1. Checklist for Grant of permission to manufacture/import of Bulk Drug already approved in the country

S no	Documents required to be submitted	Enclosed		Page no
		Yes	No	
1.	Name of Applicant with address			
2.	Name of Drug			
3.	Therapeutic Class			
4.	Date of Approval			
5.	Application in Form-44 duly filled and signed by the competent authority			
6.	Treasury Challan of INR 50,000/- upto 1 year from initial approval and INR 15,000/- for other drugs upto 4 years			
7a.	For manufacturing:- Copy of manufacturing license in Form-25/ Form-26 for any bulk drug to manufacturer and Form-29			
7b.	For import:- Copy of drug sale license in Form 20B and 21B			
8.	Pharmaceutical & Chemical Information			
A.	Manufacturing Process including flowcharts detailed manufacturing procedure,			
	i. In process check procedure and report control			
	ii. Batch manufacturing record			
	iii. Process validation report.			
B.	Complete monograph Specifications, methods of analysis including analytical method validation report, with			
	i. Identification/ quantification of impurities			
	ii. Enantiomeric purity			
	iii. Residual solvent/ other volatile impurities (OVI) estimation			
C.	Structural elucidation data			
D.	Three batch Certificate of analysis			
E.	Stability data of three different lots as per Schedule –Y of Drugs and Cosmetics Rules (should be presented in tabular form with details of Batch no, Batch size, Date of manufacturing, Date of initiation, Packaging details)			
F.	Material Safety data sheet			
G.	Reference product characterization			
H.	Draft specimen Label			
9.	Sub-acute toxicity data generated with the applicant's bulk drug in two species.			
10.	CDTL/IPC Test report *			

* In case of application is for grant of NOC for lab testing serial no 10 may be submitted at the time of approval of bulk drug.

Note:

A) Submission requirements / methodology:

i. Please submit ONE hard copy and THREE soft copies i.e. Compact Disc (CD) (PDF format, properly bookmarked for navigation) of the dossier.

ii. Hard copy: Sides and front of each volume/ file /binder must be labelled with the name of the applicant company, date of submission, name of the drug(s) and the file number (Numbering of files: 'x' of 'y' files e.g. if there are 10 files, file number 6 will be labelled as File No. 6 / 10).

iii. Use of multiple volumes/ files/ binders is recommended than binding all the documents and modules in a very huge file. Preferably volumes/ files /binders should not be more than 3 inches thick and use of good quality binders is recommended. All the files should be kept together, bound by a good quality wire or thread (If there are too many volumes e.g. more than 10, then multiple grouping should be done).

iv. CDs have to be labelled using a marker pen with the name of the applicant company, date of submission and name of the drug(s). If there are multiple CDs for one submission dossier, then the numbering as mentioned above should be followed.

v. Scanned copies of only signed documents like test reports, signature pages will be acceptable and rest of the document has to be in PDF format with optical character recognition (OCR).

vi. The table of content under each head should be linked to the files (s) or relevant document for easy tracking in CD's.

vii. Applicant should preserve a duplicate copy of the submitted dossier for any future reference and should be able to submit multiple copies, if required by CDSCO.

2. **Approvals of a New drug (Formulation) already approved in the country**

S No	Documents required to be submitted	Enclosed		Page no.
		Yes	No	
1.	Application for permission to Manufacture /Import: (Purpose should be mentioned clearly)			
2.	Name of the applicant and address			
3.	Name of the New Drug			
	a. Composition of the New Drug			
	b. Dosage Form			
	c. Proposed indication for the New Drug			
	d. Therapeutic rational for proposed dosage form			
4.	Details of the approval of the New Drug in the country			
	a. Approved Dosage Form			
	b. Approved composition			
	c. Approved indication			
5.	Application in Form 44 duly signed and stamped by authorized personal			
6.	Treasury challan of INR 15,000 New Drug approved in India for more than one year, or ` 50,000 of New Drug is approved for less than one year duly signed and stamped by Bank of			
7.	Copy of valid manufacturing license in Form 25/28/26			
8.	Copy of valid Test license in Form 29			
9.	Source of bulk drugs along with current regulatory status of the source with copy of Form 46A/45A. (if obtained)			
10.	Consent letter and copy of manufacturing licence form supplier of bulk drug			
11.	Information on active ingredients:			
	a) Brief Chemical & pharmaceutical data			
	b) API Specification including impurity profile			
	c) Method of Analysis with analytical method validation report			
	d) Certificate of Analysis for three batches			
12.	Data on Formulation			
	a) Master manufacturing formula			
	b) Manufacturing Procedure/ Master manufacturing Record			
	c) Product development report with Excipient compatibility study and force degradation study.			
	d) Process validation protocol and Report			
	e) Finished product specification including impurity profile			
	f) Finished product Method of Analysis			
	g) Finished product Analytical method validation report			
	h) Finished product Certificate of Analysis for three batches/ three validation batches			
	i) In process quality control check specifications			

