CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERMENT OF INDIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

TEST LICENCE DIVISION

GUIDANCE DOCUMENT ON GRANT OF LICENCE IN FORM 11(TEST LICENCE) FOR THE PURPOSE OF EXAMINATION TESTING AND ANALYSIS AS PER RULE 33 OF DRUGS AND COSMETICS ACTS AND RULES 1945

CREATED ON: - 30-05-2011

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Table of contents:-

(A.) INTRODUCTION TO FORM 11 LICENCE

IMPORT OF DRUGS FOR EXAMINATION, TEST OR ANALYSIS –

Test licence or form 11 licence is given for the Small quantities of drugs, the import of which is otherwise prohibited under section 10 of the Drugs and Cosmetics Act and Rules, 1945, may be imported for the purpose of examination, test or analysis subject to the following conditions: –

(*a*) No drug shall be imported for such purpose except under a licence in Form 11;

(*b*) The licensee shall use the substances imported under the licence exclusively for purposes 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;

(*c*) 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 and to take samples thereof;

(*d*) 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;

(*e*) 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.

Purpose : To harmonize the submission documents for applications seeking for licence to import "Drugs" for test and analytical purposes. This will alsofacilitate 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.

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 or any company authorized signatory with copy of authority letter issued by above mentioned designatory should be enclosed with application.

(ii) Bank's receipt for the payment of requisite fees by way of TR-6 Challan.

iii) Justification and utilization break-up, detailing the test parameters visà-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.

(B) DOCUMENTS NEEDED FOR SUBMISSION OF APPLICATIONS FOR GRANT OF FORM 11 LICENCES:-

B.1 COVERING LETTER:-

A covering letter is a very important part of the application; it is a letter of introduction attached alongwith a application which clearly specifies the purpose for submission of a application. A cover letter must contains the following points:-

- Name and Address of the firm.
- Purpose of submission.
- List of documents attached with the application.
- Duly signed and stamped by authorized signatory.
- Application Reference number.

NOTE:- APPLICATION SHOULD BE PUNCHED AT LEFT HAND END CORNERS

(B.2) FORM 12:

An application for a licence for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the head of the institution in which, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted. The format of the form 12 is shown below:-

FORM 12

(*See* rule 34)

Application for licence to import drugs for purpose of examination, test or analysis

I,... .....resident of ..... by occupation..... hereby apply for a licence to import the drugs specified below for the purposes of examination, test or analysis at.....from.....and I undertake to comply with the conditions applicable to the licence.

1[A fee of rupees..... has been credited to Government under the head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945—Central vide Challan No.....dated.....(attached in original).]

Names of drugs and classes of drugs: Quantities:

Date..... *Signature...*

(B.3) T.R 6 CHALLAN:-Requisite Amount should be paid in T.R 6 Challan(duly signed and stamped by the Bank Officer) alongwith the application. A challan of Rs 100/- for first product and Rs 50/- for of each additional product(irrespective of strength dosage form and pack size) must be submitted along with the Application. a format of the T.R 6 Challan is shown Below:-

T.R-6(See Rule 92)	Bank Reciept No.

Reciept of cash paid into Bank of Baroda, K.G. Marg, New Delhi-110001

To be filled by the remitter					To be filled by the Department Officer or the Treasury		
By whom Tendered	Name (designation) and address of the person on whose behalf money is paid	Full particular of the remittance and/of authority (If any)	Amount		Head of Account	Accounts Officer by whom adjustable	Order to the Bank
			Rs.	P.			
					0210-Medical + Public Health, 04-Public Health, 104-Fee and Fines	Pay and Accounts Offices, DGHS,New Delhi	Date Correct, Receive and grant receipt (Signature and full Designation of the Officer ordering the money to be paid in).
Signature		Total					
(in words) Rupees_____					To be used only in the case of remittance to the Bank through Departmental officer or the Treasury Officer.		

Received payment (in words) upees…….. …….. Bank Officer		
Cashier	Account	Date

(B.4) FORM 29 :-

Form 29 is a licence to manufacture drugs for the purpose of Examination Testing and Analysis. An application for a licence in Form 29 shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereafter in this Part referred to as the Licensing Authority) in Form 30 and shall be made by or countersigned by the head of the institution in which, or a director of the firm or company by which, the substance will be manufactured. Every application in Form 29 shall be accompanied by a fee of [3][rupees two hundred fifty].

A licence in Form 29 shall, unless sooner cancelled, be in force for a period of one year from the date of issue, and may thereafter be renewed for periods of one year at a time.

