Project Code: 2016-1-EL01-KA202-023491

Erasmus+

INNOVATIVE INTEGRATED TRAINING IN HEALING PLANTS BUSINESS

IO3 - The Total Business Plants Training Material

Module No. 3

“Quality control of the final product (Medicinal plants)”

Unit 3: Quality control of medicinal plants/ final product

- Summary

This unit is the most important unit regarding quality control, as it explains thoroughly the term quality control and it analyzes the steps taken for the successful quality control of any medicinal plant. It also analyzes the differences between macroscopic and microscopic examinations.

- Learning outcome descriptors

After the end of this unit the trainee should be able to:

1. Explain the different techniques used for quality control
2. Be able to explain how a sample is standardized
3. Be able to explain and understand the differences between microscopic and macroscopic examinations

- General and transferable skills:

1. Plan a research task
2. Work independently or with a minimal guidance where appropriate
3. Work in teams with other trainees

This project has been funded with support from the European Commission.
This publication reflects the views only of the author and the Commission cannot be held responsible for any use which may be made of the information contained therein

Co-funded by the Erasmus+ Programme of the European Union

Despite the fact that herbal products and medicinal plants have gained much popularity nowadays, there is still a problem regarding their acceptance and that is because of the lack of standard quality control profile. Quality of a medicinal plant can be described as the profile of constituents that the final product has. This can cause issues with their safety but also their efficacy. Modern analytical techniques are now able to establish quality control parameters and steps, despite the complex nature of medicinal plants' constituents (8).

It is now established that modern laboratory techniques maintain a high level of quality control for medicinal plants and their final products. There are many techniques that are being used and the most common and successful are among others,

- Determination of foreign matter
- Macroscopic and microscopic examination
- Thin layer chromatography
- Determination of extractable matter
- Determination of pesticide residues
- Determination of arsenic and toxic metals
- Determination of aflatoxins.

Another important step in quality control is the standardization of the medicinal plant (drug) and it involves adjustment of drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity by adding excipients or by mixing herbal drugs or herbal drug preparations. Standardization describes all measures taken during the manufacturing process and quality control, leading to reproducible quality of a particular product that ensures a predefined amount of quantity, quality, and therapeutic effect of ingredients in each dose (9, 10, 11). It is the process of developing and agreeing on technical standards. Specific standards are achieved by experimentation, repetition and observations, which would lead to the process of prescribing a set of characteristics exhibited by the particular herbal medicine. Hence, standardization is a tool in the quality control process (12).

Therefore, it is vital that the step of standardization is completed successfully in order to ensure reproducibility in the manufacturing of the product. Growing need for standardization and quality control of herbal medicines is recognized by the World Health Organization (WHO). Standardization of botanicals offers many obstacles, and there are several challenges such as controversial identity of various plants and deliberated adulteration of plant material. Therapeutic activity of an herbal formulation depends on its phytochemical constituents (13). The development of authentic analytical methods, which can reliably profile the phytochemical

This project has been funded with support from the European Commission.
This publication reflects the views only of the author and the Commission cannot be held responsible for any use which may be made of the information contained therein

Co-funded by the Erasmus+ Programme of the European Union

composition, including quantitative analyses of marker/bioactive compounds and other major constituents, is a major challenge to scientists.

Determination of foreign matter (Microscopic/ macroscopic examination)

After the steps of sampling and packaging according to the ways mentioned earlier, the next step for the successful quality assurance of the final products is macroscopic and microscopic examination. This will ensure that the final product will be free of any potentially harmful ingredients. The raw material being used in the preparation of herbal drugs should be pure and free from foreign materials. These exogenous materials could be consisting of parts of medicinal plant materials or materials other than those named with the limits specified for the plant material concerned, any organism, part or product of it, or mineral admixtures not adhering to the medicinal plant materials, such as soils, stones, sand, and dust. Plant materials should be free from any excreta, molds, insects, and chemical residue (14, 15, 16).

Herbal materials should be entirely free from visible signs of contamination by molds, insects, or animal excreta. No abnormal odor, discoloration or signs of deterioration should be detected but is if rarely possible to obtain any plant materials that are free of harmless foreign matter. However, it is obvious that any poison, harmful foreign matter or other residue must not be present.

Macroscopic examination can conveniently be employed for determining the presence of foreign matter in whole or cut plant materials. However, microscopy is indispensable for powdered materials (5).

Limitations regarding the definition of foreign matter should be strict and therefore, the World Health Organization has defined foreign matter as the material that contains:

— Parts of the herbal material or materials other than those named with the limits specified for the herbal material concerned;

— Any organism, part or product of an organism, other than that named in the specification and description of the herbal material concerned;

— Mineral admixtures not adhering to the herbal materials, such as soil, stones, sand and dust (5).

Macroscopic examination of the final products is probably the easiest way to assess the purity, quality and sometimes quality. It is important that any sample that differs from the standards regarding characteristics such as color, odor or taste should be removed. It is preferred that the same individual carries out the macroscopic examination because of the different judgments of different individuals for the same material. The characteristics that are examined during the

This project has been funded with support from the European Commission.
This publication reflects the views only of the author and the Commission cannot be held responsible for any use which may be made of the information contained therein

Co-funded by the Erasmus+ Programme of the European Union

macroscopic evaluation of the final products are shape, size, color, surface characteristics, texture, fracture characteristics and appearance of the cut surface.