	j) Stability study data report as per requirements of schedule Y mentioning batch size. (should be presented in tabular form with details of Batch no, Batch size, Date of manufacturing, Date of initiation, Packaging details)			
	k) Dissolution Release Profile (in case of oral dosage form)			
	l) Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)			
	m) Comparative evaluation with pharmaceutical equivalence with international brand(s) or approved Indian brands, if applicable			
	n) Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamics and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.			
	o) Draft specimen of Label and Carton			
13.	Regulatory status in other countries, as appropriate.			
	a) Names of the countries where the drug is marketed/approved for proposed Dosage Form / New Route of Administration along with package insert and/or copies of approval in key countries.			
	b) Names of the countries where the drug is withdrawn, if any, with reasons			
	c) Free sale certificate (FSC) or Certificate of Pharmaceutical Product (COPP), in case of import.			
14.	Bio Equivalence/Bioavailability study Protocol (As the case may be)			
	a) BE protocol			
	b) Study synopsis			
	c) Undertaking by investigators as per Appendix VII od schedule Y and CV.			
	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income of subjects along with, name and address of			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
15.	Justification on Bio equivalence study waiver, if requested			
16.	In case of parenteral formulation, Sub-acute toxicity data conducted with the proposed drug formulation.			

17.	Submit 11 sets of technical literature (whenever applicable) (10 soft copy and one hard copy) for expert opinion. Each attachment shall not be more than 20 MB in size and shall be properly numbered and named reflecting various sections of the application.			

Note :

A) Submission requirements / methodology

i. Please submit ONE hard copy and THREE soft copies i.e. Compact Disc (CD) (PDF format, properly bookmarked for navigation) of the dossier.

ii. Hard copy: Sides and front of each volume/ file /binder must be labelled with the name of the applicant company, date of submission, name of the drug(s) and the file number (Numbering of files: 'x' of 'y' files e.g. if there are 10 files, file number 6 will be labelled as File No. 6 / 10).

iii. Use of multiple volumes/ files/ binders is recommended than binding all the documents and modules in a very huge file. Preferably volumes/ files /binders should not be more than 3 inches thick and use of good quality binders is recommended. All the files should be kept together, bound by a good quality wire or thread (If there are too many volumes e.g. more than 10, then multiple grouping should be done).

iv. CDs have to be labelled using a marker pen with the name of the applicant company, date of submission and name of the drug(s). If there are multiple CDs for one submission dossier, then the numbering as mentioned above should be followed.

v. Scanned copies of only signed documents like test reports, signature pages will be acceptable and rest of the document has to be in PDF format with optical character recognition (OCR).

vi. The table of content under each head should be linked to the files (s) or relevant document for easy tracking in CD's.

vii. Applicant should preserve a duplicate copy of the submitted dossier for any future reference and should be able to submit multiple copies, if required by CDSCO.

B) In case the application is for Clinical Trial /Bio equivalence permission:

a. Adequate chemical and pharmaceutical information should be provided to ensure the proper identity, purity, quality & strength of the investigational product, the amount of information needed may vary with the Phase of clinical trials, proposed duration of trials, dosage forms and the amount of information otherwise available.

b. In case of applications for protocol amendments of already approved studies, applicants should submit copy of approval of protocol, amended new protocol, summarized list of all the new changes incorporated along with justification / reasons for the change.

c. Ethics Committee Approval: Ethical approval should be obtained from Ethics Committee located in the same area where the clinical trial site is located.

d. The proposed clinical trial study centres should be geographically distributed in the country and should also include clinical sites which have their own Institutional Ethics Committee.

