or animal matter to be extracted is always covered with the remaining extraction solvent. The residue may be pressed out and the expressed liquid combined with the percolate.

TESTS

Relative density (2.2.5). Where applicable, the tincture complies with the limits prescribed in the monograph.

Ethanol (2.9.10). The ethanol content complies with that prescribed.

Methanol and 2-propanol (2.9.11): maximum 0.05 per cent V/V of methanol and maximum 0.05 per cent V/V of 2-propanol, unless otherwise prescribed.

Dry residue (2.8.16). Where applicable, the tincture complies with the limits prescribed in the monograph, corrected if necessary, taking into account any excipient used.

STORAGE

Protected from light.

LABELLING

The label states in addition to the requirements listed above:

- for tinctures other than standardised and quantified tinctures, the ratio of starting material to extraction liquid or of starting material to final tincture,
- the ethanol content in per cent V/V in the final tincture.

Soft extracts — extracta spissa

DEFINITION

Soft extracts are semi-solid preparations obtained by evaporation or partial evaporation of the solvent used for extraction.

TESTS

Dry residue (2.8.16). The soft extract complies with the limits prescribed in the monograph.

Solvents. Where applicable, a monograph on a soft extract prescribes a limit test for the solvent used for extraction.

STORAGE

Protected from light.

Dry extracts — extracta sicca

DEFINITION

Dry extracts are solid preparations obtained by evaporation of the solvent used for their production. Dry extracts usually have a loss on drying or a water content of not greater than 5 per cent m/m.

TESTS

Water (2.2.13). Where applicable, the dry extract complies with the limits prescribed in the monograph.

Loss on drying (2.8.17). Where applicable, the dry extract complies with the limits prescribed in the monograph.

Solvents. Where applicable, a monograph on a dry extract prescribes a limit test for the solvent used for extraction.

STORAGE

In an airtight container, protected from light.
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.

01/2005:0084

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 immunoserum 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 immunoserum. 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.