

CHECKLIST FOR TEST LICENCE APPLICATIONS EFFECTIVE FROM 15 JUNE

2011

- 1) Application in Form -12 (**not more than 10 drugs in one form 12**) as per format given in Drugs and Cosmetics Acts and Rules clearly indicating the country of import and complete address of foreign supplier ,Generic Name, detail composition of Drug and Therapeutic class with complete address of testing location duly signed and stamped by Head of the institution proprietor or director of the company or firm or any company authorized signatory with a copy of authority letter issued by above mentioned designatory .
- 2) Separate application with requisite fees should be filled for import of same drug from more than one country and testing facility
- 3) Treasury Challan of 100/- for first product and 50/- for each additional products (irrespective of strength dosage form and pack size) should be in the Head of A/C viz. 0210-Medical & public Health, 04- Public Health. 104-Fees and Fines.

Note: The following documents are required to submitted: -

- a) Notarized/attested (by gazetted officer)/ Copy of Manufacturing Licence in Form-25/28/29 issued by SLA or DSIR approval in case of formulations)
- b) Notarized copy of detailed utilization break up for each drug indicating the nature of tests and quantity required for each test duly signed and stamped by competent authority for bulk drugs and finished formulation for R & D purposes.
- c) Whenever appreciably large quantities of drugs are required to be imported then Justification for import and utilization breakup of the proposed quantities of drugs with reference to the detailed test parameter batch manufacturing plan in accordance with official regulatory documents/guidelines circulated by the National Drug regulatory authority of the country is where the study data would required to be submitted.

- d) Undertaking by competent authority that the drugs imported under test Licence would be used for Test & Analysis only should be enclosed.
- e) Detailed information regarding import of same drug during last 3 years along with certificate of destruction of unused drug from the Competent Regulatory Authority.
- f) In case of Narcotic and Psychotropic drugs, the relevant Schedule of the NDPS Act 1985 under which the drug falls is to be indicated.
- g) Technical literature /package inserts of drugs.
- h) Applications of Test Licence for import of drug for BE studies should be submitted separately with BE protocol alongwith NOCs /approval for the same and in case of old drug regulatory status of drugs (strength and dosage form) in India indicating the year of its approval with authenticated documents (form 46 etc.)

Following documents are also required to be submitted:-

- a) Notarized/ attested (by gazetted officer) Copy of valid Manufacturing Licence for subject drugs in Form-29 in case of import of Bulk API of new drug issued by SLA.
- b) B) Notarized/ attested (by gazetted officer) Copy of valid Manufacturing Licence of subject drugs in Form-25/28 in case of import of Bulk API of Old drug issued by SLA