

Additional FAQ on New Drugs and Clinical Trial Rules, 2019

Q. Whether import license under Form 11 is required for import of drugs for conducting 'academic clinical trial'?

The definition of "academic clinical trial" has been prescribed under Rule 2(1) (a) of New Drugs and Clinical Trial Rules, 2019.

In case, the Ethics Committee has granted approval for conduct of academic clinical trial of a permitted drug formulation for a new indication or new route of administration or new dose or new dosage form and the drug is to be imported for conducting the academic clinical trial in accordance with Rule 28 of the said Rules, no import license is required, if copy of the ethics committee approval for the said clinical trial of the drug to be imported is furnished to the concerned Port office at the time of import along with an undertaking mentioning the quantity of the drug being imported will be used exclusively for the academic clinical trial.