

Centre for Integrative Medical Training
In Association with London Integrated Medical Health Education



Pre-membership Course in Homeopathic Pharmacy

A Blended Course in Homeopathic Medicine for Healthcare Professionals

Units 47-50

PHARMACY STUDIES Weeks 3-6

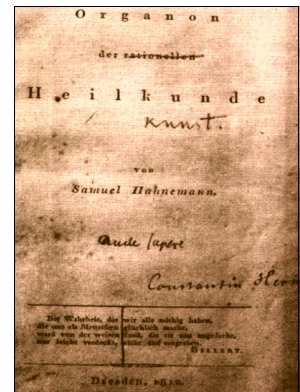
WEEKS 3-6**HOMEOPATHIC PHARMACOPOEIA** John Morgan

This section of the course introduces you the use of pharmacopoeias and application of Good Manufacturing Practice for homeopathic products. It will give you an overview of the development of pharmacopoeias since Hahnemann and the current ones used for product licensing today.

The historical development of Pharmacopoeias**Hahnemann**

The first pharmacopoeias were the materia medicas and publications written by Hahnemann himself. The Organon was his most famous treatise on homeopathy, which went through several editions, the 5th edition (1833) being the definitive work on how to prepare mother tinctures and centesimal potencies by dilution and succussion.

His *Materia Medica Pura* (1830) and *Chronic Diseases* (1838) gave precise details for the preparation of the 65 remedies mentioned in their respective prefaces. The fifth edition of the *Organon* was superseded by the 6th in 1843, for which the manuscript was prepared but never published, due to Hahnemann's death in 1843. As a result, details of the work were hidden for 80 years until, in 1920, the German manuscript came to light and Hahnemann's last revisions were revealed. It was in the 6th edition that his treatise on LM potencies was newly introduced.



LM potencies utilise a dilution scale of 1 in 50000. The other differences, in comparison to the centesimal scale, is that 100 succussions are given for each dilution and the remedies are always given in liquid form in teaspoon or tablespoonful doses. They are repeated daily and have a reputation for being non aggravating yet deeply curative.

Although each dilution step is large, the overall potency level of the LM's is low. Each 1 in 50000 step is not more than a 3c jump (i.e. 1 part in 1,000,000) so an LM 30 would be no higher than a 90c in potency, which is low in comparison to 200c and above.

Despite being hidden for so many years the last 10 years have seen a resurgence in the use of LM potencies and they are now very much part of everyday prescribing amongst homoeopaths. For further details of centesimal and LM potency preparation in the *Organon* you are referred to paragraphs §269 to §270 in the 6th edition. The subject of LM potencies will be revisited in greater detail later in the course.

The First Pharmacopoeias

There were several pharmacopoeias published in English in the 1800s. The earliest of these were those of Jahr and Grunner (1850), followed by the first British and American Homeopathic Pharmacopoeias of 1870 and 1882 respectively.

The daunting task of these works was to be true to Hahnemann's legacy while, at the same time, documenting the new remedies and preparations which were being introduced, as well as correcting errors. During the last 20 years of the nineteenth century there was large growth in homeopathic practice, particularly in America. This movement was influenced by Dr J.T. Kent who introduced the higher potencies and many new remedies.

The French, German and American pharmacopoeias were revised infrequently between the war years as homeopathy lost some of its popularity due to the huge development of new drugs. It has only been in the last 20 years that another resurgence has taken place and the reference works for pharmacists and manufacturers has grown again in content and sophistication.

The early monographs were simple affairs with details of the Latin and common names, synonyms, botanical descriptions and tincture preparation. In the absence of refined analytical reagents, inorganic remedies often had archaic nomenclature which did not describe their molecular profile. (eg. *Causticum*, *Cinnabaris*). Although the physical properties of inorganic substances were often quite well described, techniques to isolate or purify the substance were often rudimentary by modern standards. This is important to bear in mind, since these relatively impure salts may have demonstrably different clinical effects in comparison to those of their highly purified modern counterparts.

Simple chemical identification tests were available, however, and the methods of potentiation were well established. Methods for the preparation of tinctures, triturations and dilutions were exactly as described by Hahnemann and dosage forms were restricted to solid sugar pillules and oral liquids.

