

**Pre- Screening checklist for
BA/BE NOC export purpose**

1. Application for BE NOC for Export, of a new molecule not approved in India but approved in the other countries.

S. No	Documents	Yes	No
1	Application in Form-44 duly signed, stamped & dated by the competent authority with name and designation.		
2	Treasury Challan: Rs 25000/- BE NOC & T/L (Brand Name & Generic Name of the drug in form 12)		
3	A copy of the approval granted to the BE study centre by CDSCO		
4	Regulatory status of the drug in other country		
5	Names of the countries where the drug is currently being marketed (to be mentioned in the covering letter also)		
6	Prescribing information/Package literature on the international product		
7	Chemical & Pharmaceutical data including stability data		
8	Non-clinical & clinical data as per Appendix- I of schedule Y along with Published data BA/BE study carried out in healthy volunteers		
9	In the case of multiple dose BE study adequate supporting safety data including published report of BA/BE carried out in the subjects.		
10	Sponsor's Authorization letter duly signed by the competent authority on their letterhead.		
11	Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.		
12	The study synopsis		
13	The study protocols		
14	Complete Informed consent form/Patient Information Sheet Informed consent Documents should include "in case of study related injury the (<i>name of the applicant</i>) will provide complete medical care along with compensation for injury". Further compensation for participation in the study should be paid to the volunteers proportionately at the end of each period of the study.		
	IEC Location : _____ /study site location : _____ The Location of Ethics committee vis-a-vis location of the study site		

	<ul style="list-style-type: none"> • Authority under which ethics committee has been constituted. • Composition of Ethics committee • Review and decision making process of the Ethics committee. • Source and methods of recruitment for volunteers • ICF process followed for the study <p>*The above information is not required if the information already submitted earlier with application, However the firm should mention the reference of the submission.</p>		
15	Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study along with dissolution profile.		
16	In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.		
17	Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted, published report of BA/BE carried out in the subjects.		

2.Application for BE NOC for Export, of a New Drugs approved in India within period of 1 year:-

S. No	Documents	Yes	No
1	Application in Form-44 duly signed, stamped & dated by the competent authority with name and designation.		
2	Treasury Challan: Rs 25000/- BE Noc & T/L (Brand Name & Generic Name of the drug in form 12)		
3	A copy of the approval granted to the BE study centre by CDSCO		
4	Regulatory status of the drug in India		
6	Published data BA/BE study carried out in healthy volunteers		
7	Sponsor's Authorization letter duly signed by the competent authority on their letterhead.		
8	Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.		
9	The study synopsis		
10	The study protocols		
11	Complete Informed consent form/Patient Information Sheet Informed consent Documents should include "in case of study related injury the (<i>name of the applicant</i>) will provide complete medical care along with compensation for injury". Further compensation for participation in the study should be paid to the volunteers proportionately at the end of each period of the study.		
	IEC Location : /study site location : The Location of Ethics committee vis-a-vis location of the study site		
	<ul style="list-style-type: none"> • Authority under which ethics committee has been constituted. • Composition of Ethics committee • Review and decision making process of the Ethics committee. • Source and methods of recruitment for volunteers • ICF process followed for the study <p>*The above information is not required if the information already submitted earlier with application, However the firm should mention the reference of the submission.</p>		
12	Chemical & Pharmaceutical data including stability data, Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study along with dissolution		

	profile.		
13	In the case of multiple dose BE study adequate supporting safety data including published report of BA/BE carried out in the subjects.		
14	In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.		
15	Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.		
16	If the study is proposed with new dosage form, new route of administration, higher strength of the drug, supporting safety data including published report of BA/BE carried out in the subjects.		

3. Application for BE NOC for Export, of a New Drugs approved within period of more than 1 year & less than 4 years:

S. No	Documents	Yes	No
1	Application in Form-44 duly signed, stamped & dated by the competent authority with name and designation.		
2	Treasury Challan: Rs15000/- BE Noc & T/L (Brand Name & Generic Name of the drug in form 12)		
3	A copy of the approval granted to the BE study centre by CDSCO		
4	Regulatory status of the drug in India		
5	Sponsor's Authorization letter duly signed by the competent authority on their letterhead.		
6	Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.		
7	The study synopsis		
8	The study protocols		
9	Complete Informed consent form/Patient Information Sheet Informed consent Documents should include "in case of study related injury the (<i>name of the applicant</i>) will provide complete medical care along with compensation for injury". Further compensation for participation in the study should be paid to the volunteers proportionately at the end of each period of the study.		
	IEC Location : /study site location : The Location of Ethics committee vis-a-vis location of the study site		
	<ul style="list-style-type: none"> • Authority under which ethics committee has been constituted. • Composition of Ethics committee • Review and decision making process of the Ethics committee. • Source and methods of recruitment for volunteers • ICF process followed for the study <p>*The above information is not required if the information already submitted earlier with application, However the firm should mention the reference of the submission.</p>		
10	Chemical & Pharmaceutical data including stability data, Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study along with dissolution profile.		

11	In the case of multiple dose BE study adequate supporting safety data including published report of BA/BE carried out in the subjects.		
12	In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.		
13	Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.		
14	If the study is proposed with new dosage form, new route of administration, higher strength of the drug, supporting safety data including published report of BA/BE carried out in the subjects.		

4. Application for BE NOC for Export, of a drug product in modified release form irrespective of their approval status:-

S. No	Documents	Yes	No
1	Application in Form-44 duly signed, stamped & dated by the competent authority with name and designation.		
2	Treasury Challan: Rs 15000/- BE NOC & T/L (Brand Name & Generic Name of the drug in form 12)		
3	A copy of the approval granted to the BE study centre by CDSCO		
4	Regulatory status of the drug in India		
5	Sponsor's Authorization letter duly signed by the competent authority on their letterhead.		
6	Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.		
7	The study synopsis		
8	The study protocols		
9	Complete Informed consent form/Patient Information Sheet Informed consent Documents should include "in case of study related injury the (<i>name of the applicant</i>) will provide complete medical care along with compensation for injury". Further compensation for participation in the study should be paid to the volunteers proportionately at the end of each period of the study.		
	IEC Location : /study site location : The Location of Ethics committee vis-a-vis location of the study site		
	<ul style="list-style-type: none"> • Authority under which ethics committee has been constituted. • Composition of Ethics committee • Review and decision making process of the Ethics committee. • Source and methods of recruitment for volunteers • ICF process followed for the study <p>*The above information is not required if the information already submitted earlier with application, However the firm should mention the reference of the submission.</p>		
10	Chemical & Pharmaceutical data including stability data, Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study along with dissolution profile.		
11	In the case of multiple dose BE study adequate supporting safety		

	data should be submitted.		
12	In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.		
13	Depending on the nature of the drug like cytotoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.		
14	If the study is proposed with new dosage form, new route of administration, higher strength of the drug, supporting safety data including published report of BA/BE carried out in the subjects.		