3. A drug already approved by the Licensing Authority mentioned in Rule 21 proposed to be marketed with new indication

S No	Documents required to be submitted	Enclosed		Page no
		Yes	No	
1.	Application for permission to Manufacture /Import/Clinical trial: (Purpose should be mentioned clearly)			
2.	Name of the applicant with address			
3.	Name of the New Drug			
	a. Composition of the New Drug			
	b. Dosage Form			
	c. Proposed indication for the New Drug			
	d. Therapeutic rational for proposed indication			
4.	Details of the approval of the New Drug in the country			
	a. Approved Dosage Form			
	b. Approved composition			
	c. Approved indication			
5.	Application in Form 44 duly signed and stamped by authorized personal			
6.	Treasury Challan of INR 15,000 New Drug approved in India for more than one year, or INR 50,000 of New Drug is approved for less than one year and not submitted challan earlier for the same			
7.	Copy of valid manufacturing license in Form 25/28/26			
8.	Copy of valid Test license in form 29			
9.	In case of new drug, Source of bulk drugs along with current regulatory status of the source with copy of Form 46A/45A. (if obtained)			
10	Consent letter and copy of manufacturing licence form supplier of bulk drug			
11.	Information on active ingredients:			
	a) Brief Chemical & pharmaceutical data			
	b) API Specification with impurity profile			
	c) Method of Analysis with method validation report			
	d) Certificate of Analysis for three batches			
12.	Data on Formulation			
	a) Master manufacturing formula			
	b) Manufacturing Procedure/ Master manufacturing Record			
	c) Product development report with Excipient compatibility and forced degradation study			
	d) Process validation protocol/ Report			
	e) Finished product specification			
	f) Finished product Method of Analysis			
	g) Finished product Analytical method validation report			
	h) Finished product Certificate of Analysis for three consecutive batches/ three validation batches			
	i) In process quality control check specifications			
	j) Stability study data report as per requirements of schedule Y mentioning batch size. (should be presented in tabular form with details of Batch no, Batch size, Date of manufacturing, Date of initiation, Packaging details)			

	k) Dissolution Release Profile (in case of oral dosage form)			
	l) Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)			
	m) Comparative evaluation with pharmaceutical equivalence with international brand(s) or approved Indian brands, if applicable			
	n) Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamics and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.			
	o) Draft specimen of Label and Carton			
Sr No 10 to 12 is not applicable, if applicant holds manufacturing or Import and marketing permission for the proposed drug product [Except 11(n) and 11(o)]				
13.	Therapeutic Rationale and justification for the proposed Additional Indication			
14.	Regulatory status in other countries, as appropriate.			
	a) Names of the countries where the drug is Marketed/ approved for proposed indication along with package insert and/or copies of approval in key countries.			
	b) Names of the countries where the drug is withdrawn, if any, with reasons			
	c) Free sale certificate (FSC) or Certificate of Pharmaceutical Product (COPP), in case of import.			
15.	Bio Equivalence/Bioavailability study Protocol (As the case may be)			
	a) BE protocol			
	b) Study synopsis			
	c) Undertaking by investigators as per Appendix VII od schedule Y and CV.			
	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income of subjects along with, name and address of nominee.			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
16.	Clinical trial protocol in case of proposed Additional dosage form is not approved in key countries. (Checklist already given in New Drug application)			
	I. CT protocol			
	II. Study synopsis			
	III. Undertaking by investigators as per Appendix VII of schedule Y and CV.			

