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GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
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NOTIFICATION

Islamabad, the 9th June, 2023.

S.R.O. 685 (I)/2023.— In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with approval of the Federal Government, is pleased to make the following amendment in the Bio-study Rules, 2017, namely:—

In the aforesaid Rules, Form-IIA shall be substituted with the following, namely:—

"Form – IIA
[See rule 7]

Application for approval and registration of bioequivalence or bioavailability study

I/we .....
CNIC number ..... of M/s .....
business address and telephone number and fax number.....
hereby apply for approval and registration of BA or BE study, titled .....
as per detail below:

(1) Name of Investigational Product (including all available names; trade, generic or INN name, chemical code etc.).....
(2) Dosage Form of Investigational Product.....
(3) Formulation of Investigational Product.....
(4) Pharmacodynamics and Pharmacokinetics of Investigational Product.....
(5) Purpose of study defining the indication along with the anticipated cost of the project and sources of fund.....
(6) Proposed center for study.....
(7) Investigational design and study plan.....
(8) Pre-clinical or clinical data or safety studies.....
(9) Final protocol.....
(10) Detail of the investigator (Principal investigator, analysts and others along with CV)..
(11) IRB approval.....
(12) Ethical committee composition (names and designations).....
(13) BA/BE Study Site approval by DRAP.....
(14) Informed consent (English and Urdu).....
(15) Summary of the protocol or synopsis (Investigational Product).....
(16) Adverse Event Reporting Form.....
(17) Name of the monitor or clinical research associate.....

(18) Certificate of Analysis of Test Product and GMP Certificate or Drug Manufacturing License of the Manufacturer.....

(19) Details regarding reference product (Country of origin, mode of purchase, shipment procedure) along with any other relevant documents if available.....

(20) Proposed label of investigational product.....

(21) Quantity of investigational product to be used in the study along with justification (Note: All the quantities of each of investigational product should be procured from one single source) .....

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

Note: In case of approval of the applied BA/BE Studies, the applicant will apply for Import license on Form-III of the Drugs (Import and Export) Rules, 1976."

[No. F.8-36/2022-Misc.(DD)]

AAMAR LATIF,
Additional Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
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