




**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

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Annexure-3

FORM Title: Checklist for NOC Application for Donation and Assessment

	
Form No. NRA-MA-010/F03-01	Page No. 01 of 01
Version No. 01	Authorized by 
Effective Date DEC' 21	Date 17-11-21
Review Date DEC' 26	

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			DGDA Screening
		Yes	No	NA	Yes	No	NA	
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Assessment Outcome
2.	Commercial invoice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Ministry recommendation (if needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	Recommendation from Ministry of Health (Donation from Government to Government)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Assessment Completed on		Total Duration						
Assessment Summary		Assessment Done By/Date#						
Recommendation of Head of Vaccine and Biologics		Head of Vaccine & Biologics Sign/Date						



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 Recommendation of Head of Vaccine and Biologics
 MINISTRY OF HEALTH AND FAMILY WELFARE
 BANGLADESH




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Issue Date: 18 NOV 2021

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Annexure-4

			
FORM Title: Checklist for NOC Application to Import Raw material/ RS (Reference Standard)/ Innovator product/Impurity standard for Product Development and Assessment			
Form No.	Version No.	Effective Date	Date
NRA-MA-010/F04-01	01	DEC' 21	17-11-21
		Review Date	Authorized by
		DEC' 26	
			Page No.
			01 of 01

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			Total Duration	DGDA Screening	Assessment Outcome
		Yes	No	NA	Yes	No	NA			
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
2.	Commercial/Proforma Invoice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
3.	Challan with VAT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
4.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

Assessment Completed on	Assessment Done By/Date
 Assessment Summary Recommendation of Head of Vaccine and Biologics	Head of Vaccine & Biologics Sign/Date

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Annexure-5

FORM Title: Checklist for NOC Application to Export/Import Placebo and Assessment



Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-010/F05-01	01	DEC' 21	DEC' 26	<i>[Signature]</i>	17.11.21	01 of 01

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			DGDA Screening	Assessment Outcome
		Yes	No	NA	Yes	No	NA		
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Commercial/Proforma invoice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Placebo certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Assessment Completed on								Total Duration	

Assessment Summary	Assessment Done By/Date
Recommendation of Head of Vaccine and Biologics	Head of Vaccine & Biologics Sign/Date



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Annexure-6

FORM Title: Checklist for NOC Application for Export Purpose to get Registered and Assessment



Form No. NRA-MA-010/F06-01	Version No. 01	Effective Date DEC' 21	Review Date DEC' 26	Authorized by 	Date 17.11.21	Page No. 01 of 01
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Assessment Started on:

Section	Documents	Documents Availability			Submitted?			Total Duration	DGDA Screening	Assessment Outcome
		Yes	No	NA	Yes	No	NA			
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
2.	Commercial/Proforma invoice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
3.	Letter from exporting country	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
4.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

Assessment Completed on

Assessment Summary	Assessment Done By/Date
 Recommendation of Head of Vaccine and Biologics	Head of Vaccine & Biologics Sign/Date

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Annexure-7

			
FORM Title: Checklist for NOC Application for the Medicine to Personal Use and Assessment			
Form No.	Version No.	Effective Date	Date
NRA-MA-010/F07-01	01	DEC' 21	17-11-21
	Authorized by	Review Date	Page No.
		DEC' 26	01 of 01

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			DGDA Screening Assessment Outcome
		Yes	No	NA	Yes	No	NA	
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Commercial/Proforma invoice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Doctor's Prescription	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	Details Quantity/Amount	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Assessment Completed on		Total Duration						
Assessment Summary		Assessment Done By/Date						
Recommendation of Head of Vaccine and Biologics		Head of Vaccine & Biologics Sign/Date						

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Annexure-8

FORM Title: Checklist for NOC Application for Drugs/Medicine/Medical Device/IVD for Research Purpose and Assessment

Form No. NRA-MA-010/F08-01	Page No. 01 of 01
Version No. 01	Date 17.11.21
Effective Date DEC' 21	Authorized by
Review Date DEC' 26	

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			DGDA Screening Assessment Outcome
		Yes	No	NA	Yes	No	NA	
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Commercial/Proforma invoice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Protocol approval certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	IND certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Placebo certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.	Certificate of analysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Assessment Completed on		Total Duration						
Assessment Summary		Assessment Done By/Date						
Recommendation of Head of Vaccine and Biologics		Head of Vaccine & Biologics Sign/Date						

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Annexure-9

			
FORM Title: Checklist for NOC Application to Supply in Govt. Agency/Hospital and Assessment			
Form No.	Version No.	Effective Date	Date
NRA-MA-010/F09-01	01	DEC' 21	17/11/21
Review Date	Authorized by		
DEC' 26			

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			Assessment Outcome
		Yes		Sign	Yes		NA	
		No	NA	No	NA			
1.	Application as per Annexure-1	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		DGDA Screening
2.	Commercial/Proforma invoice	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
3.	Work order/Award of Tender with specific amount	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
4.	COPP (One of seven reference countries)/EMA/WHO prequalified/SRAs (For Vaccine and Biological products)	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
5.	If the supplier is the agent to supply to the hospital both parties must have the agreement on supply including date, amount, originator country of medicine, brand name, generic name etc.	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
6.	Certificate of origin	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
7.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		
Assessment Completed on		Total Duration			Assessment Done By/Date			
Assessment Summary					Head of Vaccine & Biologics Sign/Date			
Recommendation of Head of Vaccine and Biologics								


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Annexure-10

FORM Title: Checklist for NOC Application for Sending Samples to Another Country for Testing Purposes and Assessment



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Form No. NRA-MA-010/F10-01	Version No. 01	Effective Date DEC' 21	Review Date DEC' 26	Authorized by 	Date [7-11-21]
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Assessment Started on:

Section	Documents	Documents Availability			Submitted?			Total Duration	DGDA Screening Assessment Outcome
		Yes	No	NA	Yes	No	NA		
1.	Application as per Annexure-1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Contract agreement/ any documents like copy of communication through mail	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Fees voucher	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Assessment Completed on

Assessment Done By/Date

Assessment Summary

Recommendation of Head of Vaccine and Biologics

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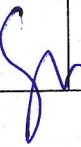
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Annexure-11

		FORM Title: Checklist for NOC Application for Other Purposes and Assessment			
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date
NRA-MA-010/F11-01	01	DEC' 21	DEC' 26		17-11-21
					Page No. 01 of 01

Assessment Started on:

Section	Documents	Documents Availability			Submitted?			DGDA Screening	Assessment Outcome
		Yes	No	NA	Sign	Yes	No		
1.	Application as per Annexure-1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Documents as per International guideline requirement case by case	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Fees voucher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Assessment Completed on		Total Duration							
Issued by: 		Assessment Done By/Date							
Recommendation of Head of Vaccine and Biologics		Head of Vaccine & Biologics Sign/Date							


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