F. No. DCG(I)/Misc./15/2013/DC
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
O/o Drugs Controller General (I)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated : 03 JUL 2015

OFFICE ORDER

Subject: Transfer of certain functions and delegation of powers to the Zonal offices of CDSCO under Rule 22 of the Drugs and Cosmetics Rules, 1945 – reg.

In continuation to this Office Order issued on 30.9.2014, 16.10.2014 and 06.1.2015 on the subject matter, it has been decided to modify the delegation of power to sign test license on Form 11 already granted to the Zonal offices of Central Drugs Standard Control Organization (CDSCO) under their jurisdiction under Rule 22 of the Drugs and Cosmetics Rules, 1945. The Zonal officer are hereby authorized / delegated to sign test licenses in Form 11 of the Drugs and Cosmetics Rules, 1945 for import of small quantities of drugs which are approved for more than four years in the country intended for conducting Bioavailability / Bioequivalence study for the purpose of export in healthy human volunteers subject to the following conditions:

a) The dosage form must be approved by CDSCO and must be more than four years old.

b) The strength must be same as approved. In case the strength is not mentioned in the new drug data base, the study of lower strength be only considered.

c) The study must be conducted in healthy and adult human volunteers only. The application for study in patients must not be accepted.

2. In order to have uniformity in disposal, the application of BA/BE center located under your jurisdiction will only be accepted for pre-screening. The following procedure is to be followed:

a) The applications are to be scrutinized as per checklist no. 5 published in the CDSCO website (copy enclosed as F/A). Any other categories of applications are not to be accepted.

b) The review of application to be carried out as per enclosed format (F/B)

c) The test license is to be issued with conditions as per attached format (F/C)

d) The applications are to be disposed of in 10 working days (two weeks).

3. The records of such applications received, reviewed and disposed are to be maintained by each zone. All zonal heads are required to submit monthly status report of such applications to this office for information and records.

(Dr. G.N. Singh)
Drugs Controller General (India)

To,

All the Zonal Heads of CDSCO

Copy forwarded for information to :

1. PS to JS (R), Min. of Health and Family Welfare.
2. All JDC(I)s / DDC(I)s CDSCO(HQ)
3. DDA(D), CDSCO (HQ)
4. Guard file

F/A

5. Application for Test license (Form11) for BA/BE study of old drugs (Drugs approved for more than 4 years):-

S. No	Documents	Yes	No
1	Covering letter of firm		
2	Regulatory status of the Drug in India indicating strength & dosage form.		
3	Form-12 along with relevant Treasury Challan (TR – 6), if applicable as per cdsco.nic.in		
4	The study protocols, Informed Consent Form (ICF) or Patient Information Sheet (PIS) along with audio-visual recording system as per Schedule Y guidelines; & copy of approval of protocol from the IEC, if available		
5	The study synopsis		

Note: All above applications should be consisting of proper index with sequence of respective checklist, along with page numbers, separator, in legible form to ensure Good Documentation Practices.

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File No.

From:

.....

.....

To

M/s. «NAME_OF_THE_COMPANY»,
«Address_1»,
«Address_2»,
«State_with_Pin_Code»

Sir,

With reference to your letter and application No. «Your_letter_No» dated «DATE» (our diary no. «Dy_No_» dt. «DATE1»), Protocol No. «Protocol_No_1»«Protocol_No_2»«Protocol_No_3»«Protocol_No_4»«Protocol_No_5»«Protocol_No_6» for import of drugs for Bioavailability/Bioequivalence for export purpose only, please find enclosed herewith the "licence for examination, test and analysis" bearing no. **T-BE-**_____under the provisions of Drugs and Cosmetics Act & Rules to import the drug/drugs mentioned therein.

The Test Licence bearing no. **T-BE-**_____is issued for conduct of BA/BE study with following conditions:

1. Bioequivalence study shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.
2. Any report of serious adverse event occurring during bioequivalence study to the subject, after due analysis, shall be forwarded within ten days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.
3. Approval of the Ethics Committee (duly registered under Rule-122DD) for the subject study shall be submitted to CDSCO (.....) before initiation of the study (if not submitted already).
4. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.
5. You should ensure that, during informed consent process, information to the subjects is provided individually and not in a group. The whole Informed Consent Process should be documented through audio visual means maintaining the principle of confidentiality.
6. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and bioequivalence study sites and the Investigator shall allow officers authorised by the Central Drugs Standard Control Organisation, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and bioequivalence study sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to bioequivalence studies and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of bioequivalence study.
7. Informed Consent Form (ICF) & Patient Information Sheet (PIS) in regional language approved by Ethics Committee should be submitted before recruitment of the subjects.

8. Unless expressly permitted, pregnant and lactating women shall be excluded from the study.

Kindly acknowledge receipt of this letter and its enclosures.

