Form 44

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

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

I/We*…… (Name of the Authorised Person) of M/s..... (Full address, Telephone no, Fax No and e-mail) hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information / data is given below :

I. Particulars of Subject device

i. Generic name

ii. Brand name

iii. Composition of device

iv. Specifications/standards of device

v. Qualitative and quantitative particulars of the constituents

vi. Information on sterility and stability of the product

vii. Labeling details

viii. Variations in shape, style or size of the device, if applicable

ix. Physician manual and promotional literature (Literature insert) in English. (If any)

x. Packaging description including pack sizes

xi. Risk classification (in country of origin as well as in 5 GHTF countries i.e. EU, USA, Japan, Canada, Australia)

xii. List of accessories or device to be used in conjunction with subject medical device

xiii. Indication w.r.t. Which clinical study is to be carried out

xiv. Name and address of the manufacturer/contract manufacturer(s)

xv. Regulatory status of the subject device (particularly in 5 GHTF countries i.e. EU, USA, Japan, Canada, Australia)

II. Technical data submitted along with the application as per Annex II. All the information provided with the application should be indexed properly with page no's.

A total fee of rupees ..... (in words)..... has been credited to the Government under the Head of Account ..... (Photocopy of receipt is enclosed).

Place.....
Dated :.....

Signature of the Applicant
(Name & Designation)
Seal / Stamp

Note: **Delete whichever is not applicable.*