

## SCHEDULE 1

### PARTICULARS TO BE CONTAINED IN AN APPLICATION FOR A CERTIFICATE

#### **Part II—**

##### **Analytical information**

1. Qualitative and quantitative particulars relating to the product, which shall include—
  - (a) the monograph name, or if none the specification, of each ingredient, whether active or not, but if there is no name or specification, details sufficient to identify and characterise each batch of each ingredient used in the product shall be given,
  - (b) a description of the product's container and its closures, and any special directions for storage or transport of the product, and
  - (c) the specification of the product, giving its qualitative and quantitative composition.
2. The method of preparation of the product and of its ingredients whether active or not.
3. Details of any substances of animal origin used in the manufacture of the active ingredient, including, for a biological product, details of the master seed and master cell-bank.
4. Details of the in-process control tests to be carried out during the manufacture of the product, and of the control tests to be carried out on the finished product.
5. Proposals for a shelf-life and in-use shelf-life for the product.