	IV. Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income of subjects along with, name and address of nominee.			
	V. Compensation clause as per Rule 122 DAB			
	VI. Copy of 'Ethics Committee' approval letters along with registration details.			
	VII. Case record form (CRF)			
	VIII. Site details, which includes Investigators name and address, Type of Hospital (Multispecialty/ Government/ Private) , Number of beds, emergency facilities, Ethics Committee registration details, etc)			
17.	Justification on Clinical trial waiver, if requested.			
18.	Published report of Clinical trial/Journal/literature with respect to proposed Additional Indication.			
19	Submit 11 sets of technical literature (whenever applicable) (10 soft copy and one hard copy) for expert opinion. Each attachment shall not be more than 20 MB in size and shall be properly numbered and named reflecting various sections of the application.			

Note:

A) Submission requirements / methodology

i. Please submit ONE hard copy and THREE soft copies i.e. Compact Disc (CD) (PDF format) of the dossier.

ii. Hard copy: Sides and front of each volume/ file /binder must be labelled with the name of the applicant company, date of submission, name of the drug(s) and the file number (Numbering of files: 'x' of 'y' files e.g. if there are 10 files, file number 6 will be labelled as File No. 6 / 10).

iii. Use of multiple volumes/ files/ binders is recommended than binding all the documents and modules in a very huge file. Preferably volumes/ files /binders should not be more than 3 inches thick and use of good quality binders is recommended. All the files should be kept together, bound by a good quality wire or thread (If there are too many volumes e.g. more than 10, then multiple grouping should be done).

iv. CDs have to be labelled using a marker pen with the name of the applicant company, date of submission and name of the drug(s). If there are multiple CDs for one submission dossier, then the numbering as mentioned above should be followed.

v. Scanned copies of only signed documents like test reports, signature pages will be acceptable and rest of the document has to be in PDF format with optical character recognition (OCR).

vi. The table of content under each head should be linked to the files (s) or relevant document for easy tracking in CD's.

vii. Applicant should preserve a duplicate copy of the submitted dossier for any future reference and should be able to submit multiple copies, if required by CDSCO.

B) In case the application is for clinical trial / Bio equivalence permission:

a. Adequate chemical and pharmaceutical information should be provided to ensure the proper identity, purity, quality & strength of the investigational product, the amount of information

needed may vary with the Phase of clinical trials, proposed duration of trials, dosage forms and the amount of information otherwise available.

b. In case of applications for protocol amendments of already approved studies, applicants should submit copy of approval of protocol, amended new protocol, summarized list of all the new changes incorporated along with justification / reasons for the change.

c. Ethics Committee Approval: Ethical approval should be obtained from Ethics Committee located in the same area where the clinical trial site is located.

d. The proposed clinical trial study centres should be geographically distributed in the country and should also include clinical sites which have their own Institutional Ethics Committee.

4. A drug already approved by the Licensing Authority mentioned in Rule 21 and proposed to be marketed as a 'New Dosage Form / New Route of Administration'.

S No	Documents required to be submitted	Enclosed		Page No
		Yes	No	
1.	Application for permission to Manufacture /Import/Clinical trial: (Purpose should be mentioned clearly)			
2.	Name of the applicant with address			
3.	Name of the New Drug			
	a. Composition of the New Drug			
	b. Proposed Dosage Form			
	c. Proposed indication			
	d. Therapeutic rational for proposed New Dosage Form / New Route			
4.	Details of the approval of the New Drug in the country			
	a. Approved Dosage Form and route of administration			
	b. Approved composition			
	c. Approved indication			
5.	Application in Form 44 duly signed and stamped by authorized personal			
6.	Treasury Challan of INR 15,000 New Drug approved in India for more than one year, or INR 50,000 of New Drug is approved for less than one year and not submitted challan earlier for the same drug.			
7.	Copy of valid manufacturing license in Form 25/28/26			
8.	Copy of Test license in form 29			
9.	In case of new drug, Source of bulk drugs along with current regulatory status of the source with copy of Form 46A/45A. (if obtained)			
10.	Consent letter and copy of manufacturing licence form supplier of bulk drug			
11.	Information on active ingredients:			
	a) Brief Chemical & pharmaceutical data			
	b) API Specification with impurity profile			
	c) Method of Analysis with method validation report			
	d) Certificate of Analysis for three batches			
12.	Data on Formulation			
	a) Master manufacturing formula			
	b) Manufacturing Procedure/ Master manufacturing Record			
	c) Product development report with Excipient compatibility study and forced degradation study.			
	d) Process validation protocol/ Report			
	e) Finished product specification			
	f) Finished product Method of Analysis			
	g) Finished product Analytical method validation report			
	h) Finished product Certificate of Analysis for three consecutive batches/ three validation batches			
	i) In process quality control check specifications			

