A Guide to the Deposit of Cultures for Patent Purposes at NIBSC

Detailed guidance can be found in the documents produced by the World Intellectual Property Organisation (WIPO) which can be found at www.wipo.org. NIBSC accepts the following as Patent deposits under the Budapest Treaty 1977.

- Human cell lines (including embryonic and somatic stem cell lines)
- Animal cell lines
- Genetically modified animal and human cell lines

This guide provides you with information and instructions on making a patent deposit and how to send your deposit to NIBSC.

General Conditions of Acceptance for all Patent Deposits

1. Complete the Patent Deposit Form and the Biohazard Risk Assessment in full for each deposit (see links at the bottom of the page) and send both forms to NIBSC at the address given on the form. Do not ship samples at this stage.
2. Once the forms have been received, reviewed and accepted by NIBSC, you will be issued with a reference number that will need to be quoted in all future correspondence (and on your samples).
3. A purchase order number (quoting this reference number) will need to be faxed to NIBSC as soon as possible after acceptance by NIBSC. It is only then that NIBSC can receive your sample.
4. NIBSC will require a minimum 12 ampoules/straws of the cryopreserved cell line for deposit. NIBSC does not accept growing cultures. Specific technical details can be found in the WIPO guidance document. It is essential for quality control purposes that all ampoules are prepared at the same time.
5. It is important to ensure that when you deposit any cell line, the name of the cell line is written in full on the vial. If you have already labeled the vial, then the information provided on the vial must match that provided by you in the appropriate section of the Patent Deposit Form. The full name must also be provided in the Identification Section of the Patent Deposit Form. Incomplete or incorrect information may result in the return of your material.
6. The depositor may only use a courier approved by NIBSC and material must be shipped under conditions that maintain the appropriate storage temperature (e.g. a liquid nitrogen dry-shipper for vitrified material). Material received by NIBSC at an inappropriate temperature may not be accepted for deposit and may be returned to the Depositor at their expense.
7. On receipt of the deposit at NIBSC, a provisional Accession Number is allocated to the Depositor. This number remains provisional until the successful completion of quality control procedures.
8. The content of at least one ampoule will be examined according to the quality control criteria listed below. Cultures must be replaced if consistent low viability or contamination is identified.
9. If any problems arise, the Depositor will be informed immediately, and a further course of action discussed and agreed between NIBSC and the Depositor.
10. Following successful completion of quality control procedures, NIBSC will confirm the Accession Number and issue a Receipt, a Certificate of Viability and a Certificate of Deposition.
11. The Depositor agrees to pay the statutory fee(s). NIBSC will issue an invoice after deposition formalities have been completed.
12. On acceptance, NIBSC agree to hold the deposit under the terms and conditions of the Budapest Treaty, 1977.
13. Deposits are held on condition that they can be preserved without significant change or loss of properties during long term storage.

14. Depositors are required to supply a sufficient quantity of any special growth factors or feeder cells which may be required during culture and quality control procedures for any deposit.

15. NIBSC reserves the right to refuse deposits which in its opinion represent unacceptable hazards, significant technical or other difficulties, or where ethical considerations are inconsistent with those applied in the UK.

Individual Requirements for Each Category of Organism being Deposited for Patent Purposes

Human cell lines (including embryonic and somatic stem cell lines)

1. Cultured cell monolayers or cell suspensions: each ampoule of cryopreserved cells must contain at least 1 x 10^6 cells/ampoule with good viability on resuscitation and be free of microbial contaminants (mycoplasma, bacteria and fungi).

2. Cell lines cultured as colonies (including embryonic stem cells): each ampoule or straw must contain at least 4 cryopreserved colony fragments with good viability on resuscitation and be free of microbial contaminants (mycoplasma, bacteria and fungi).

3. Quality control procedures undertaken are:

    - Assessment of viability (using an appropriate viability assay)
    - Assessment for mycoplasma contamination
    - Assessment for bacterial and fungal contamination.
    - Quality control procedures may take between 14 and 28 days to complete or longer in certain circumstances.

Animal cell lines

1. Cultured cell monolayers or cell suspensions: each ampoule of cryopreserved cells must contain at least 1 x 10^6 cells/ampoule with good viability on resuscitation and be free of microbial contaminants (mycoplasma, bacteria and fungi).

Please contact NIBSC before shipping samples.

Shipping Instructions

1. Inform NIBSC at least 48 hours before shipping cells.

2. Only use a courier approved by NIBSC. NIBSC approved couriers ship door-to-door.

3. Provide all necessary information to NIBSC (including date and time of arrival, flight information (Airway Bill No. etc) and name of courier).

4. Cells must be shipped under conditions that maintain a storage temperature consistent with maintaining the essential properties of the material (e.g. liquid nitrogen dry-shippers for vitrified materials). Cells received by NIBSC at an inappropriate temperature may not be accepted for deposit and may be returned to the Depositor at their expense.

5. NIBSC approved couriers will provide Depositors with the correct packaging and labeling instructions. It is the responsibility of the Depositor to ensure that all national and international regulations have been complied with and all permissions received.