MEDI HERB
a phytotherapist's perspective
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Quality Aspects of Herbal Preparations

Extraction of dried plant material provides a concentrated preparation. There are 4 main procedures used in extraction: infusion, decoction, maceration and percolation. Infusion and decoction use water as the solvent (menstruum), maceration and percolation usually use an alcohol/water mixture as the menstruum.[1]

Infusion and decoction are very familiar practices. Maceration is a process by which the herb is steeped (soaked) in the menstruum. After a period of time the liquid is drained off, the herb material pressed, and the liquid collected. This produces a tincture for example, containing 1 part of herb to 5 parts of liquid (1:5 tincture).[1]

Traditionally percolation is regarded as probably the most efficient method of extraction. The menstruum trickles down through the pre-moistened plant material, which has been placed in a column-like percolator. Sufficient menstruum is added to cover the herb completely. After a period of time the drainage is opened and liquid is allowed through at a particular rate. There are many ways to percolate, and it is possible to obtain liquid preparations that are quite concentrated, for example up to 1:1 (1 part of herb to 1 part of liquid).[1] Refer below for more information about liquid extracts.

The liquid preparations produced by maceration and percolation are usually more concentrated than the infusion or decoction, so a smaller dosage is necessary.[1]

Liquid preparations made using these traditional techniques extract a comprehensive spectrum of the plant's constituents, and are referred to as galenical extracts.

Why 1:2 Liquid Extracts?

Despite opinions to the contrary, it is possible to make a 1:2 liquid extract that has all the benefits of a tincture in terms of extraction efficiency, stability and potency. In particular, the unique percolation process developed by Kerry Bone and used at MediHerb has been validated to produce 1:2 extracts that are at least twice as strong as 1:4 tinctures. This has been established by extensive phytochemical testing for active and marker compounds.

One of the advantages of using liquid extracts (also called fluid extracts) is that they are more concentrated, and so a lower amount of alcohol is administered in the daily dose to patients. In the words of the 19th Century American Eclectic physician Finley Ellingwood "a large amount of alcohol must be administered in order to get the full therapeutical drug effect of a tincture".[2]

Ellingwood was referring here to the amount of alcohol required in the manufacture of the tincture but the statement applies equally to the amount of alcohol given in daily dosage. Consider the following comparisons for liquid extracts and tinctures which are based on dosages from the *British Herbal Pharmacopoeia* 1983.[3] A larger amount of alcohol is often consumed by the patient if the tincture is administered at the recommended dosage. The doses of alcohol would be very high if using tinctures to prepare a multiherb formulation.

Liquid Preparation	Dose	Alcohol in Maximum Daily Dose
Example 1: Elecampane		
Elecampane Liquid Extract 1:1, 25% ethanol	1–2 mL mL tds = 3–6 mL/day	1.5 mL
Elecampane Tincture 1:5, 25% ethanol	3–5 mL tds = 9–15 mL/day	3.75 mL
→ 1:5 has 2.5 times the alcohol of 1:1 in the maximum recommended daily dose		
Example 2: Ginger		
Strong Ginger Tincture BP 1:2, 90% ethanol	0.25–0.5 mL tds = 0.75–1.5 mL/day	1.35 mL
Weak Ginger Tincture BP 1:5, 90% ethanol	1.5–3 mL tds = 4.5–9 mL/day	8.1 mL
→ 1:5 has 6 times the alcohol of 1:2 in the maximum recommended daily dose		

Erroneously 1:2 liquid extracts are sometimes thought of as lacking traditional validity, a sort of 'modern' invention. In fact, they are mentioned in several 19th century traditional (American Eclectic) texts.[2,4,5] The seventh edition of the German pharmacopoeia (*Deutsches Arzneibuch* (DAB)) published in 1968 actually *defines* a liquid extract as a 1:2 extract.[6] This definition continued in more recent editions of the DAB, and the percolation method does not use heat or vacuum.[7] There are also examples of 1:2 liquid preparations in the *British*

Pharmacopoeia, for example, the 1932 edition includes Strong Ginger Tincture 1:2 prepared by percolation.[8]

There are traditional references for 1:2 liquid extracts

As noted above MediHerb uses a method of cold percolation developed by Kerry Bone, combining traditional methods, scientific knowledge and subsequent testing. Cold percolation means percolation done at room temperature i.e. heat is not used in the extraction.

