

Grant of Licence in Form-11 to import Drugs for the purpose of test and analysis

This guideline speaks about the contemporary thinking of CDSCO on the issues pertaining to import of small quantities of drugs for use in pharmaceutical research and development works. If any concerned individual or company gets affected by any way, they may send their views with clarification to CDSCO (HQ) by any of the following;

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Purpose : To harmonize the submission documents for applications seeking for licence to import “Drugs” for test and analytical purposes. This will also facilitate the examiners/ reviewers to take uniform decisions and thereby shorten the application processing time.

Scope : The focus of this guide line is only on drugs for human use which undergo systemic circulation. It is not applicable for import of Diagnostic kits, Veterinary drugs, Medical Devices, and drugs of biological origin.

Back ground

The provision of granting licence in Form-11 to import drugs for examination, test or analysis is made under Rule-33 in Drugs and Cosmetics Rules-1945. This provision entitles that a small quantity of drug which is otherwise not allowed under Section-10 , can be licensed for import in “Small Quantities” only in Form-11.

Current Practices

As on date the documents to be furnished to the O/o DCG(I) to obtain a Form-11 Licence, are listed below:

- (i) Application in form-12 shall be made or countersigned by
 - a) the Head of the Institution in which the test and analytical works would be carried out, OR
 - b) Proprietor or Director of the company or firm by which the tests are to be carried out.
- (ii) Bank’s receipt for the payment of requisite fees by way of TR-6 Challan.
 - c) Justification and utilization break-up, detailing the test parameters vis-à-vis quantities of the drugs, batch manufacturing plan.

However, recently this has been observed that in many cases the manufacturers, CROs and other importers are submitting applications for the import of reasonably large quantities of API and /or drug formulations which do not comply with the provisions of Rule-33. There is no provision as such to define the term “Small Quantity” under this Rule. However, to facilitate the research and development activities on pharmaceutical products and contract research facilities to boost up the scientific and technological activities in this knowledge based industry, it is decided that import of apparently large quantities of drugs should be justified with test parameters, batch sizes, no. of batches, categories of batches etc. vis-à-vis official monographs, official guidelines only.

Proposal

It is therefore conveyed to all applicant firms to furnish the following additional documents along with their applications for Form-11 Licence whenever an appreciably large quantities of drugs are required to be imported;

- 1) Justification of import and utilization break-up of the proposed quantities of drug with reference to the detailed test parameters, batch manufacturing plan , in accordance with official regulatory documents/ guidelines circulated by the National Drug regulatory authority of the country where the study data would required to be submitted.
- 2) Indent letter(s) from overseas partner(s) delivering the specific job assignments (for example stability studies , pre-formulation & formulation developments, exhibit batches, pilot batches, pivotal batches, scale-up batches etc.) to the applicant Indian firm for the claimed quantities of drug(s).

For the import of any drug (bulk / formulation) which is listed in Schedules of Narcotic drug and Psychotropic substances in NDPS Act, 1985, it is hereby advised that each import quantity should be justified with utilization break-up, calculated on the basis of official guidelines/ documents of the concerned National Drug Regulatory Authority along with the acceptable copy of job assignment from approved firms, apart from necessary approvals from other competent Authorities including Central Bureau of Narcotics, Gwalior (MP).

It is also noticed that applications are being filed in this office asking for import of finished dosage forms for use as reference formulation in bio-equivalence studies. Since bioequivalence studies are considered as “ Special studies” on “New drugs” as per Schedule-Y, such applications for Form-11 licence should accompany NOCs /approval for the same.

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