

IN - INDIA

MICROBIAL TYPE CULTURE COLLECTION AND GENE BANK (MTCC)

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1. Requirements for Deposit

(a) Kinds of Microorganisms that May Be Deposited

The MTCC will accept bacteria, fungi, yeasts, bacteriophages, plasmids in a host and/or as isolated DNA preparations belonging to Hazard Groups 1 and 2 as per classification of the Indian authority.

Genetically manipulated microorganisms and isolated DNA will be accepted if they can be processed in the S1 or S2 facility or conform to Group 1 or 2 organisms.

The MTCC reserves the right to refuse to accept a deposit if, in its view, the deposit may be an unacceptable hazard or the MTCC may not be in a position to process it. Deposit of bacteria and fungi from other countries pathogenic to plants and animals, which can be processed in the S1 or S2 facility, will be accepted only if cleared by the appropriate authority in India.

(b) Technical Requirements and Procedures

(i) Form and Quantity

Materials for deposit should be pure (uncontaminated) and should be sent in the following form:

Bacteria and fungi (including yeasts)	10 freeze-dried ampoules and 2 active cultures (on slants). If freeze-dried cultures cannot be submitted the MTCC may do the freeze-drying on payment by the depositor
Bacteriophages	5 x 2 ml quantity with a minimum titre of 1×10^9 pfu per ml. Suitable host of the bacteriophage also needs to be deposited in active form (2 slants)
Plasmids	5 x 20 micrograms of isolated and purified DNA preparations. Suitable host of the plasmid also needs to be deposited in active form (2 slants)

The deposit should be accompanied by appropriate forms duly completed by the depositor. These forms can be obtained from the MTCC. Separate forms need to be used for bacteria, fungi (including yeasts), bacteriophages and plasmids. A fee for storage (Rule 12.1(a)(i) of the Regulations under the Budapest Treaty) must be paid for each deposit.

(ii) Time Required for Viability Testing

The MTCC will test viability as quickly as possible. Since microorganisms may grow quite slowly, the time required for viability testing for different microorganisms varies. The average time that will be required for viability testing is indicated below:

Bacteria, yeast, bacteriophages and plasmids	4 days to 3 weeks
Fungi	7 days to 4 weeks

(iii) Depositor Checks and Renewal of Stocks

The MTCC may prepare, as and when it finds necessary, new batch(es) of lyophilized and frozen (in liquid nitrogen) cultures by subculturing materials supplied by the depositor. The MTCC will send samples of the new batch and the depositor is required to check the authenticity of such microorganisms.

(c) Administrative Requirements and Procedures

(i) General

Language. The language of communication of the MTCC and of the forms will be English. Communication in Hindi is also acceptable. However, in case of any dispute, the English version will prevail.

Import and/or Quarantine Regulations. Cultures of microorganisms from outside India may require import clearance and/or be subjected to quarantine regulations. The depositor from outside India should communicate with the MTCC regarding such deposits before dispatching cultures.

(ii) Making the Original Deposit

Requirements to Be Met by the Depositor. A depositor will be required to send a completed BP/1 Form which is the accession form for a deposit under the Budapest Treaty. For amendments to the scientific description or taxonomic designation a depositor will be required to send a completed BP/7 Form.

Official Notification to the Depositor. The receipt and viability statement will be issued in English on the mandatory “international forms” BP/4 and BP/9, respectively. The attestation of receipt of an amendment of scientific description or taxonomic designation will be issued on BP/8 Form. The notification of furnishing a sample to third parties will be issued on BP/14 Form.

Unofficial Notification to the Depositor. If requested, the MTCC may communicate the date of deposit and accession number before the official receipt is issued only after the viability test is completed and a positive result is obtained.

Supply of Information to a Patent Agent. If requested by the depositor, the MTCC will send copies of the receipt and viability statement to both the depositor and his/her patent agent.

(iii) Converting a Previous Deposit

In case of a deposit made in the MTCC earlier, outside the provisions of the Budapest Treaty, the original depositor may convert the same to a Budapest Treaty deposit. However, if the original deposit was in the general category and is listed in the MTCC catalogue (printed or electronic) and had no restriction for distribution by the MTCC, the depositor will be requested to authorize the MTCC not to restrict distribution of such a deposit and waive his/her right to notification of release of the sample. If this condition is not acceptable then a fresh deposit of the material under the Budapest Treaty will be required. Deposits previously made with the MTCC for patent procedure or for safekeeping also can be converted to deposits under the Budapest Treaty.

Administrative requirements and fees for conversion will be the same as for the original deposit under the Budapest Treaty.

(iv) Making a New Deposit

For making a new deposit the completed BP/2 Form will be required along with relevant documents as required under Rule 6.2. A receipt and viability statement for such a deposit will be issued on BP/5 and BP/9 Forms respectively.

2. Furnishing of Samples

(a) Request for Samples

The MTCC will follow procedures as provided under the provisions of the Budapest Treaty for furnishing samples to third parties. For proof of entitlement BP/12 Form and for request BP/13 Form will be used in furnishing samples. For hazardous microorganisms the requesting party has to provide evidence that the proper facility is available and he/she has the requisite permission to work on such organisms.

A requesting party from outside India also has to provide an import permit if it is required for that country.

The MTCC will furnish samples prepared by it from the deposited sample(s).

(b) Notification of the Depositor

A depositor will be notified on BP/14 Form when samples of their deposit have been furnished to third parties.

(c) Cataloguing of Budapest Treaty Deposits

Materials deposited under the Budapest Treaty will not be published in the MTCC catalogue (printed or electronic) or displayed on the Internet.

3. Schedule of Fees

	<u>INR</u>
(a) Storage	15,000
(b) Conversion of a deposit	15,000
(c) Extension of duration storage (per year)	2,000
(d) Issuance of a viability statement on the basis of test	3,000
(e) Issuance of a viability statement on the basis of last viability test	1,000
(f) Furnishing of a sample	3,000
(g) Communication of information	1,000
(h) Issuance of an attestation	1,000

4. Guidance for Depositors

The MTCC will be happy to provide written notes or advice to prospective depositors.