Herbal drugs comply with the requirements for pesticide residues (2.8.13). The requirements take into account the nature of the plant, where necessary the preparation in which the plant might be used, and where available the knowledge of the complete record of treatment of the batch of the plant. The content of pesticide residues may be determined by the method described in the annex to the general method.

The risk of contamination of herbal drugs by heavy metals must be considered. If an individual monograph does not prescribe limits for heavy metals or specific elements such limits may be required if justified.

Recommendations on the microbiological quality of products consisting solely of one or more herbal drugs are given in the text on Microbiological quality of pharmaceutical preparations (5.1.4. – Category 4).

Where necessary limits for aflatoxins may be required. In some specific circumstances, the risk of radioactive contamination is to be considered.

ASSAY
Unless otherwise justified and authorised herbal drugs are assayed by an appropriate method.

STORAGE
Store protected from light.

01/2005:1435

HERBAL TEAS

Planta ad ptisanam

DEFINITION
Herbal teas consist exclusively of one or more herbal drugs intended for oral aqueous preparations by means of decoction, infusion or maceration. The preparation is prepared immediately before use.

Herbal teas are usually supplied in bulk form or in sachets. The herbal drugs used comply with the appropriate individual European Pharmacopoeia monographs or in their absence to the general monograph on Herbal drugs (1433).

Recommendations on the microbiological quality of herbal teas (5.1.4. – Category 4) take into account the prescribed preparation method (use of boiling or non-boiling water).

IDENTIFICATION
The identity of herbal drugs present in herbal teas is checked by botanical examinations.

TESTS
The proportion of herbal drugs present in herbal teas is checked by appropriate methods.

Herbal teas in sachets comply with the following test:

Uniformity of mass. Determine the average mass of twenty randomly chosen units as follows: weigh a single full sachet of herbal tea, open it without losing any fragments. Empty it completely using a brush. Weigh the empty sachet and calculate the mass of the contents by subtraction. Repeat the operation on the nineteen remaining sachets. Unless otherwise justified not more than two of the twenty individual masses of the contents deviate from the average mass of the contents by more than the percentage deviation shown in the table below and none deviates by more than twice that percentage.

<table>
<thead>
<tr>
<th>Average mass</th>
<th>Percentage deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 1.5 g</td>
<td>15 per cent</td>
</tr>
<tr>
<td>1.5 g to 2.0 g included</td>
<td>10 per cent</td>
</tr>
<tr>
<td>more than 2.0 g</td>
<td>7.5 per cent</td>
</tr>
</tbody>
</table>

STORAGE
Store protected from light.

01/2005:0084

IMMUNOSERA FOR HUMAN USE, ANIMAL

Immunosera ex animale ad usum humanum

DEFINITION
Animal immunosera for human use are liquid or freeze-dried preparations containing purified immunoglobulins or immunoglobulin fragments obtained from serum or plasma of immunised animals of different species.

The immunoglobulins or immunoglobulin fragments have the power of specifically neutralising or binding to the antigen used for immunisation. The antigens include microbial or other toxins, human antigens, suspensions of bacterial and viral antigens and venoms of snakes, scorpions and spiders. The preparation is intended for intravenous or intramuscular administration, after dilution where applicable.

PRODUCTION

GENERAL PROVISIONS
The production method shall have been shown to yield consistently immunosera of acceptable safety, potency in man and stability.

Any reagent of biological origin used in the production of immunosera shall be free of contamination with bacteria, fungi and viruses. The method of preparation includes a step or steps that have been shown to remove or inactivate known agents of infection.

Methods used for production are validated, effective, reproducible and do not impair biological activity of the product.

The production method is validated to demonstrate that the product, if tested, would comply with the test for abnormal toxicity for immunosera and vaccines for human use (2.6.9).

Reference preparation. A batch shown to be suitable in clinical trials, or a batch representative thereof, is used as the reference preparation for the tests for high molecular mass proteins and purity.

ANIMALS
The animals used are of a species approved by the competent authority, are healthy and exclusively reserved for production of immunosera. They are tested and shown to be free from a defined list of infectious agents.

The introduction of animals into a closed herd follows specified procedures, including definition of quarantine measures. Where appropriate, additional specific agents are considered depending on the geographical localisation of the establishment used for the breeding and production of the animals. The feed originates from a controlled source and no animal proteins are added. The suppliers of animals are certified by the competent authority.