FORM 16
PERMIT FOR CONDUCT OF PRECLINICAL SAFETY STUDIES OF rDNA PRODUCT(S) IN HEALTHCARE

PERMIT NUMBER: **DATE OF ISSUE:**
DATE OF EXPIRY:

Permittee:

Name of Organization: _____

Address: _____

Phone, fax & e-mail: _____

IBSC Code: _____

Subject: ----------

AUTHORISATION: This is in response to your letter No. _____ dated _____ on the above mentioned subject. It is informed that your application was considered by the Review Committee on genetic Manipulation (RCGM) in its meeting held on _____. On the basis of the recommendations of the RCGM and comments of the experts on the dossier, you are allowed to conduct pre-clinical safety studies on_____ on the premises located at_____, subject to the acceptance of the following terms and conditions:

a) There would be no change in the protocols approved by RCGM which includes: _____ _____ _____ _____ _____ _____ You would follow the protocols as per the Schedule "Y" of the Drugs and Cosmetics Act of 1940 and Rules-1945 of the Govt. of India.

b) The route of administration of the product in lab animals would be the same as of therapeutic route of administration and any other route specified in the protocols.

c) You would conduct laboratory studies with proper controls and reference materials.

d) You are also directed to include a control group of animals by taking innovator's product as gold standard in toxicity studies for comparison as per the Schedule "Y" of the Drugs and Cosmetics Act of 1940 and Rules-1945 of the Govt. of India.

e) You would be using the protocols in terms of dose fixation as was submitted to the RCGM Secretariat.

f) You would use the formulated material of _____in these studies as far as equivalent to the final product to be used commercially at later

stage. You would maintain sufficient stocks of the formulated materials as reference inventory in proper storage conditions with the batch details of such stocks, which would be provided by you to the Competent Authority before starting the experiments as well as after completion of the studies. There would not be any subsequent major modifications or changes in the composition of the formulated material utilized in toxicology studies in animals after finalization of studies. In case of any subsequent change, the production methods or the quality of the bulk as well as the formulated material, it is to be brought to the notice of the Competent Authority and no such altered materials be used by you for commercial purpose or other wise without prior approval from the Statutory and Competent Authority.

g) You would ascertain and maintain that only company's authorized personnel would be allowed to visit the experimental lab and the details of personnel visiting the lab. with dates, purpose(s) etc. would be maintained in register, which may be available for inspection, whenever required by the Competent Authority.

h) You would inform the RCGM through your Institutional Biosafety Committee (IBSC) the progress of work from time to time. The IBSC will collect all the information on experiments and would submit the consolidated information/data/results on experiments to the RCGM once in a year.

i) You would adhere to the Recombinant DNA Safety Guidelines, 1990 and also follow the other Guidelines for generating pre-clinical and clinical data for r-DNA based vaccines, diagnostics and other biologicals brought out by the Department of Biotechnology, the Government of India, from time to time. Accidents, if any, arising out of the experiments would be brought to the notice of the Govt. immediately.

j) You are required to confirm the acceptance of the above conditions to the DBT at your earliest convenience before starting the toxicity studies. You are further informed that you may contact the Department of Biotechnology for any clarification in the matter, which you may require.

PERIOD: The permit letter shall be in force from ____ to ____ unless it is sooner suspended or cancelled under the said Rules.

Signature & title of issuing officer

(Member Secretary, RCGM)

Copy for information to:

1. The Chairman, GEAC, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi-110 003
2. The Secretary, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi-1.
3. The Drugs Controller General of India, FDA Bhawan, Kotla Road, New Delhi – 110 002.
4. The Director General, Indian Council of Medical Research, Ansari Nagar, Post Box No.4911, New Delhi – 110 029.
5. Office copy for file
6. Guard File

(Member Secretary, RCGM)