**Form -I**

**[See rule 3]**

**Application for license to act as centre, clinical trial site, CRO or laboratory**

I/we ………………………………………………………………………………………………..……..

NIC number……………………………….....of M/s …………………………………..……….………

business address and telephone number and fax number…………………………….………………….

………………………………………….………………………………………………………………..

hereby apply for grant of license to the site for centers or clinical trial site or CRO or laboratory, situated at …………………………………………………………………………………………………………

2. Type of the site meant for (whichever is applicable):-

(i) Bio-equivalence and Bio-availability studies

(ii) CRO

(iii) Laboratory

(iv) Clinical trials-

(a) Phase I

(b) Phase II

(c) Phase III

(d) Phase IV

3. I enclose:-

(a) Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).

(b) Details of premises including layout plan of the site.

(c) Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.

(d) Names and qualifications of the above sections along with their staff.

(e) Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc,.

**UNDERTAKING**

I/we hereby undertake / certify that the contents stated above are correct to the best of my/our knowledge and belief.

Name of the applicant

Signature

Date:……. Seal of the firm/Company