Pre-Screening revised checklist for BA/BE NOC for Export Purpose

O/o Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, New Delhi
(With effective from 25th April 2014)

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

1. Application for BE NOC for Export of new molecule (New Chemical entity) not approved in India but approved in other countries.

S. No	Documents	Yes	No
1	Application in Form-44 duly signed, by the Authorized signatory with details of name and designation.		
2	Treasury Challan (TR – 6) of ` 25000/- as per Drugs & Cosmetic Rules (Medical and Public Health Account: 0210). Brand name and Generic name of the Drug in Form 12		
3	Undertaking by the Principal Investigator (PI) in original duly signed on a company letterhead as per appendix VII of Schedule "Y" of Drugs and Cosmetic Rules.		
4	BA/BE Centre approval copy issued by DCG(I), New Delhi, and also furnish the detail of number of beds provided at the Centre (CRO) including ICU beds for effective handling of SAEs in emergency situations.		
5	Sponsor's Authorization letter duly signed by the Authorized Signatory on company letterhead.		
6	The study protocols, Informed Consent Form (ICF) or Patient Information Sheet (PIS) along with audio-visual recording system as per Schedule Y guidelines; & copy of approval of protocol from the IEC, if available.		
7	Copy of registration of Independent/Institutional Ethics Committee (IEC) under Rule-122DD from the Office of Drugs Controller General (India), New Delhi.		
8	The study synopsis.		
9	Undertaking letter from the sponsor/applicant stating that you will provide complete medical care as well as compensation for the injury or Death and statement to this effect should be incorporated in the Informed Consent Form further in case of such injuries or Deaths the details of compensation provided should be intimated to this Directorate as per Rule 122 DAB of D&C Act 1940 & Rules there under.		
10	Non-clinical and clinical data as per Appendix-I of Schedule Y of D & C Act 1940.		

11	Published reports of Pharmacokinetic and Pharmacodynamics studies carried out in healthy subjects/ patients demonstrating safety and tolerability of the molecule.		
12	Regulatory approval status of the drug indicating the strength, dosage form and countries.		
13	Names of the countries where the drug is currently being marketed (to be mention in the covering letter also).		
14	Package insert/prescribing information of the product.		
15	Chemical and Pharmaceutical data including stability data		
16	Certificate of Analysis (COA) of representative batches (both Test & Reference formulations) to be used in the BE study along with dissolution profile in case of Oral Solid dosage forms		
17	For Multiple dose BE study adequate supporting safety data and PK/PD data should be submitted covering the duration of period for which the study has to be conducted. If Regulatory Guidance is available provide a copy of the same.		
18	For all Injectable, the sub-acute toxicity should be available on the Test product of the sponsor, studied in at least two species for minimum 14 days.		
19	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc. in Healthy Human subjects a Scientific justification with special emphasis on Safety of subjects with a proper Risk Mitigation Strategy shall be submitted. If Regulatory Guidance is available, enclose a copy of the same.		
20	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc. in Patients a Scientific justification with special emphasis on Safety with a proper Risk Mitigation Strategy should be submitted.		
21	Report of any study related deaths during last 3 years at BA/BE centre.		
22	Address details of the IEC Location and study site location.		

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

S. No	Documents	Yes	No
1	Application in Form-44 duly signed, by the Authorized signatory with details of name and designation.		
2	Treasury Challan (TR – 6) of ` 25000/- as per Drugs & Cosmetic Rules (Medical and Public Health Account: 0210).		
3	Undertaking by the Principal Investigator (PI) in original duly signed on a company letterhead as per appendix VII of Schedule "Y" of Drugs and Cosmetic Rules.		
4	Regulatory status of the Drug in India indicating strength & dosage.		
5	BA/BE Centre approval copy issued by DCG(I), New Delhi, and also furnish the detail of number of beds provided at the Centre (CRO) including ICU beds for effective handling of SAEs in emergency situations.		
6	Sponsor's Authorization letter duly signed by the Authorized Signatory on company letterhead		
7	The study protocols, Informed Consent Form (ICF) or Patient Information Sheet (PIS) along with audio-visual recording system as per Schedule Y guidelines; & copy of approval of protocol from the IEC, if available.		
8	Copy of registration of Independent/Institutional Ethics Committee (IEC) under Rule-122DD from the Office of Drugs Controller General (India), New Delhi		
9	The study synopsis		
10	Undertaking letter from the sponsor/applicant stating that you will provide complete medical care as well as compensation for the injury or Death and statement to this effect should be incorporated in the Informed Consent Form further in case of such injuries or Deaths the details of compensation provided should be intimated to this Directorate as per Rule 122 DAB of		

