**SCHEDULE D-I**
**[See Rule 21 (d) and rule 24 A]**

INFORMATION AND UNDERTAKING REQUIRED TO BE SUBMITTED BY THE MANUFACTURER OR HIS AUTHORIZED AGENT WITH THE APPLICATION FORM FOR A REGISTRATION CERTIFICATE. THE FORMAT SHALL BE PROPERLY FILLED IN FOR EACH APPLICATION IN FORM 40. THE DETAILED INFORMATION, SECRET IN NATURE, MAY BE FURNISHED ON A COMPUTER FLOPPY.

**1. PARTICULARS OF THE MANUFACTURER AND MANUFACTURING PREMISES:-**

**1.1 Name and address of the manufacturing premises to be registered.**

**1.2 Name (s) and address(es) of the Proprietor/Partners/Directors**

**1.3 Name and address of the authorized Agent in India, responsible for the business of the manufacturer.**

**1.4 A brief profile of the manufacturer's business activity, in domestic as well as global market.**

**1.5 A copy of Plant Master File (duly notarized)-**

**1.6 A copy of Plant Registration / Approval Certificate issued by the Ministry of Health /National Regulatory Authority of the foreign country concerned (duly notarized)**

**1.7 A brief profile of the manufacturer's research activity.**

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**2 PARTICULARS OF THE MANUFACTURED DRUGS TO BE REGISTERED UNDER REGISTRATION CERTIFICATE:-**

**2.1 Names of drugs (Bulk / Formulation /Special product) to be registered meant for import into use in India.**

**2.2 A copy of the approved list showing the bulk drugs/formulations / special products mentioned in 2.1 above are permitted for manufacturing /marketing in the country of origin (duly notarized).**

**2.3 A copy of Good Manufacturing Practice (GMP) certificate, as per WHO-GMP guidelines, or Certificate of Pharmaceutical Products (CPP), issued by the National Regulatory Authority of the foreign country concerned, in relation to the bulk drugs or formulations or special products, meant for import into India.**

**2.4 The domestic prices of the drugs to be registered in India, in the currency of the country of origin.**

**2.5 The name(s) of the drug(s), which are original research products of the manufacturer.**

**3 UNDERTAKING TO DECLARE THAT:-**

**3.1 We shall comply with all the conditions imposed on the Registration Certificate, read with rules 74 and 78 of the Drugs and Cosmetics Rules, 1945.**

**3.2 We declare that we are carrying on the manufacture of the drugs mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is Carried on in more than one factory any change in the distribution of functions between the factories.**

**3.3 We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.**

**3.4 Every drug manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity conforms with the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules 1945, and their amendments from time to time.**

**3.5 We shall from time to time report for any change or manufacturing process or in packaging or in labeling, or in testing, or in documentation of any of the drugs, pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the drugs under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the licensing authority, in writing within 30 days form the date of such changes. In such cases, where there will be any major change / modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the licensing authority, we shall obtain necessary approval within 30 days by submitting a separate application, along with the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.**

**3.6 We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and /or " not of standard quality report of any drug pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the drug is marketed / sold or distributed. The dispatch and marketing of the drug in such cases shall be stopped immediately and the licensing authority shall be informed immediately. Further action in respect of stop marketing of drug shall be taken as per the directions of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug(s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the licensing authority. The licensing authority may direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.**

**3.7 We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules, made there under.**

**3.8 We shall allow the licensing authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any drug manufactured by us for which the application for Registration Certificate has been made**

**3.9 We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the drugs concerned for test, analysis or examination if considered necessary by the licensing authority.**

*Place :*
*Date :*

*Signature of the manufacturer*
*[or his authorized agent]*

*Seal/Stamp*

**SCHEDULE D-II**
**[See Rule 21 (d) and Rule 24 A]**

INFORMATION REQUIRED TO BE SUBMITTED BY THE MANUFACTURER OR HIS AUTHORIZED AGENT WITH THE APPLICATION FORM FOR THE REGISTRATION OF A BULK DRUG/FORMULATION /SPECIAL PRODUCT FOR ITS IMPORT INTO INDIA. THE FORMAT SHALL BE PROPERLY FILLED IN AND THE DETAILED INFORMATION, SECRET IN NATURE, MAY BE FURNISHED INTO A COMPUTER FLOPPY.

