	TITLE	SOP No.	EP-INS-006
	Procedure for forwarding of Non Compliances to EU	Effective Date	
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		Supersedes	NA
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Prepared By		Checked By		Approved By		Authorized By	
Name		Name		Name		Name	
Designation	Drugs Inspector	Designation		Designation		Designation	
Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

Control Status

1.0 Purpose

To lay down a procedure for forwarding of Non Compliances to EU.

2.0 Scope

This document is applicable to forwarding of Non Compliances to EU for the manufacturers to whom "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 have already been issued.

3.0 Responsibility:

3.1 The personnel at a level of DI shall review the inspection report.

3.2 The ADC (I) shall be responsible for implementation of the SOP.

3.3 DDC (I) shall be responsible for the regular monitoring of compliance of this SOP.

3.4 DCG(I) shall be the "Competent Authority" to forward Non Compliances to EU.

4.0 Accountability

Head of Export Division and DCG (I)

5.0 Procedure

5.1 The inspection or investigation report shall be reviewed and Non Compliances shall as categorized as per SOP EP-INS-005 "Procedure for review of Inspection Report and 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 Critical and Major Non Compliances shall be forwarded to EU.

5.3 Details of Show Cause issued and any suitable action, if taken, shall be forwarded to EU.

5.4 The following information needs to be submitted to the EU:

- Contact details of the notifying authority

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- Manufacturer name and address
- Product-related information
  - Human / Veterinary / IMP / API / export only
  - Products / dosage forms / buildings / lines affected
- Non-compliance issues
  - EU GMP non-compliances
  - Exporting country GMP non-compliances

5.5 In case a “Written Confirmation” is suspended or cancelled, after successful compliance of Non Compliances observed during inspection by the firm the “Written Confirmation” shall be re issued and same shall be informed to EU.

5.6 EU shall be informed by e-mail at qdefect@ema.europa.eu or by mail at the following address “Commission europeénne/Europese Commissie, Helath and Consumers Directorate-General, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË”.

6.0 Annexure

NIL

7.0 References

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

8.0 Abbreviation

Acronym	Full Form
DCGI	Drugs Controller General, India
QA	Quality Assurance
ADC (I)	Assistant Drug Controller, India

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DI	Drug Inspector
DDC (I)	Deputy Director Controller, India
SOP	Standard Operating Procedure
EU	European Union
INS	Inspection
EC	European Council
IMP	Innovative Pharmaceutical Molecule
API	Active Pharmaceutical Ingredient

9.0 Revision History

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