Conditions of licence. –A licence in Form 29 shall be subject to the following conditions—

(a) the licensee shall use the drugs manufactured under the licence exclusively for purpose of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the licence;

(b) the licensee shall allow any [4]Inspector appointed under the Act to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that only examination, test or analysis work is being conducted;

(c) the licensee shall keep a record of the quantity of drugs manufactured for examination, test or analysis and of any person or persons to whom the drugs have been supplied.

A format of the form 29 is shown below:-

FORM 29

(*See* rule 89)

Licence to manufacture drugs for purposes of examination, test or analysis

1. ...

.....of.....
.....

is hereby licensed to manufacture the drugs specified below for purposes of examination, test or analysis at .....

2. This licence is subject to the conditions prescribed in Part VIII of the Drugs and Cosmetics Rules, 1945.

3. This licence shall be in force for one year from date specified below.

Names of drugs

Date : ..... *Licensing Authority.....*

Note: -when a firm applying for import of bulk drugs under form 11 licence for the purpose of testing and analysis then they have to submit a copy of valid form 29 in case of New Drug however form 25 with manufacturing permission of same drug going to be imported is needed in case of old drug bulk API . Testing location address mentioned in form 29 must be same as mentioned in form12.

(B.5) UTILIZATION/JUSTIFICATION

Quantities of drugs imported under form11 licence should be justified with test parameters, batch sizes; no. of batches, categories of batches etc. utilization/justification submitted by the firm should include the following points:

1. Utilization/justification should be duly signed by the Authorized Signatory.
2. Details of each testing parameters mentioning the quantity required for each tests.
3. If the firm wants to conduct BE studies then detail utilization Break up for BE studies must be submitted.

(B.6) NOTARIZED UNDERTAKING/AFFIDAVIT

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 mentioning the quantity required for each tests, batch sizes, no. of batches, categories of batches etc in the Notarized Undertaking/Affidavit.

(B.7) BE NOC

Applications of Test Licence for import of drug for BE, studies under form 11 licence should be submitted alongwith BE protocol .In case firm wants to conduct BE studies on New Drugs then firm should submit copy of BE NOC for that drugs.and in case of old drug regulatory status of drugs (strength and dosage form) in India indicating the year of its approval,

In case of dosage form which is not conventional (EXTENDED RELESE /DELAYED RELESE /MODIFIED RELESE / CONTROL RELESE / SUSTAINED RELESE.) then it is considered as a New Drug so BE NOC should be submitted for that drugs.

(B.8) NOTARIZED AGREMENT

In case, when firm applied for grant of licence in form 11 and use testing facility of another firm then firm should submitted copy of notarized agreement between the two firms duly authenticated by the applicant.

(B.9) DSIR APPROVAL

Applicant must submit a copy of valid DSIR (Department of Scientific and industrial research) approval certificate.

(B.10) REPLIES IN RESPONSE TO QUERIES

When any deficiency found in application and query letter has been issued then in response to the query the firm must submit the reply in proper manner .reply submitted by the firm should includes the following:-

1. Reply of queries in proper manner as per the letter issued by the Directorate.

2. Copy of the Query Letter.

3 Application reference Letter.

4. Covering letter with file no. Of the query letter mentioned on it.

5. Seprate reply for each application.

(B.11) AUTHORITY LETTER AT THE TIME OF COLLECTION OF APPROVAL/QUERY LETTERS.

A valid authority letter should be presented at the time of collection of approval/query letters by the person who collects the letters.Authority Letter should be duly signed and stamped by the authorized signatory.

The sign of the person must be attested by the authorized signatory in the authority Letter.

The person who collects the letter must show their ID proof at the time of collection

(B.12) FORM 25 / FORM 28

FORM 25

Form 25 is a Licence to manufacture for sale or for distribution of] drugs other than those specified in 2[Schedules C and C(1) and X] of the drug and cosmetics acts and rules 1945.a sample format of the form 25 is shown below:-

Drugs and Cosmetics Rules, 1945

FORM 25

(*See* rule 70)

1*[Licence to manufacture for sale or for distribution of] drugs other than those specified in*
2[*Schedules C and C(1) and X*]

Number of Licence and date of issue.....

1.....is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in 2[Schedules C and C (1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at.....under the direction and supervision of the following 3[competent technical staff]:

(a) 2[Competent technical staff].(Names).....

(b) Names of Drugs (each item to be separately specified).....

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force from.....to.....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

4[*Date*.....

Signature.....

Designation.....

*Licensing Authority_____

*Central Licence Approving Authority.]

FORM 28

Form 28 is a Licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1) 2[excluding those specified in Schedule X] of the drugs and cosmetics acts and rules 1945. The format of the form 28 is shown below:-

Drugs and Cosmetics Rules, 1945

FORM 28

(*See* rule 76)

1[*Licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1)* 2[*excluding those specified in Schedule X*]

Number of Licence and date of issue.....

