1[FORM 44]

(See rules 122A, 122B, 122D and 122 DA)

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Application for grant of pe	rmission to import or manufacture	a New Drug or to undertake clinical trial.
grant of permission for impo	ort of and/or clinical trial or for ap	(address) hereby apply for proval to manufacture a new drug or fixed ved new drug. The necessary information /
1. Particulars of new drug:		
(1) Name of the drug.		
(2) Dosage form.		
(3) Composition of the	formulation :	
(4) Test specification. (i) active ingredients. (ii) inactive in	ngredients.
(5) Pharmacological cla	assification of the drug.	
(6) Indications for wl	hich proposed to be used.	
(7) Manufacturer of t	he raw material (bulk drug subs	tances).
(8) Patent status of th	e drug.	
2. Data submitted along numbers:)	with the application (as per	Schedule Y with indexing and page
A. Permission to marke	et a new drug:	
(1) Chemical and Ph	narmaceutical information.	
(2) Animal Pharmac	cology.	
(3) Animal Toxicolo	ogy.	
(4) Human / Clinica	l Pharmacology (Phase I).	
(5) Exploratory Clin	nical Trials (Phase II).	
(6) Confirmatory Cl	inical Trials (Phase III) (includi	ng published review articles)
(7) Bio-availability,	dissolution and stability study of	lata.
(8) Regulatory statu	s in other countries.	
(9) Marketing inform	nation:	
(a) Propos	sed product monograph.	
(b) Drafts	of labels and cartons.	

(10) Application for test licence.

B. Subsequent approval / permission for manufacture of already approved new drug :
(a) Formulation:
(1) Bio-availability / bio-equivalence protocol.
(2) Name of the investigator/center.
(3) Source of raw material (bulk drug substances) and stability study data.
(b) Raw material (bulk drug substances):
(1) Manufacturing method.
(2) Quality control parameters and/or analytical specification, stability report.
(3) Animal toxicity data.
C. Approval / Permission for fixed dose combination:
(1) Therapeutic Justification.
(authentic literature in pre-reviewed journals/text books)
(2) Data on pharmacokinetics/pharmacodynamics combination.
(3) Any other data generated by the applicant on the safety and efficacy of the
combination.
D. Subsequent Approval or approval for new indication - new dosage form:
(1) Number and date of Approval / permission already granted.
(2) Therapeutic justification for new claim / modified dosage form
(3) Data generated on safety, efficacy and quality parameters.
A total fee of rupees
credited to the Government under the Head of Account(Photocopy of receipt is enclosed).
Dated : Signature
Designation
Note: *Delete whichever is not applicable.
1. Forms 44 to 46 A ins. by No.G.S.R. 900 (E), dt. 12.12.2001.