The present day

Today the status of homeopathic remedies as medicines has subjected their commercial manufacture to the same standards of quality control and analysis as orthodox drugs. Modern pharmacopoeias have the same overall descriptive data as the older editions but include a comprehensive array of macroscopical characteristics, chemical identification tests, assays for impurities or alkaloids, thin layer chromatography and dry residue limits.

Many new formulations have been added such as ointments, creams, eye and nose drops, suppositories etc. The number of methods of preparation has grown with the increased diversity of source materials. The latest *German Homeopathic Pharmacopoeia* (GHP) has over 50 methods. It includes remedies traditionally used in Germany such as *Spagyric*, where tinctures are subjected to heat or fermentation before use, and anthroposophical medicines first developed by the humanist philosopher Rudolph Steiner. An example is the remedy *Ferrum Sidereum* which is an iron preparation sourced from fallen meteors.

The *Homeopathic Pharmacopoeia of the United States* (HPUS) has grown enormously in recent years and, like others, is housed in ring binders to allow additions and updates. It presently contains around 1200 monographs. Although it has only recently begun to add testing methods and is not complete enough to use for licensing, it is a very important and widely used reference.

Historical journal articles on Homeopathic Pharmacy & Pharmacopoeia

Ehrhart R, *Homeopathic pharmacy yesterday and tomorrow*,
J Am Inst Homeopath 1968 Apr-Jun;61(4-6): 111-115

Boiron H, *Evolution de la pharmacie et du médicament au cours des 50 dernières années*,
Homeopathie 1990 Dec;7(4):23-8

Burnford G, *Recent advances in homeopathic pharmacy initiated at the London Homeopathic Hospital*,
Homeopathic World 1926 May;61(725): 117-121

Homeopathic pharmacy, Homeopathic World 1918 Feb;53(2): 59-73

Hale EM, *The characteristics of the new remedies*, 3rd edition, Detroit, US: Lodge's Homeopathic Pharmacy, 1873.,

Hale EM, *New remedies in homeopathic practice*, Detroit: EA Lodge Homeopathic Pharmacy, 1864.

Boericke FA, Anschutz EP, *The elements of homeopathic theory, practice, materia medica, dosage and pharmacy*, Boericke & Tafel Philadelphia, US 1914

Winston J, *A brief history of potentizing machines*, Br Homoeopath J 1989 78: 59

Your notes: history of homeopathic pharmacopoeia

British Homeopathic Pharmacopoeia

The first British Homeopathic Pharmacopoeia was a very important tome in the evolution of homeopathic pharmacy, as will be mentioned later, but was unfortunately not updated from the 1882 version. However a new British (B.Hom.P) was introduced in 1991 by the British Association of Homeopathic Manufacturers (BAHM), to preserve our traditional medicines, and is an annex to the German.

It contains monographs for remedies and methods not found in the GHP such as the Bach Flower remedies. Although not officially part of the B.P. it is recognised by the Medicines Control Agency as a legitimate source of monographs and can be used for the licensing of remedies.

In 1992 an EEC directive 92/73 was introduced to harmonise the regulations concerning homeopathic medicinal products and created a simple registration scheme for licensing dilutions of 4x and above. In the absence of a European Homeopathic Pharmacopoeia EU member states are allowed to use the pharmacopoeia of their choice. The most commonly used are the German, French and British which have analytical methods in all the monographs. If a monograph is not present it is possible to propose a testing protocol oneself, but justification of the traditional homeopathic use of the substance is then required.

BRITISH

British Homeopathic Pharmacopoeia, 3rd edition, Drury, W.V.(ed.), Faculty of Homeopathy London, British Homeopathic Society, London: E Gould, 1882.,

British Homeopathic Pharmacopoeia 2nd edition, Faculty of Homeopathy London, British Homeopathic Society, London: British Homeopathic Society, 1876

British Homeopathic Pharmacopoeia 0-9521708-0-9, British Assoc. of Homeopathic Manufacturers Ilkeston, UK 1993,

AMERICAN

The New Homeopathic Pharmacopoeia and Posology, Hempel C.J, New York: William Radde, 1850, Translation from German works of Buckner and Gruer, and French of Jahr.