Yours faithfully,

( )
Dy. Drugs Controller (India)

Copy together with a copy of licence No. T-BE-
Forwarded for information:

1. The Asstt. Drugs Controller (India), New Custom House, Annexe, Mumbai-38.
2. The Asstt. Drugs Controller (India), Custom House, Kolkata.
3. The Asstt. Drugs Controller (India), Custom House, Chennai.
4. The Asstt. Drugs Controller (India), IGI Airport, Air Cargo Complex, New Delhi-110 037.

File No.

THE DRUGS AND COSMETICS RULES, 1945

(SEE RULE 33) FORM-11

LICENCE TO IMPORT DRUGS FOR THE PURPOSE OF EXAMINATION, TEST OR ANALYSIS

Number of Licence **T-BE-**_____

1. **M/s. «NAME_OF_THE_COMPANY», «Address_1», «Address_2», «State_with_Pin_Code»** is hereby licensed to import from **«Country_of_Import»** the drugs specified below for the purpose of examination, test or analysis at **«Test_or_Analysis_At»** or in such other places as the licensing authority may from time to time authorize.

2. The licence is subject to the condition prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This license shall unless previously suspended or revoked, be in force for a period of one year from date specified below.

NAME OF DRUGS	QUANTITIES, WHICH MAY BE IMPORTED
1. «NAME_OF_DRUG_1»	«Quantity_of_Drug»
2. «NAME_OF_DRUG_2»	«Quantity_of_Drug1»

(Items TWO (02) Only)

Not for any Commercial Purposes

New Delhi

Dated:

( )
Dy. Drugs Controller (India)
and Licensing Authority

Condition of Licence

1. The licensee shall use the substances imported under the licence exclusively for purpose of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the licence, or in such other places as the licensing authority may from time to time authorise.
2. The licensee shall allow any inspector authorized by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises, and investigate the manner in which the substances are being used to take samples thereof;
3. The licensee shall keep a record of, and shall report to the licensing authority, the substances imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer.
4. The licensee shall comply with such further requirements, if any, applicable to the holders of licences for examination, test or analysis as may be specified in any rules subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice.
5. The drugs imported under this license shall not be directed to or for Commercial Marketing including export purposes.
6. The firm shall obtain No Objection Certificate from the Narcotics Commissioner of India, 19, The Mall Morar, Gwalior for the import of drugs under Narcotic Drugs and Psychotropic Substances Act and Rules, 1985.

File No.12-09/2015/BE EXP/_____/DC

DGHS (CDSCO-HQ)

Subject: Permission to conduct BA/BE study of _____
_____ for export purpose only.

Serial No. --

Diary No._____Dated_____ FTS_____/2015

1) Applicant ; M/s. ----------

2) Sponsor-

3) Study Site/CRO:_____DISTT./STATE_____PINCODE_____

4) IEC:

5) Name of the drug (Test) :-_____

(Reference):-_____ _____

6) Composition of the drug:

7) Status of the drug:

BE-NOC granted to:

8) Indication for the drug:

9) Applied in FORM-44 (Signed / company letter head / stamped / complete in (all parameters / condensed) along with TR- 6 Challan of ₹_____

10) Application in Form-12 to import (Test Drug / Reference drug product)
TR-6 for T/L (₹_____) No. of Form-12:.....

11) Stability data_____

Parameters

Results

12) Chemical & Pharmaceutical information

Safety and efficacy data (for unapproved drug- as per App-I of Sch-Y)

Published BE study reports

13) Certificate of analysis (Test product/Reference product) _____

Dissolution data:

14)

S. No	Protocol No.	Study design	Dosing	No. of subjects
	Version No.: **Dated:** (FASTING/FED)			
	Version No.: **Dated:** (FASTING/FED)			
	Version No.: **Dated:** (FASTING/FED)			
	Version No.: **Dated:** (FASTING/FED)			

15) SUBJECT (Male/ Female / Both), (Healthy / Patients), (Adult / Others)

Inclusion criteria:

16) Washout period:

17) SPONSOR'S LETTER (Submitted / unavailable) and (Signed / unsigned), (Letter head / White page)

18) ICF/ PIS : (Yes / No)

Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research (Y/N)
2. Expected duration of the Subject's participation (Y/N)
3. Description of the procedures to be followed, including all invasive procedures (Y/N)
4. Description of any reasonably foreseeable risks or discomforts to the Subject (Y/N)
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this. (Y/N)
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject. (Y/N)
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records (Y/N)
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials) (Y/N)
9. Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury (Y/N)
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury (Y/N)
11. The anticipated prorated payment, if any, to the Subject for participating in the trial (Y/N)
12. Subject's responsibilities on participation in the trial (Y/N)
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled (Y/N)

19) PI's undertaking: (Yes / No)

20) International prescribing information: (Yes/No)

Comments : --

P.T.O