**1. GENERAL**

**1.1 Name of the drug/formulation/special product, a brief description and the therapeutic class to which it belongs.**

**1.2 Regulatory status of the drug. Free Sale Certificate and/or Certificate of Pharmaceutical Products (CPP) issued by the Regulatory Authority of the country of origin. Free sale approval issued by the Regulatory Authorities of other major countries.**

**1.3 Drugs Master File (DMF) for the drug to be registered.**

**1.4 GMP Certificate in WHO formats or Certificate of Pharmaceuticals Products (CPP) issued by National Regulatory Authority of the country of origin (duly notarized).**

**1.5 List of countries where marketing authorization or import permission for the said drug is granted with date.**

**1.6 List of countries where marketing authorization or import permission for the said drug is cancelled/withdrawn with date.**

**1.7 List of countries where marketing authorization or import permission for the said drug is pending since (date).**

**1.8 Domestic price of the drug in the currency followed in the country of origin.**

**1.9 List of countries where the said drug is patented.**

**2. CHEMICAL AND PHARMACEUTICAL INFORMATION OF DRUGS**

**2.1 Chemical name:**

**Code name or number, if any :**

**Non-proprietary or generic name, if any:**

**Structure**

**Physico-chemical properties**

**2.2 Dosage form and its composition**

**Qualitative and quantitative composition in terms of the active substance(s) and excipient(s):**

**List of active substance(s) separately from the constituent(s) of excipients.**

**2.3 Specifications of active and inactive ingredient(s) including Pharmacopeal references.**

**2.4 Source of active ingredient(s), name and address.**

**2.5 Tests for identification of the active ingredient(s),**

**Method of its assay and tests for impurity profile with reference standards for the impurities (Protocol to be submitted along with reference standards for the impurities/relative substances).**

**2.6 Outline method and flow chart of manufacture of the bulk drug or finished formulation or special product.**

**2.7 Detailed test protocol for the drug with Pharmacopeal reference or in house specification as approved by the registration authority, in the country of origin.**

**2.8 Stability data including accelerated stability and real time stability analysis.**

**2.9 Documentation on pack size.**

**2.10 Numerical expression on EAN bar code on the labels and cartons.**

**2.11 Safety documents on containers and closer.**

**2.12 Documentation on storage conditions.**

**2.13** **Three samples of medicinal product/drug and outer packaging are to be submitted with the batch certificates. Additional samples as well as reference substances with the batch certificates including date of manufacture, shelf life, and storage conditions of reference substance may be required both during registration procedure and during validity of registration decision.**

**2.14** **Batch test reports/certificate of five consecutive production batches in details of the medicinal product are to be submitted for every site of manufacturing premises.**

**2.15** **Manner of labeling as per Rule 96 of the Drugs and Cosmetics Rules, 1945.**

**2.16** **Package insert.**

**2.17** **Details of safety handling procedure of the drug.**

**2.18** **Details of PMS study report for marketing period not exceeding five years.**

## 3 BIOLOGICAL AND BIOPHARMACEUTICAL INFORMATION OF DRUGS.

**3.1** **Biological control tests applied on the starting material, if applicable.**

**3.2** **Biological control tests applied on the intermediate products, if applicable.**

**3.3** **Biological control tests applied on the finished medical products, if applicable.**

**3.4** **Stability of the finished product in terms of biological potency of the drug, if applicable.**

**3.5** **Sterility tests, if applicable, specification and protocol therein.**

**3.6** **Pyrogen tests, if applicable specification and protocol therein.**

**3.7** **Acute and sub acute toxicity tests, if applicable specification and protocol therein.**

**3.8** **Bio-availability studies and bio-equivalence data, if applicable.**

**3.9 Data relating to the environmental risk assessment for r-DNA products.**

**3.10 Other information relevant under the section.**

## 4. PHARMACOLOGICAL AND TOXICOLOGICAL INFORMATION OF DRUGS

Executive summary of the product is to be submitted mentioning the specific and general pharmacological actions of the drug pharmacokinetic studies of absorption, metabolism, distribution and excretion. A separate note is to be given on acute and sub-acute toxicity studies and long-term toxicity studies. Specific studies on reproductive toxicity, local toxicity and carcinogenic activity of the drug is to be elaborated, as far as possible.

## 5. CLINICAL DOCUMENTATION

A new drug as defined under rule 122-E of the Drugs and Cosmetics Rules, 1945 is required to be permitted separately by the licensing authority under rule 122-A of the said rules prior to its registration. Such a new drug requires a brief summary on clinical documentation, along with permission under 122-A of the said rules for its Registration Certificate.