Cold Percolation: high efficiency of extraction without damaging the plant constituents

Best of both worlds: tradition + science

In other words by using 1:2 liquid extracts made by cold percolation, all the beneficial properties of tinctures are preserved in a concentrated preparation. This translates to lower dose, lower alcohol, lower cost and greater patient compliance.

Standardised Extracts

A "standardised extract" is one that is manufactured to contain a consistent level of one or more plant constituents which are derived from the original plant material.

But the term "standardised extract" means different things to different people, and rightly so, as the method of manufacture is an important determining factor. It may mean for example,

- a highly and artificially concentrated plant extract
- an extract containing one plant constituent (or group of constituents) from the herb at the expense of others
- an extract adulterated with pure chemicals which are added back to the extract to give it the desired level of "active constituent"

But the best quality standardised extract will be achieved by a carefully prepared extract including those made by traditional extraction, from high quality raw material which contains the complete spectrum of plant constituents, but is able to maximise key constituents.

There are times when practitioners will want to use standardised extracts, for example, where there is strong clinical data supporting the use of a particular standardised extract e.g. Ginkgo.

Best of both worlds: top quality standardised extract containing the full spectrum of plant constituents including a defined amount of key constituent

Quality Tablets

There are two main ways to put herbs into a solid dosage form:

- powdered dried herbs into tablets or capsules
- liquid preparations dried into tablets or capsules

The problem with the former is many dosage units often need to be consumed to achieve pharmacological doses. The latter allows for a potent tablet.

In the MediHerb tabletting process the starting herb is used to make a liquid extract or tincture made using percolation. The liquid preparation is then concentrated using low temperatures under vacuum. This step minimises the exposure of the delicate plant constituents to the damaging effects of heat and oxidation. Granulation and pressing produces the tablet. MediHerb tablets are subject to testing throughout this process and in order to comply with pharmaceutical good manufacturing practice (pGMP), tablets must disintegrate in less than 30 minutes.

Are tablets as easily absorbed as liquid preparations? Tablets manufactured from powdered herb are not likely to be absorbed as well as herbs extracted with water and alcohol. MediHerb tablets are likely to work just as well as liquids because they are made using extracts (not the powdered herb) and are manufactured to pharmaceutical standards to ensure rapid disintegration. This was verified in a clinical study which compared equivalent doses of Echinacea Premium in liquid or in tablet form. The total amount of the alkylamides (important active constituents) absorbed into the bloodstream (i.e. the bioavailability) was *essentially the same* for both the tablet and the liquid preparation.[9]

High quality, bioavailable tablets can be made from liquid extracted herb

General Quality Issues

Quality is determined by many factors in the manufacture of herbal products. One form of product (e.g. tincture) is not necessarily of higher quality than another form (e.g. tablet, liquid extract). For example, each of the following preparations are characterised by poor quality:

- bag of dried herbs in which the herbs have been poorly harvested, stored and/or dried,[1]
- liquid extract of an essential-oil containing herb made using heat,[1]
- liquid extract reconstituted from a overheated (caramelised) concentrated extract,[1]
- tincture reconstituted from a poor quality extract (often not containing all the plant constituents).

Poor quality manufacturing produces poor quality final product

And in each of the above examples, if the quality of the starting plant material were poor, the quality of the finished good would be further reduced. Substitution with an incorrect species would have resulted in a poor quality product at best and a safety risk at worst.

Poor quality starting herb produces poor quality final product

Pharmaceutical good manufacturing practice (pGMP) and quality control go a long way towards ensuring the quality and safety of herbal products. Governments in many countries require herbal products to be manufactured to pGMP guidelines.