Homeopathic Pharmacopoeia of the United States American Institute of Homeopathy, Pharmacopoeia Convention of AIH Falls Church, Virginia, US 1979

The homeopathic pharmacopocia of the United States, 7th edition, Philadelphia: Boericke & Tafel, 1964

Pharmacopoea homeopathica polyglotta Schwabe W, Boericke & Tafel New York, U.S.A. 1880

GERMAN

Homeopathic Pharmacopoeia, 2nd edition, Schwabe W, Leipzig: 1929

INDIA

Homeopathic Pharmacopoeia of India Government of India, Ministry of Health, Delhi, India 1986

The evolution of homeopathic preparation methodology

Generally speaking, the basic principles of methodologies for homeopathic remedy preparation have not changed radically since Hahnemann introduced them.

Trituration using a mortar and pestle is still described with the 6 minutes of grinding and 4 minutes of scraping as given in Unit 1. Directions for preparation in larger volumes are not given and machinery to grind is now accepted. Sometimes there are improvements - for example the GHP has also added a particle size test at 2c (4x) to ensure the grinding has been efficient.

Journal articles on Trituration

Dellmour F. [*Importance of the 3c trituration in the manufacture of homeopathic medicines.*](#)
Br Homoeopath J, 1994, Jan;83(1):8-13,

[*Baudry's mechanical triturator and dynamizer.*](#) Br Homoeopath J 1923 13: 493

Your notes on evolution of homeopathic preparation methods:

Self Study & Parallel Reading

Study paragraphs 269 and 270 in: *The Organon*, S. Hahnemann. (Pp 235-242 O'Reilly ed.)

Potentisation uses dilution and succussion with the serial dilution 1 to 100 or 1 to 10 ratios and although alcohol concentrations used vary between the pharmacopoeias, this does not affect the quality of the potency produced.

Further reading

Modern techniques in potentisation

Jolivet A
Comm Br Homoeopath res Grp 1984 Aug;(12): 47-50

A rationale for the potentising process in homeopathic remedies

Tiller WA
Homeopathy 1980 6(6): 169-172

The mathematics of the potencies

Kyle D
Homeopathic world 1926 mar;61(723): 80-81

NMR spectra of sulphur potencies: artefacts of potentising

Parsch T
Berlin J Res homoeopath 1991 Mar;1(2) 132-3

Guidelines for the exact description and mode of application of serial dilutions and potencies in publications on ultra low dose effects and homeopathic research- a proposal

Hornung J, Linde K
Berlin J res homoeopath 1991 mar;1(2):121-3

Homeopathic potentisation. problems of quality control

Cook TM
Hahnemannian Gleanings 1980 Jul;47(7):300-314

Potentisation

Ross
Homeopathy 1982 32:114-115

The Law of potency

Williams HN
J Am Inst Homeopath 1984 Jun;77(2):67-71

Towards a standardisation for the preparation of homeopathic potencies used in research

Ulbricht AH
Comm Br Homoeopath res Grp 1989 mar;19:39-42

A mathematical explanation of the process of potentisation

Hubbard M
J Am Inst Homeopath 1978 jun;71(2):95-98

Activity of potentised substances

Pelikan W, Unger G
Br Homoeopath J 1972 61:86

Spectrophotometric analysis of potentisation of *euphrasia officinalis*

Gautam RS, tewari KP, Roper NK, Mishra RK
J Am Inst Homeopath 1977 mar; 70(1):299-303

What's going on here anyway? A review of Boyd's "Biochemical and biological evidence of the activity of high potencies"

Mock D.
J Am Inst Homeopath 1969 dec;62(4): 197-198

Biochemical and biological evidence of the activity of high potencies

Boyd WE
J Am Inst Homeopath 1969 Dec;62(4) :199-251

Hahnemann's theories of potentisation

Clover AM
Br Homoeopath J 1987 Oct;76(4):195-8

Homeopathische Potenzierungsverfahren und moderne pharmakotechnische Erfordernisse

Broese R
Allgem Homoeopath Zeit 1987 Nov-Dec;232(6):235-7

A brief history of potentising machines

Winston J
Br Homoeopath J 1989 Apr;78(2):59-68

Potentisation and the peripheral forces of nature

Adams G
Br Homoeopathi J 1989 Apr;78(2):69-79

Preparation of potencies

Ainsworth JB
Mid homoeopath Res Grp Newsletter 1979 Jul;(2):21-23

Segall E. A fresh look at potentisation.