1. ..... is hereby licensed to manufacture at the premises situated at the following drugs, being drugs specified in Schedules C and C (1) 2[excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Names of drugs.....

2. Names of approved 3[competent technical staff].

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence will be in force from.....to.....

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date:- signature .....

Designation.....

Licensing Authority.....

Central licence approval authority.....

C. GENERAL FORMATS:-

FORM 12

FORM 12

(*See* rule 34)

Application for licence to import drugs for purpose of examination, test or analysis

I,... .....resident of ..... by occupation..... hereby apply for a licence to import the drugs specified below for the purposes of examination, test or analysis at.....from.....and I undertake to comply with the conditions applicable to the licence.

1[A fee of rupees..... has been credited to Government under the head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945—Central vide Challan No.....dated.....(attached in original).]

Names of drugs	*classes of drugs:*	*Quantities:*

Date..... *Signature.....*

ANNEXURE SHEET

Annexure Sheet
(To be filled up by the firm)

1. Application Ref No. : _____

- Application Date : _____

2. Name of the Company : _____

- Address of the Company : _____

3. Subject: _____

4. Challan Fees/No./Date : _____

5. Basic Division : _____
(New Drugs, / Import Division / Biological (Vaccine, Stem Cell, Blood Products, recombinant products) / Medical Devices / Diagnostic Kits / Blood Bank / Cosmetics / Narcotic Drug / Export & Neutral Codes / Test license / LVP Division Pharmacovigilance)

6. Type of Application : _____(Choose the type from the list given in page/2).

I Mr./ Dr. / Mrs _____
representing M/s _____

Hereby solemnly affirm that the information furnished as above are absolutely true and is based on the facts.

Signature & Seal

T.R 6 CHALLAN

T.R-6(See Rule 92)	Bank Reciept No.

Reciept of cash paid into Bank of Baroda, K.G. Marg, New Delhi-110001

To be filled by the remitter					To be filled by the Department Officer or the Treasury		
By whom Tendered	Name (designation) and address of the person on whose behalf money is paid	Full particular of the remittance and/of authority (If any)	Amount		Head of Account	Accounts Officer by whom adjustable	Order to the Bank
			Rs.	P.			
					0210-Medical + Public Health, 04-Public Health, 104-Fee and Fines	Pay and Accounts Offices, DGHS,New Delhi	Date Correct, Receive and grant receipt (Signature and full Designation of the Officer ordering the money to be paid in).
Signature		Total					
(in words) Rupees_____					To be used only in the case of remittance to the Bank through Departmental officer or the Treasury Officer.		

Received payment (in words) upees…….. …….. Bank Officer		
Cashier	Account	Date

Form 29

FORM 29

(*See* rule 89)

Licence to manufacture drugs for purposes of examination, test or analysis

1. ...

.....of.....

.....

is hereby licensed to manufacture the drugs specified below for purposes of examination, test or analysis at .....

2. This licence is subject to the conditions prescribed in Part VIII of the Drugs and Cosmetics Rules, 1945.

3. This licence shall be in force for one year from date specified below.

Names of drugs

Date : ..... *Licensing Authority.....*

Form 25

FORM 25

(*See* rule 70)

1*[Licence to manufacture for sale or for distribution of] drugs other than those specified in*

2[*Schedules C and C(1) and X*]

Number of Licence and date of issue.....

1.....is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in 2[Schedules C and C (1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated

at.....under the direction and supervision of the following 3[competent technical staff]:

(a) 2[Competent technical staff].(Names).....

(b) Names of Drugs (each item to be separately specified).....

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force from.....to.....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

4[*Date*.....

Signature.....

Designation.....

*Licensing Authority_____

*Central Licence Approving Authority.]

Form 28

Drugs and Cosmetics Rules, 1945

FORM 28

(*See* rule 76)

1[*Licence to manufacture for sale or for distribution of*] *drugs specified in*

Schedules C and C (1) 2[*excluding those specified in Schedule X*]

Number of Licence and date of issue.....

1. ..... is hereby licensed to manufacture at the premises situated at the following drugs, being drugs specified in Schedules C and C (1) 2[excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Names of drugs.....

2. Names of approved 3[competent technical staff].

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence will be in force from.....to.....

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date:- signature .....

Designation.....

Licensing Authority.....

Central licence approval authority.....

Form 20(B)

FORM 20B

[*See* rule 61 (1)]

1*[Licence to sell, stock or exhibit or offer for sale, or distribute] by wholesale, drugs other than those specified in* 1[*Schedules C, C(I) and X*]

1.....is hereby 1[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs other than those specified in 1[Schedules C, C(1) and X] on the premises situated at.....subject to the conditions specified below and to the

provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder.

