- *Tanacetum parthenium* (feverfew), used to treat migraine headache
- *Allium sativum* (garlic), used to lower low-density protein cholesterol and some cardiovascular disturbances
- *Matricaria chamomilla* (chamomile), recommended as a carminative, anti-inflammatory, and antispasmodic
- *Silybum marianum* (milk thistle), used for repairing liver function, including cirrhosis
- *Valeriana officinalis* (valerian), used as a sedative and sleeping aid
- *Piper methysticum* (kava kava), used as an anxiolytic
- *Aesculus hippocastanum* (horse chestnut), used for the treatment of chronic venous insufficiency
- *Cassia acutifolia* (senna) and *Rhamnus purshiana* (cascara sagrada), which are used as laxatives
- *Echinacea purpurea* (echinacea), used as an anti-inflammatory and immunostimulant
- *Arnica montana* (arnica), used to treat post-traumatic and postoperative conditions
- *Serenoa repens* (saw palmetto), used for the treatment of benign prostatic hyperplasia

10.2.4 Regulatory Filing Procedure

In general, the chemistry, manufacturing, and control (CMC) requirements for standard synthetic/semisynthetic drugs are as follows:

- Synthesis of the drug
- Manufacturing of the product that is administered to the patient
- Control of these processes

Thus, the drug and the product are made reproducibly to provide assurance that only active ingredients are administered to patients and toxic contaminants are not.

More specific CMC requirements, for example, for a plant substance that is later made into a pure drug (e.g., digitalis for heart failure and artemisinin for malaria), are shown in column 3 of Table 10.2.

10.2.4.1 Plant Substance

- Description of the plant
- Procedure by which a part of the plant is extracted
- Quantity of the active ingredient in the extract
- How the active ingredient is identified
- Stability of the active ingredient (at least over the time of the trial)