Homeopathy, 1996, Dec;46(6):135-136



Self Study & Parallel Reading

Study the following section in your companion text: pp 48-52 *Homeopathic Pharmacy*: S Kayne

Medication principles are also based on the wetting procedure given by Hahnemann.

Remedy sources occasionally show inconsistencies between pharmacopoeias e.g. the parts used to make *Calendula* is given as the flowering tips in the HPUS, the fresh leaf tips in the French and the whole aerial flowering parts in the GHP. It is very important that the pharmacopoeias mirror the originally proved procedure as closely as possible in order to preserve the integrity of the symptom picture it is to cure. Having said this the overall accuracy of information is consistent and will carry the traditions of the past into the future.



Gathering from natural habitat is preferred

Journal References on Sourcing Botanical Remedies

Derham P, [The gathering of homeopathic flora](#), 1981 Summer;1(4):23-6

Ibarra R, [Importance and possible application of physiology in the collection of homeopathic plants](#), Homeopathy 1983 33: 124-126

Ovando RI, [The importance of plant physiology in the collection of botanicals for homeopathic medicines](#).

J Am Inst Homeopath 1982 Sept;75(3):46-8

Ibarra R, [The importance of plant physiology in the collection of botanicals for homeopathic medicines](#), J Am Inst Homeopath 1982 Sep;75(3): 46-49

Your notes on remedy sources

Self Study & Parallel Reading

Study paragraphs 264- 268 in: *The Organon*, S. Hahnemann. (Pp 232-235 O'Reilly ed.)

Mother Tinctures preparation methods show the most radical changes since Hahnemann's time. The differences that have evolved have caused some conflict between national pharmacopoeial committees. In fact the absence of a European Homeopathic Pharmacopoeia has been due to disagreements in tincture protocol and the method which would be given in a future EHP. As the B.Hom.P of 1870 had a key role in this change it is worth studying the history and gives us a greater understanding of the standardisation of mother tinctures.

Hahnemann's Methods and the GAP

The details for potentiating plant material begins with the mother tincture. Hahnemann used four different methods in the monographs of his *Materia Medica Pura*, because of differences in the water content of plants. Plant material varies in water content between different species and even between different batches.

Choosing which Hahnemannian method to use subsequently was difficult without testing each time for moisture content, but the important principle he laid down was that the one part of drug strength was based on the watery juice present in the fresh plant. The German GAP still uses these classes but has some adaptation for accuracy and standardisation.

They are as follows:

METHOD 1 - This method was first described in *Materia Medica Pura* under *Belladonna*

- ▶ The fresh plant is chopped and pounded to a pulp and the juice pressed out.
- ▶ This is mixed with an equal volume of strong ethanol (86%) shaken and allowed to stand for at least five days, to allow settling, before use.
- ▶ The drug power is stated as $\frac{1}{2}$ (1 in 2) relating to the expressed juice and the final ethanolic concentration is 43%.
- ▶ The first centesimal potency 1c is prepared by adding 2 parts of the tincture to 98 parts of diluent (43% ethanol to maintain solubility)

METHOD 2 -The method was first described in *Materia Medica Pura* under *Thuja*.

- ▶ Two parts 86% ethanol is added to every three parts of fresh plant pulp.
- ▶ This also gives a drug strength of $\frac{1}{2}$ (1 in 2) as the loss on drying for these plants is in the region of two thirds and the final tincture is still equal parts of juice to added ethanol.
- ▶ The GAP gives a formula which gives precision to this method and always measures the ethanol by weight not volume.

$$E = M \times D/100 \text{ (kg)}$$

where:

- E** = 86% ethanol to be added
- M** = weight of fresh plant material
- D** = loss on drying of a sample, in per cent.

