File No.: I C-21011/41/2026-eoffice/34688
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date
27 MAR 2026

CIRCULAR

Subject: Streamlining the procedure for disposal of applications for "Written Confirmation" (WC) for Active Substances Exported to the EU for Human Use in accordance with Article 46(2)(b) of Directive 2001/83/EC received in CDSCO SUGAM Portal – Reg.

In order to streamline the processing and ensure time-bound disposal of applications pertaining to written confirmations received on SUGAM Portal of CDSCO, it has been decided that following procedures to be followed which simplify the existing process by eliminating the double layer of review:-

1) Upon receipt of applications on said portal, the Zonal/Sub-zonal offices of CDSCO shall verify appropriateness of document submitted by the applicant. The inspection report (IR), compliance verification report (CVR) and recommendation letter shall be uploaded and thereafter application shall be forwarded to Head Quarter (HQ) within three (03) weeks of receipt of application.
2) International Cell, CDSCO HQ shall review the adequacy of documents for its disposal within three (03) weeks of receipt of application. Query will be issued by HQ based on the input from the Zonal/Sub-Zonal offices of CDSCO.

Encl.: SOPs

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

1) All Zonal/Sub-zonal offices/International Cell of CDSCO
2) All Stakeholders through CDSCO Website

	TITLE	SOP No.	INC-WCC-002
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 International Cell, Head Quarter of CDSCO	Effective Date	27/03/2026
		Review Date	26/03/2029
		Supersedes	00
		Revision No.	01
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Prepared By		Checked By		Approved By		Authorized By	
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Designation	Drugs Inspector	Designation	ADC (I)	Designation	DDC(I)	Designation	JDC(I)
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Date	27/03/26	Date	27/03/26	Date	27/3/2026	Date	27/03/26

Control Status
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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.

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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 International Cell, Head Quarter of CDSCO	Effective Date	27/03/2026
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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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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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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

	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
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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.

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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
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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

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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.

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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

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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

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