2. The licence shall be in force from.....to.....

3[3. The sale shall be made under the personal supervision of a competent person (Name of the competent person.)]

Date *licence No...*

Licensing Authority.

Conditions of Licence

1. This licence shall be displayed in a prominent place in part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.

4[3 (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale of any drug shall be made to a person not holding the requisite 1[licence to sell, stock or exhibit for sale, or distribute] the drug. Provided that this condition shall not apply to the sale of any drug to—

(a) an officer or authority purchasing on behalf of Government, or

(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or

5[(c) a manufacturer of beverages, confectionery biscuits and other non-medicinal products, where such drugs are required for processing these products.]

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution

FORM 21(B)

FORM 21B

[*See* rule 61(2)]

1[*Licence to sell, stock or exhibit or offer for sale, or distribute*] *by wholesale drugs specified in Schedules C and C (1)* 2[*excluding those specified in Schedule X*

1. .....is hereby 1[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale on the premises situated at the following categories of drugs specified in Schedule. C and C (1) 2[excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Categories of drugs

2. This licence shall be in force from.....to.....

3[2A. The sale shall be made under the personal supervision of a competent person. (Name of the competent person)].

3. This licence is subject to the conditions stated below and to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder.

Licence No.....

Date..... *Licensing Authority.*

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

4* * * * *

3. If the licensee wants to sell, stock or exhibit for sale or distribute during the currency of the licence additional categories of drugs listed in Schedules C and C (1) 2[excluding those specified in Schedule X] but not included in this licence, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the *Drugs and Cosmetics Rules, 1945* 199 Licensing Authority.

5[4. (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.

(ii) No sale of any drug shall be made for purposes of resale to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug:

Provided that this condition shall not apply to the sale of any drug to —

(a) an officer or authority purchasing on behalf of Government, or

(b) a hospital, medical, educational or research institute or a registered medical practitioner for the purpose of supply to his patients, or

6[(c) a manufacturer of hydrogenated vegetable oils, beverages, confectionary and other non-medicinal products, where such drugs are required for processing these products.]

7 * * * * *

6. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from Licensing Authority in the name of the firm with the changed constitution.

(D.)RULES RELATED TO IMPORT OF SMALL QUANTITIES OF DRUGS FOR THE PURPOSE OF EXAMINATION TESTING AND ANALYSIS

DRUG AND COSMETICS ACT RULE 33

Import of drugs for examination, test or analysis — Small quantities of drugs the import of which is otherwise prohibited under section 10 of the Drugs and Cosmetics Act and rules, may be imported for the purpose of examination, test or analysis subject to the following conditions:—

(a)No drug shall be imported for such purpose except under a licence in Form 11;

(b) The licensee shall use the substances imported under the licence exclusively for purposes 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;

(c)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 and to take samples thereof;

(d)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;

(e)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.

made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice;

(f)The drug shall be stocked under proper storage conditions and shall be dispensed under the supervision of a registered pharmacist;

(g)The quantity of any single drug so imported shall not exceed 100 average dosages per patient:

Provided that the licensing authority may, in exceptional circumstances, sanction the import of drug of a larger quantity.

DRUG AND COSMETICS ACT RULE 34

Application for licence for examination, test or analysis.— *(1)* An application for a licence for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the head of the institution in which, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted. *(2)* The licensing authority may require such further particulars to be supplied as he may consider necessary.

(3) Every application in Form 12 shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.

(4) The fees shall be paid through a challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other Bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account 0210-Medical and Public Health, 04- Public Health, 104- Fees and Fines.]

DRUG AND COSMETICS ACT RULE 35

Cancellation of licence for examination, test or analysis.—

(1) A licence for examination, test or analysis may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued.

(2) A licensee whose licence has been cancelled may appeal to the Central Government within three months of the date of the order.]

DRUG AND COSMETICS ACT RULE 89

If the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drugs he shall, before commencing such manufacture, obtain a licence in Form 29:
Provided that in the case of a drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use, no licence in Form 29 shall be granted unless the applicant produces a certificate from the "Licensing Authority" mentioned in Rule 21, to the effect that there would be no objection to such licence being granted.

RENEWAL OF FORM 11 LICENCE

No test licence is renewed the firm should submit fresh application in form 12 with T R 6 challan and documents as per checklist.

REJECTION:-

Application for grant of test licence in form 11 for Examination Testing and analysis cannot be considered in following cases:

1. No test licence will be issued in case of banned drugs
2. No test licence will be issued in case of starting material
3. No test licence will be issued in case of Herbal/agricultural products
4. No test licence will be issued in case of Exciepients