By this formula the ethanol added is equal to the juice in the sample.

- ▶ The macerating mixture is left to stand, for a minimum of 10 days, with shaking, then expressed and filtered.
- ▶ The final ethanolic concentration is also 43%
- ▶ 1c is prepared by adding 2 parts of the tincture to 98 parts of diluent (43% ethanol) as in method 1

**SAQ P1**

You have 2.57 kg of fresh Thuja leaves to prepare a tincture. How many kgs of 86% ethanol would you add to make it. Loss on drying for Thuja is 58%.

Answer: please refer to the back of your workbook

METHOD 3 - This method was first described in *Materia Medica Pura* under *Scilla* ...

...where 100 grains (6.4gm) of fresh bulb was mixed with 600 drops (approximately 24mls) of strong ethanol.

- ▶ *Scilla* contains approximately 75% water to the ratio of juice in this example is 4.8mls in 28.8mls = 1/6 (1 in 6)
- ▶ 1c is prepared by adding 6 parts of the tincture to 94 parts of diluent (62% ethanol)

Method 3 in the GAP works with a different ratio as given in the following formula:

$$E = 2 \times M \times D/100 \text{ (kg)}$$

- ▶ In this method there is always the equivalent of 2 parts of ethanol to every 1 part of juice giving a drug strength of 1/3.
- ▶ This results in a final ethanolic concentration of 62%.
- ▶ 1c is prepared by adding 3 parts of the tincture to 97 parts of diluent (62% ethanol)

METHOD 4 - This method was first described in *Materia Medica Pura* under *Staphisagria*

Five parts ethanol is added to every one part of plant material.

This method is used for dry plants or those with very low moisture contents and the stated drug strength is 1/10

1c is prepared by adding 10 parts of the tincture to 90 parts of diluent.

The GAP has changed this to 10 parts ethanol (of a suitable concentration) to one part plant material and uses this method for plants with less than 10% water content.

N.B.

The GAP also has methods 2b and 3b which use 62% and 73% ethanol respectively instead of 86%. Lower ethanolic concentrations are also used as the diluent for the 1c potency. This ensures that solubility of constituents is maintained at all times as the ethanol added is chosen to suit each remedy.

The British modifications of 1870

When new plant remedies were introduced choosing the appropriate Hahnemannian method was not always easy. To facilitate this and create a universal standard another approach was taken up and revealed in the B.Hom.P of 1870. This work was compiled by Dr Frederick Quin who had studied with Hahnemann and was responsible for bringing homeopathy to Britain. In fact the Royal London Homeopathic Hospital was founded by Quin in 1850.

Their approach to the problem was to consider the dry weight of the plant, rather than the juice, to be the one part and formulated a method which would add enough ethanol to make the juice and the alcohol added the equivalent of 10 parts. Thus every mother tincture was standardised to contain 1 grain in 10 minims i.e. a 1/10 w/v as in Method 4 given above. The strength of alcohol in the final tincture was chosen for each plant and sufficient water and ethanol are added to achieve this.

The HPUS and French Hom.P have taken up this protocol and although different from the above German methods give minimal differences at the 1c level.

Example: The following example taken from the British Homeopathic Pharmacopoeia 1870 shows the original method. Firstly the loss on drying is determined by simply weighing a fresh sample, drying it fully and weighing it again.

THUJA.

Contraction—Thu.

Thuja occidentalis, Willd. *Nat. ord.*, CONIFERAE.

Synonyms—Arbor Vitae, Cedrus Lycea.

Fig.—Flora Horn., pl. 73.

American *Arbor Vitae*. German, *Abendlandischer Lebensbaum*; French, *Thuja du Canada*.

Habitat Canada and United States. Extensively cultivated as an evergreen.

Flowering time May and June.

Parts employed The young shoots.

Characters. Young shoots compressed, vertical, covered with closely imbricated leaves, which are small, obtuse, with a point, smooth; those of the 2 opposite rows compressed and keeled; the intermediate ones flat, with a glandular point or cell of resin at the back. When rubbed between the hands it gives off a peculiar aromatic resinous odour.

Time for collecting At the commencement of flowering.