	D&C Act 1940 & Rules there under.		
11	Published reports of Pharmacokinetic and Pharmacodynamics studies carried out in healthy subjects/ patients demonstrating safety and tolerability of the molecule		
12	Package insert/prescribing information of the product.		
13	Chemical and Pharmaceutical data including stability data		
14	Certificate of Analysis (COA) of representative batches (both Test & Reference formulations) to be used in the BE study along with dissolution profile in case of Oral Solid dosage forms		
15	For Multiple dose BE study adequate supporting safety data and PK/PD data should be submitted covering the duration of period for which the study has to be conducted. If Regulatory Guidance is available provide a copy of the same.		
16	For all Injectable, the sub-acute toxicity should be available on the Test product of the sponsor, studied in at least two species for minimum 14 days.		
17	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc in Healthy Human subjects a Scientific justification with special emphasis on Safety of subjects with a proper Risk Mitigation Strategy shall be submitted. If Regulatory Guidance is available, enclose a copy of the same.		
18	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc in Patients a Scientific justification with special emphasis on Safety with a proper Risk Mitigation Strategy should be submitted.		
19	Report of any study related deaths during last 3 years at BA/BE centre.		
20	Address details of the IEC Location and study site location.		

3. Application for BE NOC for Export, of 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, by the Authorized signatory with details of name and designation		
2	Treasury Challan (TR – 6) of ` 15000/- as per Drugs & Cosmetic Rules (Medical and Public Health Account: 0210).		
3	Undertaking by the Principal Investigator (PI) in original duly signed on a company letterhead as per appendix VII of Schedule "Y" of Drugs and Cosmetic Rules.		
4	Regulatory status of the Drug in India indicating strength & dosage.		
5	BA/BE Centre approval copy issued by DCG(I), New Delhi, and also furnish the detail of number of beds provided at the Centre (CRO) including ICU beds for effective handling of SAEs in emergency situations.		
6	Sponsor's Authorization letter duly signed by the Authorized Signatory on company letterhead.		
7	The study protocols, Informed Consent Form (ICF) or Patient Information Sheet (PIS) along with audio-visual recording system as per Schedule Y guidelines; & copy of approval of protocol from the IEC, if available.		
8	Copy of registration of Independent/Institutional Ethics Committee (IEC) under Rule-122DD from the Office of Drugs Controller General (India), New Delhi.		
9	The study synopsis		
10	Undertaking letter from the sponsor/applicant stating that you will provide complete medical care as well as compensation for the injury or Death and statement to this effect should be incorporated in the Informed Consent Form further in case of such injuries or Deaths the details of compensation provided should be intimated to this Directorate as per Rule 122 DAB		

	of D&C Act 1940 & Rules there under.		
11	Chemical and Pharmaceutical data including stability data		
12	Certificate of Analysis (COA) of representative batches (both Test & Reference formulations) to be used in the BE study along with dissolution profile in case of Oral Solid dosage forms		
13	For Multiple dose BE study adequate supporting safety data and PK/PD data should be submitted covering the duration of period for which the study has to be conducted. If Regulatory Guidance is available provide a copy of the same.		
14	For all Injectable, the sub-acute toxicity should be available on the Test product of the sponsor, studied in at least two species for minimum 14 days.		
15	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc in Healthy Human subjects a Scientific justification with special emphasis on Safety of subjects with a proper Risk Mitigation Strategy shall be submitted. If Regulatory Guidance is available, enclose a copy of the same.		
16	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc in Patients a Scientific justification with special emphasis on Safety with a proper Risk Mitigation Strategy should be submitted.		
17	Report of any study related deaths during last 3 years at BA/BE centre.		
18	Address details of the IEC Location and study site location.		