	j) Stability study data report as per requirements of schedule Y mentioning batch size. (should be presented in tabular form with details of Batch no, Batch size, Date of manufacturing, Date of initiation, Packaging details)			
	k) Dissolution Release Profile (in case of oral dosage form)			
	l) Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)			
	m) Comparative evaluation with pharmaceutical equivalence with international brand(s) or approved Indian brands, if applicable			
	n) Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamic and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.			
	o) Draft specimen of Label and Carton			
13.	Therapeutic Rationale and justification for the proposed new dosage form / new route of administration			
14.	Regulatory status in other countries, as appropriate.			
	a) Names of the countries where the drug is marketed/approved for proposed Dosage Form / New Route of Administration along with package insert and/or copies of approval in key countries.			
	b) Names of the countries where the drug is withdrawn, if any, with reasons			
	c) Free sale certificate (FSC) or Certificate of Pharmaceutical Product (COPP), in case of import.			
15.	Bio Equivalence/Bioavailability study Protocol (As the case may be)			
	a) BE protocol			
	b) Study synopsis			
	c) Undertaking by investigators as per Appendix VII od schedule Y and CV.			
	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
16.	Clinical trial protocol in case of proposed Additional dosage form is not approved in key countries. (Checklist already given in New Drug application)			
	a) CT protocol			
	b) Study synopsis			

	c) Undertaking by investigators as per Appendix VII of schedule Y and CV.			
	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income of subjects along with, name and address of nominee.			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
	g) Case record form (CRF)			
	h) Site details, which includes Investigators name and address, Type of Hospital (Multispecialty/ Government/ Private) , Number of beds, emergency facilities, Ethics Committee registration details, etc)			
17.	Bio Equivalence study requirement (in case of oral dosage form as appropriate as per Appendix X of Schedule Y)			
18.	Justification on Clinical trial and Bio equivalence study waiver, if requested.			
19.	Animal toxicology data as per Schedule Y.			
	a). Systemic toxicity studies,			
	i. single dose toxicity			
	ii. repeated dose toxicity			
	b). Local toxicity			
	i. **Dermal toxicity** (for products meant for topical (dermal) application)			
	ii. **Ocular toxicity** (for products meant for ocular instillation)			
	iii. **Inhalation toxicity** (conducted with the formulation proposed to be used via inhalation route)			
	iv. **Vaginal toxicity** (for products meant for topical application to vaginal mucosa)			
	v. **Photoallergy or dermal phototoxicity** (required if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential)			
	c). Rectal tolerance test (For all preparations meant for rectal administration)			
20.	Published report of Clinical trial/Journal/literature with respect to proposed Dosage Form / New Route of Administration.			
21.	Submit 11 sets of technical literature (whenever applicable) (10 soft copy and one hard copy) for expert opinion. Each attachment shall not be more than 20 MB in size and shall be properly numbered and named reflecting various sections of the application.			

Note:

A) Submission requirements / methodology

i. Please submit ONE hard copy and THREE soft copies i.e. Compact Disc (CD) (PDF format) of the dossier.

ii. Hard copy: Sides and front of each volume/ file /binder must be labelled with the name of the applicant company, date of submission, name of the drug(s) and the file number

(Numbering of files: 'x' of 'y' files e.g. if there are 10 files, file number 6 will be labelled as File No. 6 / 10).

iii. Use of multiple volumes/ files/ binders is recommended than binding all the documents and modules in a very huge file. Preferably volumes/ files /binders should not be more than 3 inches thick and use of good quality binders is recommended. All the files should be kept together, bound by a good quality wire or thread (If there are too many volumes e.g. more than 10, then multiple grouping should be done).

iv. CDs have to be labelled using a marker pen with the name of the applicant company, date of submission and name of the drug(s). If there are multiple CDs for one submission dossier, then the numbering as mentioned above should be followed.

v. Scanned copies of only signed documents like test reports, signature pages will be acceptable and rest of the document has to be in PDF format with optical character recognition (OCR).

vi. The table of content under each head should be linked to the files (s) or relevant document for easy tracking in CD's.

vii. Applicant should preserve a duplicate copy of the submitted dossier for any future reference and should be able to submit multiple copies, if required by CDSCO.

