

*longa*, which contains curcuminoids that have a yellow or orange colour. Beta-carotene is another example and has an orange-yellow colour. Commercial beta-carotene is derived from algae or is synthesized and is oil-soluble, but it can also be made into a water-dispersible emulsion. These natural yellow to orange colours are an alternative to synthetic yellow dyes. Other plant-based colours include anthocyanins or tomato extract, which can produce a range of red colours in place of synthetic red dyes.

The possible use of plant extracts for colouring formulations has been extensively researched over a number of years, but the major problem is that they usually tend to be unstable in varying pH conditions, and are particularly prone to degradation.

**Flavours.** Plant extracts are often bitter or astringent and masking this with sweeteners or flavours is widely employed. Flavours are invariably included in liquid oral formulations to mask these bitter or unpleasant tastes, to improve patient compliance. Apart from volatile oils, which are selectively used for flavouring formulations designed for different patient groups, a wide range of soft fruit flavours such as banana or strawberry, either natural or synthetic, are also used for flavouring.

### Biotechnological production of plant products

A number of major prescription medicines are currently produced using *in vitro* techniques. Currently, digoxin, taxol and vincristine amongst a small number of medicines, are derived from plant cell culture techniques, and commercially manufactured and extracted in a complete 'in-house' procedure. These procedures are excessively expensive, consequently only products with the highest value can be commercially exploited using plant cell culture.

Due to commercial sensitivity, biotechnology procedures are not published in detail, however they are similar to those used for whole plant material, without the need for drying and size reduction, but are produced by simply leaching out the active constituents followed by purification and later formulation as for single chemical entities.

## Quality of finished products

### Quality of formulated herbal products

Unlike prescription products, there are few agreed standards for formulated herbal remedies. A survey

of a large number of herbal products from a range of manufacturers found incorrect/inadequate labelling, products with wide ranging content claims, wide ranging recommended daily dosage, a range of different plant parts used and from a number of claimed sources of botanical origins. Wide ranging values for active constituent content have been reported for parthenolide in Feverfew and for the active constituent(s) in Ginseng, Ginkgo, Echinacea, Hypericum and others (Ruparel and Lockwood, 2011). This demonstrates the possible risk to patients and the urgent need for standards (Heptinstall et al, 1992).

### Shelf-life of formulated products

Labelling of shelf-life or expiry date is presently not mandatory for all formulated plant products. Scientific knowledge about degradation and acceptable shelf-life is obviously necessary for these complex products. Improved packaging designs are now being used to limit degradation, but control of storage conditions from warehouse to point-of-sale are of major importance. There are a number of difficulties in conducting shelf-life determinations with complex products, and often simplistic parameters are used, such as colour and consistency of the formulation, in addition to chemical evaluation. Further, detailed real-time and accelerated testing may be carried out at specific temperature and humidities, as for conventional pharmaceuticals. These techniques are particularly useful to speed up data collection and for determining suitable formulations (Houghton and Mukherjee, 2009).

### Bioequivalence of different formulations

The issue of bioequivalence of different formulations of conventional pharmaceuticals is well researched. However, such information is less detailed when comparing different formulations of plant medicines. Data from a limited number of single component herbal medicines, showing variable plasma concentrations for each, are available. However, major complications occur when a herbal medicine's activity is derived from a range of components. In this instance, plasma concentrations are often insufficient to determine levels of activity, and therefore assays for effects on biomarkers are required in order to show comparative activities of different formulations. Further problems are clearly evident when the active constituent(s) of a