Preparation. Tincture, corresponding in alcoholic strength with 20 O.P. spirit.

Process I.

Proper forms for dispensing. \emptyset and upwards, Tincture, Tincture-trituration, Pillules, or Globules.

Average loss of moisture, 58 per cent.

Notes on the B.Hom.P example above

- ▶ The Process 1 referred to is actually a percolation method whereby the ethanol is added gradually and allowed to pass through the fresh pulp before pressing out all the liquids present.
- ▶ The strength of alcohol of the final tincture should be 20OP spirit and Thuja has a 58% loss on drying.
- ▶ Tables are given to show how much rectified spirit (60OP) should be added to mix with the juice to create 20OP, then the mixture is topped up with 20OP spirit to reach the final concentration.
- ▶ For each ounce (437.5 grains) of fresh plant material 1.57 fl. oz of rectified spirit and 1.70 fl oz of 20OP spirit are added.
- ▶ This gives a final ratio of 0.42 oz (dry plant material) plus the following volume of spirit:
0.58 fl oz (juice) + 1.57 (60OP) + 1.70 (20OP) = 3.85 fl oz (20OP)
- ▶ Final concentration 0.42 oz (184 grains) in 3.85 fl oz (1848 minims)

Your notes on the British Homeopathic Pharmacopoeia:

The new method today

The French Fr.Hom.P and American HPUS have metricated the calculations from the old British system and the HPUS uses a coefficient to facilitate the calculations.

The particular ethanolic strengths for each tincture are chosen as follows:

- ▶ tinctures with an alcohol content of 90% v/v: when the botanical substance is a gum or resin, or when it contains volatile oils, provided the moisture content is less than 42 percent (example: *Asafoetida*); Coefficient = 9.27
- ▶ tinctures with an alcohol content of 65% v/v: when the botanical substance contains volatile oils, tannins or alkaloids, provided the moisture content is less than 79 percent (example: *Millefolium*, *Cinchona*); Coefficient = 6.19
- ▶ tinctures with an alcohol content of 55% v/v: when the botanical substance contains volatile oils, tannins or alkaloids, provided the moisture content is not higher than 83 percent (example: *Berberis vulgaris*); Coefficient = 5.11
- ▶ tinctures with an alcohol content of 45% v/v: when the botanical substance contains mucilage, sugars, etc., provided the moisture content is less than 85 percent (example: *Allium cepa*); Coefficient = 4.10
- ▶ tinctures with an alcohol content of 35% v/v: when specified in the individual monograph (example: *Avena sativa*). Coefficient = 3.13

Method for high moisture plants

Botanical substances with a moisture content higher than 85 percent, such as mushrooms, succulent plants or fruits (e.g. *Citrus limonum*), or fleshy roots (e.g. *Raphanus sativus*), cannot be used for preparing 1/10 tinctures, as the alcohol content of such tinctures would not be high enough to enable them to be stored. Tinctures of such substances are therefore prepared with a drug content of 1/20, and will be so noted in the appropriate monograph.

The formulae given are: **A (87% ethanol to add) = DD x C**
W (water to add) = (DD x 10) - A - M

where:

DD = weight of fresh moist material
 M = weight of the moisture
 C = coefficient given as above.

Example

In the **monograph for *Arnica*** (cf. GAP method below) it states that it is a 45% strength tincture. *Arnica* has a loss on drying of 75% and is relatively juicy.

So for 1 kg of fresh *Arnica* containing the equivalent of 0.25 kg dry material we should add:

$$0.25 \times 4.10 \text{ (i.e. the coefficient given above)} = 1.025 \text{ litres 87\% ethanol}$$

and

$$(0.25 \times 10) - 1.025 - 0.75 = 0.725 \text{ litres water}$$

Total liquid present = 1.025 + 0.725 + 0.75 (juice) = 2.5 litres i.e. 0.25 kg in 2.5 litres (45% ethanol)

The 1c is prepared by 10 parts tincture to 90 parts (45% ethanol)
i.e. 1 in 100 relating to the dry weight of plant.

If we go back to the Hahnemannian principle of juice content we see that this tincture contains 0.75 kg of juice in 2.5 litres total liquid i.e. approx. 1/3.33 drug strength.