B) In case the application is for clinical trial / Bio equivalence permission:

a. Adequate chemical and pharmaceutical information should be provided to ensure the proper identity, purity, quality & strength of the investigational product, the amount of information needed may vary with the Phase of clinical trials, proposed duration of trials, dosage forms and the amount of information otherwise available.

b. In case of applications for protocol amendments of already approved studies, applicants should submit copy of approval of protocol, amended new protocol, summarized list of all the new changes incorporated along with justification / reasons for the change.

c. Ethics Committee Approval: Ethical approval should be obtained from Ethics Committee located in the same area where the clinical trial site is located.

d. The proposed clinical trial study centres should be geographically distributed in the country and should also include clinical sites which have their own Institutional Ethics Committee.

5. A drug already approved by the Licensing Authority mentioned in Rule 21 now proposed to be marketed as a 'Modified release dosage form'.

S No	Documents required to be submitted	Enclosed		Page no
		Yes	No	
1.	Application for permission to Manufacture /Import/Clinical trial: (Purpose should be mentioned clearly)			
2.	Name of the applicant with address			
3.	Name of the New Drug			
	a. Composition of the New Drug			
	b. Dosage Form			
	c. Proposed indication for the New Drug			
	d. Therapeutic rational for Modified release dosage form			
4.	Details of the approval of the New Drug in the country			
	a. Approved Dosage Form and route of administration			
	b. Approved composition			
	c. Approved indication			
5.	Application in Form 44 duly signed and stamped by authorized personal			
6.	Treasury Challan of INR 15,000 New Drug approved in India for more than one year, or INR 50,000 of New Drug is approved for less than one year and not submitted challan earlier for the same drug.			
7.	Copy of valid manufacturing license in Form 25/28/26			
8.	Copy of valid Test license in form 29			
9.	In case of new drug, Source of bulk drugs along with current regulatory status of the source with copy of Form 46A/45A. (if obtained)			
10.	Consent letter and copy of manufacturing licence form supplier of bulk drug			
11.	Information on active ingredients:			
	a) Brief Chemical & pharmaceutical data			
	b) API Specification with impurity profiling			
	c) Method of Analysis with method validation report			
	d) Certificate of Analysis for three batches			
12.	Data on Formulation			
	Data on Formulation			
	a) Master manufacturing formula			
	b) Manufacturing Procedure/ Master manufacturing Record			
	c) Product development report with Excipient compatibility study and forced degradation study.			
	d) Process validation protocol/ Report			
	e) Finished product specification			
	f) Finished product Method of Analysis			
	g) Finished product Analytical method validation report			
	h) Finished product Certificate of Analysis for three consecutive batches/ three validation batches			
	i) In process quality control check specification			
	j) Stability study data report as per requirements of schedule Y mentioning batch size. (should be presented in tabular form with details of Batch no, Batch size, Date of manufacturing, Date of initiation, Packaging details)			
	k) Dissolution Release Profile (in case of oral dosage form)			

	l) Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)			
	m) Comparative evaluation with pharmaceutical equivalence international brand(s) or approved Indian brands, if applicable			
	n) Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamic and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.			
	o) Draft specimen of Label and Carton			
13.	Therapeutic Rationale and justification for the proposed new dosage form / new route of administration			
14.	Regulatory status in other countries, as appropriate.			
	a) Names of the countries where the drug is marketed/approved for proposed Modified Dosage Form along with package insert and/or copies of approval in key countries.			
	b) Names of the countries where the drug is withdrawn, if any, with reasons			
	c) Free sale certificate (FSC) or Certificate of Pharmaceutical Product (COPP), in case of import.			
15.	Bio Equivalence/Bioavailability study Protocol (As the case may be)			
	a) BE protocol			
	b) Study synopsis			
	c) Undertaking by investigators as per Appendix VII od schedule Y and CV.			
	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
16.	Clinical trial protocol in case of proposed Additional dosage form is not approved in key countries. (Checklist already given in New Drug application)			
	a) CT protocol			
	b) Study synopsis			
	c) Undertaking by investigators as per Appendix VII of schedule Y and CV.			