On the other hand, microscopic examination and evaluation involves the use of a microscope and sometimes the treatment of the final product with a chemical reagent. The features under study include various cellular tissues, trichomes, stomata, starch granules, calcium oxalate crystals, and aleurone grains (17). A complete identification of the final product can be achieved only with the combination of microscopy and other analytical methods.

Physical constants are sometimes considered to evaluate certain drugs. These include moisture content, specific gravity, optical rotation, refractivity, melting point, viscosity, and solubility in different solvents. All these physical properties are useful in identification and detection of constituents present in plants. In addition, they also include foreign matter, total ash, acid-insoluble ash, water soluble ash, swelling and foaming indexes, successive extractive values, moisture content, viscosity, pH, disintegration time, friability, hardness, flow capacity, flocculation, sedimentation, and alcohol content (18).

Macroscopic examination:

- Color: Product should be examined in daylight or in light whose wavelengths similar to those of daylight. The color of the sample should be compared with that of a reference sample.

- Surface characteristics and texture: The sample of the product can be examined with the use of a magnifying glass. The material can be wet with water or reagents, as required, in order to observe the characteristics of a cut surface. The sample should be touched to determine if it is soft or hard; bended and ruptured to obtain information on brittleness and the appearance of the fracture plane — whether it is fibrous, smooth, rough, granular, etc.

- Odor: A harmless material can be placed on the palm of the hand and the individual can slowly and repeatedly inhale the air over the material. If there is no distinct odor, you crush the sample between your thumb and index finger or between the palms of your hands by utilizing gentle pressure. If the material is known to be dangerous, crush by mechanical means and then pour a small quantity of boiling water onto the crushed sample in a beaker. First, determine the strength of the odor (none, weak, distinct, strong) and then the odor sensation (aromatic, fruity, musty, moldy, rancid, etc.). A direct comparison of the odor with a defined substance is advisable (e.g., peppermint should have an odor similar to menthol, cloves should have an odor similar to eugenol) (5).

This project has been funded with support from the European Commission.
This publication reflects the views only of the author and the Commission cannot be held responsible for any use which may be made of the information contained therein

Co-funded by the Erasmus+ Programme of the European Union

Microscopic examination:

The following are required:

— A microscope equipped with lenses providing a wide range of magnification and a sub stage condenser, a graduated mechanical stage, objectives with a magnification of 4×, 10× and 40×, and color filters of ground glass, blue-green; high eye point eyepieces are preferred for wearers of spectacles;

— A lamp, either separate or incorporated into the microscope;

— A set of polarizing filters;

— A stage micrometer and an ocular micrometer to be inserted into a 6x eyepiece and placed on the diaphragm or, preferably, a micrometer eyepiece;

— A set of drawing attachments for the microscope;

— A micro burner (Bunsen type);

— Slides and cover glasses of standard size;

— A set of botanical dissecting instruments.

References

5. Iqbal Ahmad, Mohd Sajjad Ahmad Khan and Swaranjit Singh Cameotra, Quality Assessment of Herbal Drugs and Medicinal Plant Products, 2014, Encyclopedia of Analytical Chemistry, Online ©2006–2014 John Wiley & Sons, Ltd

8. Bandaranayake,W.M. (2006) Quality control, screening, toxicity, and regulation of herbal drugs In Modern Phytomedicine. Turning Medicinal Plants into Drugs, eds. Ahmad, I., Aqil, F., Owais, M., Wiley-VCH Verlag GmbH: Weinheim, Germany, 25-57.

9. WHO, (1988) The International Pharmacopeia, vol. 3: Quality Specifications for Pharmaceutical Substances, Excipients, and Dosage forms. (3rd edn.). World Health Organization, Geneva.

10. Zafar, R., Panwar, R., and Sagar Bhanu, P. S. (2005) Ind. Pharmac., 4, 21–25

This project has been funded with support from the European Commission.
This publication reflects the views only of the author and the Commission cannot be held responsible for any use which may be made of the information contained therein

Co-funded by the Erasmus+ Programme of the European Union

11. Madhav, N. V. S., Upadhya, K., and Bisht, A. (2011) Ind. J. Physiol. Pharmacol., 3, 235–238.

12. Kunle, F. O., Egharevba, O. H., and Ahmadu, O. P. (2012) Int. J. Biodivers. Conserv., 4, 101–112.

13. Choudhary, N., and Sekhon, B. S. (2011) J. Pharmacog., 2, 55–70

14. EMEA (2002) Points to Consider on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin, European Agency for the Evaluation of Medicinal Products (EMEA), London EMEA/HMPWP/31/99 Review.

15. WHO (2003) Guidelines on Good Agricultural Collection and Collection Practices (GACP), World Health Organization, Geneva.

16. Surekha, D., Rajan, V. S. T., Kumar, N. M., et al. (2011) Int. J. Rev. Life Sci., 1, 97–105.

17. Kamboj, A. (2012) Analytical Evaluation of Herbal Drugs, Drug Discovery Research in Pharmacognosy, Vallisuta, O. (ed.), ISBN: 978-953-51-0213-7, InTech, Croatia

18. Bele, A. A., and Khale, A. (2011) Int. Res. J. Pharm., 2, 56–60.

This project has been funded with support from the European Commission.
This publication reflects the views only of the author and the Commission cannot be held responsible for any use which may be made of the information contained therein

Co-funded by the Erasmus+ Programme of the European Union