The Germans would argue that the 1c should be made 3 parts tincture to 97 parts diluent.

If *Arnica* tincture is made by the German method 3 using 43% ethanol.

It would be as follows using 1kg of fresh plant:

$$\begin{aligned} E &= 2 \times M \times D/100 \\ &= 2 \times 1\text{kg} \times 0.75 = 1.50 \text{ kg} \end{aligned}$$

Total liquid content 2.25 kg i.e. exactly a 1/3 drug strength relating to the juice content.

Conclusion

In terms of the amount of solids actually present in most tinctures there are some differences between the two methods, but not extreme for the average plant as the *Arnica* example shows. The actual dissolved solids will still always vary from batch to batch to some degree. It is the nature of dealing with plant material.

The argument is mainly regarding the next step into dilution which is very different giving a significant difference right at the start of potentiation. How much it matters, in practise, is frankly unknown but has a practical bearing on dispensing as mentioned in Unit 1. The definition of a 1x is still not clear and will have a bearing on material strength.

An American formulation considers the mother tincture as the 1x compared with a German product which will make a 1x by diluting the mother tincture 3 parts tincture to 7 parts ethanol thus providing a much weaker solution. Until a European Hom.P emerges we will have to live with the two methods for some time to come and hope a final standard can be achieved in the future.

Example monographs:

1. PLANT SOURCE In order to show a monograph which is commonly used today a good example is *Arnica* in the German Homeopathic Pharmacopoeia.

Arnica, Planta tota

Whole flowering plant of *Arnica montana* L.

DESCRIPTION

All parts of the plant have a pleasantly aromatic odour.

The rhizomes are up to 10 cm long and 1 cm thick, yellowy or pale grey, often curved, sometimes branching or with multiple heads with small knots, annulation, and with blackish brown remnants of scale leaves in the thickened axes. They bear numerous elongated roots that are up to 3mm thick and only have thin adventitious roots in their lower parts. In transverse section the rhizome has a narrow cortex and a central cylinder occupying about two thirds of the diameter with a yellowy stellate woody part and soft light-coloured medulla. The roots have a wide cortical zone, with the central cylinder occupying not more than half the diameter.

The leaves forming a rosette at the base are elongated, obovate and narrow down to a leaf base that in part is narrow and drawn out to appear like a petiole. They are up to 10cm long and up to 4cm wide, with margins entire; slightly wavy in the margin with the apex obtuse or acute.

The main vein is clearly marked and projects on the underside, 2 - 4 delicate veins run lengthwise through the leaf. The leaves are more or less covered with shaggy glandular trichomes and the margins are ciliate.

The round, hollow stem is 20 - 60 cm high, simple or with a few branches; the upper part in particular bears glandular hairs. The stem bears 1 or 2 pairs of opposite or distantly paired leaves that are smaller than the leaves in the rosette.

The stem usually bears one capitulum; only rarely do a few more grow from the axils of the upper leaves on the stem. The capitula are 6 - 8 cm wide and golden to orange yellow. Each is invested with a bell-shaped involucre of 20 - 40 narrow lanceolate bracts arranged in 2 rows; these are 1.3cm long, pointed, with short shaggy hairs green, sometimes with a red tinge. The disc is 0.6 - 1 cm wide, slightly convex and invested with short, stiff white hairs. The 14 - 20 yellow ligulate ray florets are 13 - 23 mm long, usually all female, their corollas are tubular at the base and hairy on the outside and terminate in a 3-toothed ligule that is more or less and irregularly reflexed. Pistil, ovary and pappus are like those of the tubular florets. The 30 or more tubular ray florets open from periphery to centre; they are hermaphrodite and up to 1.3 cm long; the lower part of the corolla is pale yellow, bulbous tubular and hairy on the outside; it widens half way up and terminates in an orangy yellow seam that has five divisions, each with 3 teeth that are more or less reflexed. The stamens are 5 - 6mm long, the cuticulae on the anthers fused to a tube, with the free filaments inserted at about the centre of the corollary tube. The connectives are drawn out into a short triangular lappet at the tip. The branches of the filiform pistil are initially close together and later reflexed apart.