	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income of subjects along with, name and address of nominee.			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
	g) Case record form (CRF)			
	h) Site details, which includes Investigators name and address, Type of Hospital (Multispecialty/ Government/ Private) , Number of beds, emergency facilities, Ethics Committee registration details, etc)			
17.	Bio Equivalence study requirement (in case of oral dosage form as appropriate as per Appendix X of Schedule Y)			
18.	Justification on Clinical trial and Bio equivalence study waiver, if requested.			
19.	Published report of Clinical trial/Journal/ literature with respect to proposed Modified Dosage Form.			
20.	In case of injectable formulation, sub-acute toxicity data conducted with the applicant drug formulation.			
21.	Submit 11 sets of technical literature (whenever applicable) (10 soft copy and one hard copy) for expert opinion. Each attachment shall not be more than 20 MB in size and shall be properly numbered and named reflecting various sections of the application.			

Note:

A) Submission requirements / methodology

i. Please submit ONE hard copy and THREE soft copies i.e. Compact Disc (CD) (PDF format) of the dossier.

ii. Hard copy: Sides and front of each volume/ file /binder must be labelled with the name of the applicant company, date of submission, name of the drug(s) and the file number (Numbering of files: 'x' of 'y' files e.g. if there are 10 files, file number 6 will be labelled as File No. 6 / 10).

iii. Use of multiple volumes/ files/ binders is recommended than binding all the documents and modules in a very huge file. Preferably volumes/ files /binders should not be more than 3 inches thick and use of good quality binders is recommended. All the files should be kept together, bound by a good quality wire or thread (If there are too many volumes e.g. more than 10, then multiple grouping should be done).

iv. CDs have to be labelled using a marker pen with the name of the applicant company, date of submission and name of the drug(s). If there are multiple CDs for one submission dossier, then the numbering as mentioned above should be followed.

v. Scanned copies of only signed documents like test reports, signature pages will be acceptable and rest of the document has to be in PDF format with optical character recognition (OCR).

vi. The table of content under each head should be linked to the files (s) or relevant document for easy tracking in CD's.

vii. Applicant should preserve a duplicate copy of the submitted dossier for any future

reference and should be able to submit multiple copies, if required by CDSCO.

B) In case the application is for clinical trial / Bio equivalence permission:

a. Adequate chemical and pharmaceutical information should be provided to ensure the proper identity, purity, quality & strength of the investigational product, the amount of information needed may vary with the Phase of clinical trials, proposed duration of trials, dosage forms and the amount of information otherwise available.

b. In case of applications for protocol amendments of already approved studies, applicants should submit copy of approval of protocol, amended new protocol, summarized list of all the new changes incorporated along with justification / reasons for the change.

c. Ethics Committee Approval: Ethical approval should be obtained from Ethics Committee located in the same area where the clinical trial site is located.

d. The proposed clinical trial study centres should be geographically distributed in the country and should also include clinical sites which have their own Institutional Ethics Committee.

6. A drug already approved by the Licensing Authority mentioned in Rule 21 proposed to be marketed with Additional Strength