Pharmaceutical GMP helps ensure product quality by setting and requiring adherence to standards and practices for product manufacturing, specifications, storage, handling and distribution.[10] pGMP includes requirements for maintenance of the manufacturing equipment and mandatory record keeping provisions. Manufacturers are required to evaluate the identity, purity, quality, strength and composition of raw materials and final products. The provisions are intended to ensure that a product contains what is listed on the label.[11]

At MediHerb for example, depending upon the specific herb, we test the raw material for colour, aroma, texture, content of specified actives, thin layer chromatography fingerprinting, microbial levels, amount of extraneous matter, pesticides and herbicides, heavy metals, aflatoxins and radiation levels.

The mere existence of pGMP however, does not always ensure quality and safety. Often this requires research. Over the years, MediHerb has found many issues relating to the quality of herbal preparations:

- Substitution of one species for another leading to reduced quality e.g. *Scutellaria* spp. instead of *Scutellaria lateriflora*
- Substitution of one species for another, potentially toxic species leading to safety risk e.g. *Aristolochia* spp. instead of *Stephania tetrandra*
- Lack of active constituent present e.g. *Andrographis paniculata* containing no andrographolide
- Contamination with colouring agent e.g. *Vaccinium myrtillus* containing colouring agent to mimic the anthocyanins (authentic blue constituents)

This confirms that customers cannot just go by the look of the product. Caramel for example, has been added to liquid extracts to make them look darker and thicker. The level of an active ingredient may be written on a label, but will be inaccurate if the wrong test method has been used in the analysis.

Product Stability

How do manufacturers arrive at a shelf life for their products? Often in the case of liquid preparations, a guess is made based on the alcohol content of the preparation (as alcohol, in a certain concentration, is a preservative against microbial contamination). The only way to be certain of shelf life is to measure the quality over time. Manufacturers need to measure the plant constituents are present at the same level from zero time to the end of shelf life plus one year beyond. This is a guarantee of efficacy, so you can be sure the product will work. Companies manufacturing to pharmaceutical pGMP (Australia) operate a stability program for just such a purpose.

Pharmaceutical good manufacturing practice (pGMP) is pre-requisite for the delivery of quality in herbal preparations, and includes measuring the stability of the product

In other words the stability of all products, be they tablets, capsules or liquid extracts, is tested and validated via an ongoing scientific program. This gives the patient full confidence that the stated shelf life of the product is based on fact, rather than just a vague opinion.

Comparison of Dosage Forms

In light of many of the quality issues discussed a short summary comparing advantages and disadvantages of herbal preparations is outlined in the following table.

Tablets/Capsules made from powdered herb	Tablets made from liquid preparations under pharmaceutical GMP	Liquid Extracts made with heat	Liquid Extracts made without heat or evaporation	Tinctures
Disadvantages Low bioavailability Contains a relatively low amount of herb per tablet May contain bulking agents to make up the volume Dried herbs in hard shell capsules will attract moisture; possible stability/efficacy issue	**Advantages** Improved patient compliance (some herbs are too awful tasting as liquids) Allow for high doses to be prescribed e.g. in acute conditions; and resinous herbs like Boswellia if given in liquid form the doses would be exceedingly high and result in poor compliance Meet the requirements of disintegration (<30 mins); same bioavailability as liquid preparations Suitable for patient groups who don't want alcohol e.g. Muslims, children, those with liver damage or alcoholism	**Advantages** Quicker to manufacture **Disadvantages** Poor quality – loss of plant constituents	**Advantages** Provides high quality without high alcohol content Useful when herb needs to be tasted e.g. bitters or to provide a topical effect e.g. licorice and sage for gargle More readily incorporated into herbal creams and ointments	**Advantages** Provides liquid preparation of low dose herbs e.g. poke root and herbs requiring a lot of menstruum e.g. myrrh (due to high resin content) **Disadvantages** A large amount of alcohol prescribed per dose Reduced patient compliance due to volume of liquid to be consumed

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