## 6. LABELLING AND PACKAGING INFORMATION OF DRUGS

**6.1 Labels should conform as per the specifications under the Drugs and Cosmetics Rules, 1945.**

**6.2 Package insert should be in English and shall indicate the following therapeutic indications: -**

Posology and method of administration.
Contra-indications.
Special warnings and special precautions for use, if any.
Interaction with other medicaments and other forms of interaction.
Pregnancy and lactation, if contra-indicated.
Effects of ability to drive and use machines, if contra-indicated.
Undesirable effects/side effects.
Antidote for overdosing

**6.3 Package insert should indicate the following pharmaceutical information:**

List of excipients.
Incompatibilities.
Shelf life in the medical product as packaged for sale.
Shelf life after dilution or reconstitution according to direction.
Shelf life after first opening the container.
Special precautions for storage.
Nature and specification of the container.
Instructions for use/ handling.

**7. SPECIFIC INFORMATION REQUIRED FOR THE SPECIAL PRODUCTS (TO BE SUPPLIED, SEPARATELY IN ANNEXURES, AS 'A', 'B' AND 'C')**

Module 'A' and 'B' are not applicable.

Module C is attached

The information submitted above is true to the best of my knowledge and belief.

*Place :* *Signature of the manufacturer*
*Date :* *[or his authorized agent]*

*Seal/Stamp*

**NB:**

1. Any change in the process of manufacture, method of testing, labeling, packaging, designing of the sale pack, medical literature and documentation is to be intimated to the licensing authority forthwith and permission to be obtained from him within 30 days' time period.

2. Information relating to Serial No. 4 and Serial No. 5 are not applicable for drugs figuring in Indian Pharmacopoeia and also for the drugs figuring in United States Pharmacopoeia, European Pharmacopoeia and British Pharmacopoeia provided such drugs have already been approved for marketing in India for the applicant under Rules 122-A, 122-B, 122-C or 122-D of the Drugs and Cosmetics Rules, 1945.

**Annexure C**
**[See Schedule D-II, item No.7]**

**INFORMATION TO BE SUBMITTED IN SCHEDULE D-II**
**SPECIFIC INFORMATION REQUIRED FOR VACCINES**

**A product dossier showing the:**

**1. History, source, date of receipt, storage, identity and characterization of seed strain.**

**2 Detail flow chart of manufacturing process showing all the details of in process control on toxicity, potency study and stability data of the final bulk and the final finished product including the storage temperature.**

**3 Complete details of chemical and pharmaceutical data for the product. Composition and dosage form-method of manufacture with detailed flow chart-control of starting material-control tests on intermediate and finished products-certificate of analysis of finished products-validation of critical manufacturing steps.**

**4 Test protocol of the vaccines showing the specification and method of testing including Pharmacopeal specification.**

**5 Specimen batch test report for at least consecutive three batches showing the specification of each testing parameter.**

**6 The detailed test reports of all the components used / packed in the finished vaccine.**

**7 Pack-size and labeling.**

**8 Product insert**

**9 Specimen batch release certificates issued by the National Regulatory Authority of the country of origin.**

**10 Summary of pre-clinical and clinical data including:**

**(a) Prescribing information.**
**(b) Pharmacological and toxicological information data pertaining to tests on animals Characterization of immuno response and safety study in human use, in specific conditions.**

Specific information on source of seed strain, its characterization, inactivation etc and processings like safe handling material control, area control, process control, stability studies, storage at quarantine stage and finished stage, packaging should be highlighted in the product dossier.

Specimen production and quality control protocols for at least three consecutive lots showing the specifications for each quality control parameter including pharmacopeal requirement shall be submitted for study.

The information submitted above is true to the best of my knowledge and belief.

*Place :* *Signature of the manufacturer*
*Date :* *Seal/Stamp*

**NB:**

1. Any change in the process of manufacture, method of testing, labeling, packaging, designing of the sale pack. Medical literature and documentation is to be intimated to the licensing authority forthwith and permission to be obtained from within 30 days time period.

2. All vaccines shall be new drugs unless certified otherwise by the licensing authority approved under rule 21 of the Drugs and Cosmetics rules, 1945, A copy of approval of the vaccine issued by the said licensing authority is to be enclosed, prior to issue of Registration certificate of the said vaccines.