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, by the Authorized signatory with details of name and designation		
2	Treasury Challan (TR – 6) of 15000/- as per Drugs & Cosmetic Rules (Medical and Public Health Account: 0210) for drugs approved in India or TR- 6 of 25000/- in case of drugs not approved in India (New Chemical entity).		
3	Undertaking by the Principal Investigator (PI) in original duly signed on a company letterhead as per appendix VII of Schedule “Y” of Drugs and Cosmetic Rules.		
4	Regulatory status of the Drug in India/Other Countries indicating strength & dosage form.		
5	BA/BE Centre approval copy issued by DCG(I), New Delhi, and also furnish the detail of number of beds provided at the Centre (CRO) including ICU beds for effective handling of SAEs in emergency situations.		
6	Sponsor’s Authorization letter duly signed by the Authorized Signatory on company letterhead.		
7	The study protocols, Informed Consent Form (ICF) or Patient Information Sheet (PIS) along with audio-visual recording system as per Schedule Y guidelines; & copy of approval of protocol from the IEC, if available.		
8	Copy of registration of Independent/Institutional Ethics Committee (IEC) under Rule-122DD from the Office of Drugs Controller General (India), New Delhi.		
9	The study synopsis		
10	Undertaking letter from the sponsor/applicant stating that		

	you will provide complete medical care as well as compensation for the injury or Death and statement to this effect should be incorporated in the Informed Consent Form further in case of such injuries or Deaths the details of compensation provided should be intimated to this Directorate as per Rule 122 DAB of D&C Act 1940 & Rules there under.		
11	Chemical and Pharmaceutical data including stability data		
12	Certificate of Analysis (COA) of representative batches (both Test & Reference formulations) to be used in the BE study along with dissolution profile in case of Oral Solid dosage forms.		
13	For Multiple dose BE study adequate supporting safety data and PK/PD data should be submitted covering the duration of period for which the study has to be conducted. If Regulatory Guidance is available provide a copy of the same.		
14	For all Injectable, the sub-acute toxicity should be available on the Test product of the sponsor, studied in at least two species for minimum 14 days.		
15	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc in Healthy Human subjects a Scientific justification with special emphasis on Safety of subjects with a proper Risk Mitigation Strategy shall be submitted. If Regulatory Guidance is available, enclose a copy of the same.		
16	For Cytotoxic drugs, Hormonal preparations, Narcotic and Psychotropic substances etc in Patients a Scientific justification with special emphasis on Safety with a proper Risk Mitigation Strategy should be submitted.		
17	Report of any study related deaths during last 3 years at BA/BE Centre.		
18	Address details of the IEC Location and study site location.		
19	Published reports of Pharmacokinetic and Pharmacodynamics studies carried out in healthy subjects/ patients demonstrating safety and tolerability of the molecule.		
20	Package insert/prescribing information of the product.		

5. Application for Test license (Form11) for BA/BE study of old drugs (Drugs approved for more than 4 years):-

S. No	Documents	Yes	No
1	Covering letter of firm		
2	Regulatory status of the Drug in India indicating strength & dosage form.		
3	Form-12 along with relevant Treasury Challan (TR – 6), if applicable as per cdsco.nic.in		
4	The study protocols, Informed Consent Form (ICF) or Patient Information Sheet (PIS) along with audio-visual recording system as per Schedule Y guidelines; & copy of approval of protocol from the IEC, if available		
5	The study synopsis		

Note: All above applications should be consisting of proper index with sequence of respective checklist, along with page numbers, separator, in legible form to ensure Good Documentation Practices.

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