S No	Documents required to be submitted	Enclosed		Page No
		Yes	No	
1.	Application for permission to Manufacture /Import/Clinical trial: (Purpose should be mentioned clearly)			
2.	Name of the applicant with address			
3.	Name of the New Drug			
	a. Composition of the New Drug			
	b. Dosage Form			
	c. Proposed indication for the New Drug			
4.	Details of the approval of the New Drug in the country			
	a. Approved Dosage Form			
	b. Approved composition			
	c. Approved Strength along with Indication			
5.	Application in Form 44 duly signed and stamped by authorized personal			
6.	Treasury Challan of INR 15,000 New Drug approved in India for more than one year, or INR 50,000 of New Drug is approved for less than one year and not submitted challan earlier for the same			
7.	Copy of valid manufacturing license in Form 25/28/26			
8.	Copy of Test license in form 29			
9.	in case of new drug, Source of bulk drugs along with current regulatory status of the source with copy of Form 46A/45A. (If obtained)			
10.	Consent letter and copy of manufacturing licence form supplier of bulk drug			
11.	Information on active ingredients:			
	a) Brief Chemical & pharmaceutical data			
	b) API Specification with impurity			
	c) Method of Analysis with method validation report			
	d) Certificate of Analysis for three batches			
12.	Data on Formulation			
	a) Master manufacturing formula			
	b) Manufacturing Procedure/ Master manufacturing Record			
	c) Product development report			
	d) Process validation protocol/ Report with Excipient compatibility study and Forced degradation profile.			
	e) Finished product specification			
	f) Finished product Method of Analysis			
	g) Finished product Analytical method validation report			
	h) Finished product Certificate of Analysis for three consecutive batches/ three validation batches			
	i) In process quality control check specification			
	j) Stability study data evaluation a s per requirements of schedule Y mentioning batch size. . (should be presented in tabular form with details of Batch no, Batch size, Date of manufacturing, Date of initiation, Packaging details)			

	k) Dissolution Release Profile (in case of oral dosage form)			
	l) Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)			
	m) Comparative evaluation with international brand(s) or approved Indian brands, if applicable			
	n) Copy of proposed Package Insert which should include generic name of all active ingredients; composition; dosage form/s, indications; dose and method of administration; use in special populations; contraindications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamics and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.			
	o) Draft specimen of Label and Carton			
	Information on active ingredients:			
13.	Therapeutic Rationale and justification for the proposed Additional Strength			
14.	Regulatory status in other countries, as appropriate.			
	a) Names of the countries where the drug is Marketed/ approved for proposed additional strength along with package insert and/or copies of approval in key countries.			
	b) Names of the countries where the drug is withdrawn, if any, with reasons			
	c) Free sale certificate (FSC) or Certificate of Pharmaceutical Product (COPP), in case of import.			
15.	Bio Equivalence/Bioavailability study Protocol (As the case may be)			
	a) BE protocol			
	b) Study synopsis			
	c) Undertaking by investigators as per Appendix VII od schedule Y and CV.			
	d) Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income			
	e) Compensation clause as per Rule 122 DAB			
	f) Copy of 'Ethics Committee' approval letters along with registration details.			
16.	Clinical trial protocol in case of proposed Additional Strength is not approved in key countries. (Checklist already given in New Drug application)			
	a. CT protocol			
	b. Study synopsis			
	c. Undertaking by investigators as per Appendix VII of schedule Y and CV.			

	d. Inform consent form (with assurance of providing audio-video recordings, Address, qualification, occupation, annual income of subjects along with, name and address of nominee.			
	e. Compensation clause as per Rule 122 DAB			
	f. Copy of 'Ethics Committee' approval letters along with registration details.			
	g. Case record form (CRF)			
	h. Site details, which includes Investigators name and address, Type of Hospital (Multispecialty/ Government/ Private) , Number of beds, emergency facilities, Ethics Committee registration details, etc)			
17.	Justification on Clinical trial and Bio equivalence study waiver, if requested.			
18.	Published report of Clinical trial/Journal/literature with respect to proposed Additional Strength.			
19.	In case of injectable formulation, sub-acute toxicity data conducted with the applicant drug formulation.			
20.	Submit 11 sets of technical literature (whenever applicable) (10 soft copy and one hard copy) for expert opinion. Each attachment shall not be more than 20 MB in size and shall be properly numbered and named reflecting various sections of the application.			

Note:

A) Submission requirements / methodology

i. Please submit ONE hard copy and THREE soft copies i.e. Compact Disc (CD) (PDF format) of the dossier.

ii. Hard copy: Sides and front of each volume/ file /binder must be labelled with the name of the applicant company, date of submission, name of the drug(s) and the file number (Numbering of files: 'x' of 'y' files e.g. if there are 10 files, file number 6 will be labelled as File No. 6 / 10).

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