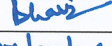
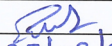
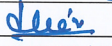
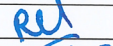
- 1.1 European Union has mandated through directives No. 2001/83/EC dated 08th June, 2011 that every consignment of Active Pharmaceutical Ingredient (API) from Non-EU/non-listed countries must be supported by a "Written Confirmation" Certificate (WCC) issued by the Competent Authority of that Country, 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 International Cell, Head Quarter 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 all 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.

 CDSCO CDSCO CENTRAL DRUGS STANDARD CONTROL ORGANIZATION MINISTRY OF HEALTH AND FAMILY WELFARE, GOVT. OF INDIA	TITLE		SOP No.	INC-WCC-002			
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Prepared By		Checked By		Approved By		Authorized By	
Name	K. Bhavani	Name	Sidhanta S Malhotra	Name	Shiv Kumar	Name	Dr. P. Chandrasekhar
Designation	Drugs Inspector	Designation	ADCG	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/SRO/DA at International Cell, Head Quarter of CDSCO, shall review the online application submitted through SUGAM portal (<https://cdscoonline.gov.in>).
- 4.2 Concerned Head of International Cell, CDSCO, HQ shall be responsible for the implementation and regular monitoring of compliance of this SOP.
- 4.3 JDC(I) shall be the "Licensing Authority" to issue "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.

5.0 Accountability


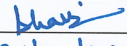
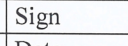
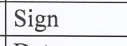

Head of International Cell (CDSCO-HQ).

6.0 Procedure

- 6.1 The online application received from the Zonal/Sub-Zonal Office shall be allotted to the concerned Reviewing Officer (RO).
- 6.2 The Reviewing Officer (RO) shall verify the availability of the Inspection Report, Compliance Report, clear Recommendation Letter of zonal/ sub-zonal head, and the list of drug substances recommended to be considered, in accordance with SOP No. INC-WCC-001. In the event that any of these documents are incomplete or unavailable, the RO may recommend that the file be returned to the concerned Zonal/Sub-zonal Office for submission of the required documents.
- 6.3 After verifying the availability of documents as per para 6.2 above, the Reviewing Officer (RO) shall review the application for the adequacy of the documents submitted. If any inadequacy is observed, the RO shall raise an appropriate query and forward the application to the Senior Reviewing Officer (SRO).

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Division Name	International Cell, CDSCO(HQ)		Page No.	3 of 4			
Prepared By		Checked By		Approved By		Authorized By	
Name	K. Bhavani	Name	Sidhant S. Malhotra	Name	Shev Kumar	Name	Dr. K. Chandrasekhar
Designation	Drugs Inspector	Designation	ADC (2)	Designation	DDC (5)	Designation	DDC (1)
Sign		Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

- 6.4 The Senior Reviewing Officer shall review the queries raised and the completeness of the application and shall forward the application to the Decision Authority (DA).
- 6.5 The Decision Authority shall review the queries and the completeness of the application and shall return the file to the applicant for submission of replies to the raised queries.
- 6.6 Upon receipt of the query reply from the applicant, the Reviewing Officer shall reassess the completeness and adequacy of the application. If the reply is found to be unsatisfactory, Steps 6.3 to 6.5 shall be repeated. If the application is found complete and adequate in all aspects, the Reviewing Officer shall write recommendations in the SUGAM note sheet and forward the application to the Senior Reviewing Officer.
- 6.7 During the review of the query reply, the RO shall ensure that no new query is raised unless it is an outcome to the reply furnished by the applicant.
- 6.8 The Senior Reviewing Officer shall verify the adequacy of the application and forward it, along with recommendations written in the SUGAM note sheet, to the Decision Authority.
- 6.9 The Decision Authority shall verify the adequacy of the application and forward it, along with recommendations written in the SUGAM note sheet, to the Licensing Authority.
- 6.10 The Licensing Authority shall verify the completeness and adequacy of the application and, based on the recommendations of the Reviewing Officer, Senior Reviewing Officer, and Decision Authority, and Zonal/Sub-zonal Office recommendations either approve or reject the Written Confirmation application.
- 6.11 Upon approval of the Written Confirmation application, the concerned Reviewing Officer shall prepare the electronic file (e-File) for issuance of the Written

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Division Name	International Cell, CDSCO(HQ)		Page No.	4 of 4	
Prepared By		Checked By	Approved By	Authorized By	
Name	K. Bhavani	Name	Sidharth Malhotra	Name	Shiv Kumar
Designation	Drugs Inspector	Designation	ADC (2)	Designation	DDC (I)
Sign		Sign		Sign	
Date	27/03/26	Date	27/03/26	Date	27/3/2026
				Name	Dr. R. Chandrashekar
				Designation	JDC (I)
				Sign	
				Date	27/03/26

Confirmation Certificate along with the covering letter and forward the hard copy for the signature of the Licensing Authority.

- 6.12 After signature of the Written Confirmation Certificate, the concerned Reviewing Officer shall upload the signed certificate to the application portal as well as to take necessary steps to upload in the CDSCO website.
- 6.13 The officers of Head Quarter dealing with the application shall ensure that the application is approved within three weeks (03) of the receipt of complete and adequate application.

7.0 Abbreviation

Acronym	Full Form
LA	Licensing Authority
DA	Decision Authority
SRO	Senior Reviewing Officer
RO	Reviewing Officer
SOP	Standard Operating Procedure
INS	Inspection
EU	European Union
JDC(I)	Joint Drugs Controller (India)

8.0 Revision History

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