

## Scope and Barriers in Clinical Trials of Herbal Drugs

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Herbal products have always been an important part of the public healthcare across the globe world. A report by WHO revealed, that approximately 65-80% of world's population living in developing countries because of poverty and lack of access to modern medicine depends essentially on plants for their primary healthcare because of being economical, long history of traditional use, better compatibility with human body, minimal side effects, enhanced tolerance and more protection. Herbal products are also prevalent in developed countries like Germany, France, Italy and U.S where required guidelines for registration of herbal medicines exist. Approximately about 25% of all modern medicines are directly or indirectly derived from plant sources. The current market size of herbal medicine is estimated about \$80-250 billion in Europe and USA whereas in China is about \$650 million. However, the contribution of developing countries in global herbal business is very poor due to the lack of quality control and standardization measures, difficulty in preparing isolated compounds, lack of sufficient safety data including drug interaction, poor information about the composition of herbal preparation, difficulty in selection of dosage regimen, lack of drug delivery platforms, adulteration, difficulty in conducting randomized clinical trials, patient selection, patient motivation, comparative placebo and end point selection, high protocol non-compliance, methodological shortcomings etc. Therefore, these pitfalls in herbal clinical trials must be addressed to generate a sustainable natural source which could cater the ever needing demand of new and safer treatments and in renewing the interest of pharmaceutical companies in herbal medicine research.

There are many forms in which herbs can be administered, the most common of which is in the form of a liquid that is drunk by the patient—either an herbal tea or a (possibly diluted) plant extract. Whole herb consumption is also practiced either fresh, in dried form or as fresh juice. Several methods of standardization may be determining the amount of herbs used. One is the ratio of raw materials to solvent. However different specimens of even the same plant species may vary in chemical content. For this reason, thin layer chromatography is sometimes used by growers to assess the content of their products before use. Another method is standardization on a signal chemical.

Leaves of Eucalyptus olida being packed into a steam distillation unit to gather its essential oil. Herbal teas, or tisanes, are the resultant liquid of extracting herbs into water, though they are made in a few different ways. Infusions are hot water extracts of herbs, such as chamomile or mint, through steeping. Decoctions are the long-term boiled extracts, usually of harder substances like roots or bark.

Maceration is the old infusion of plants with high mucilage-content, such as sage, thyme, etc. To make macerates, plants are chopped and added to cold water. They are then left to stand for 7 to 12 hours (depending on herb used). For most macerates 10 hours is used. Tinctures are alcoholic extracts of herbs, which are generally stronger than herbal teas. Tinctures are usually obtained by combining 100% pure ethanol (or a mixture of 100% ethanol with water) with the herb. A completed tincture has an ethanol percentage of at least 25% (sometimes up to 90%). Herbal wine and elixirs are alcoholic extract of herbs, usually with an ethanol percentage of 12-38%. Herbal wine is a maceration of herbs in wine, while an elixir is a maceration of herbs in spirits (e.g., vodka, grappa, etc.). Extracts include liquid extracts, dry extracts, and nebulisates. Liquid extracts are liquids with a lower ethanol percentage than tinctures. They are usually made by vacuum distilling tinctures. Dry extracts are extracts of plant material that are evaporated into a dry mass. They can then be further refined to a capsule or tablet. A nebulisate is a dry extract created by freeze-drying.[citation needed] Vinegars are prepared in the same way as tinctures, except using a solution of acetic acid as the solvent.[citation needed] Syrups are extracts of herbs made with syrup or honey. Sixty-five parts of sugar are mixed with thirty-five parts of water and herb. The whole is then boiled and macerated for three weeks.

The exact composition of an herbal product is influenced by the method of extraction. A tea will be rich in polar components because water is a polar solvent. Oil on the other hand is a non-polar solvent and it will absorb non-polar compounds. Alcohol lies somewhere in between.

Many herbs are applied topically to the skin in a variety of forms. Essential oil extracts can be applied to the skin, usually diluted in a carrier oil. Many essential oils can burn the skin or are simply too high dose used straight; diluting them in olive oil or another food grade oil such as almond oil can allow these to be used safely as a topical.[unreliable source?] Salves, oils, balms, creams and lotions are other forms of topical delivery mechanisms. Most topical applications are oil extractions of herbs. Taking a food grade oil and soaking herbs in it for anywhere from weeks to months allows certain phytochemicals to be extracted into the oil. This oil can then be made into salves, creams, lotions, or simply used as an oil for topical application. Many massage oils, antibacterial salves, and wound healing compounds are made this way. One can also make a poultice or compress using the whole herb or the appropriate part of the plant, which is usually crushed or dried and re-hydrated with a small amount of water and then applied directly in a bandage, cloth, or just as is.

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