The brownish ovary narrows slightly at the base, is 4 - 6 cm long, elliptical or faintly quadrangular or pentagonal, glabrous at the base and elsewhere, particular at the top densely hairy with trichomes pointing upwards. At the tip is a uniseriate pappus of yellowy white very friable bristles; this is 8 mm long, which is about the same length as the corolla.

MANUFACTURE

The mother tincture and liquid dilutions by Method 3c.

CHARACTERISTICS

The mother tincture is a yellow liquid with characteristic odour and bitter taste.

IDENTIFICATION

A. Dilute 0.5 ml of the mother tincture with 5 ml of water. The solution is opalescent and turns yellow on addition of 0.1 ml of dilute sodium hydroxide solution R.

B. Dilute 1 ml of the mother tincture with 1 ml of ethanol 30 per cent and add 0.2 ml of iron(III) chloride solution R 1. A yellowy green colour is produced.

C. Chromatography. Use thin-layer chromatography in a layer of silica gel H R.

Test solution :

Remove the ethanol from 25 ml of the mother tincture on a water bath. Dilute the residue to 10 ml with water and transfer the solution to a small separating funnel. Add 20 ml of ethyl acetate R and extract for 2 minutes. Add 0.5 g of powdered tragacanth R to the organic phase, filter and evaporate. Dissolve the residue in 1 ml of ethyl acetate R.

Control solution:

Dissolve 10mg of caffeic acid R and 10mg of rutin R in 10 ml of methanol R.

Apply separately 20 μ l of the test solution and 10 microlitres of the control solution. The mobile phase is a mixture of 50 parts by volume of chloroform *I*, 42 parts by volume of acetic acid 98 per cent R and 8 parts by volume of water. Allow the solvent front to rise 15 cm above the line of application. Following complete evaporation of the mobile phase, spray first with a 1 per cent solution (w/v) of diphenylboryloxyethylamine R in methanol R, and then with a 5 per cent solution (w/v) of polyethylene glycol 400 R. Evaluate under ultra-violet light (365 nm).

The chromatogram for the control solution has the orange spot of the rutin standard in the lower and the greeny blue spot of the caffeic acid standard in the middle part.

The chromatogram of the test solution has one to three greeny blue spots, a blue spot and an orange one in ascending order in the range covered by the two standards. Immediately above the caffeic acid standard is a greeny blue spot. Two or three further greeny blue spots appear in the upper part of the chromatogram.

ASSAY FOR PURITY

Relative density (Eur.P.): 0.955-0.969.

Dry residue (German P.): Not less than 1.0 per cent.

STORAGE Protected from light.

Notes on plant monograph example above

As you can see the botanical description is extensive and an independent expert botanist is needed decipher the details. The identification at source, to prove the species is correct, can be facilitated by verification of seeds used as well as a botanical and microscopical examination. The other identification tests are quite straightforward pharmacognosical procedures in the hands of a trained operator. For licensing purposes three batches of tincture have to be tested to show consistency of method and sample quality.

Habitat and collection

Information is also required concerning the growing conditions, i.e. the place and type of soil (organic or otherwise) in which it is grown. The ideal situation is to collect plants in their natural habitats but these are becoming less and less pesticide free and well as being covered by legal restrictions on picking wild flowers and plants.

The time and place of collection, the storage conditions between picking and processing (this should be as soon as possible) and even the type of vessel used for maceration of the tincture must be documented.

Stability and shelf life

Stability data is required for tinctures unless it is freshly prepared for immediate use, and on going stability studies to determine a shelf life is permitted if necessary. The average tincture shelf life is two years.



Study at least two of the following articles on plant tinctures

Journal articles on quality control and standardisation of plant tinctures

- | | |
|--|--|
| Varma PN, Talwar SK, Satsangi AK, <u><i>Statutory control of mother tinctures: Acalypha indica, acalypha indica</i></u> , Hahnemannian Gleanings 1977 Mar;44(3): 126-128 | Varma PN, Saxena VK, Satsangi AK, <u><i>Agaricus muscarius: a method for its identification by thin layer chromatography</i></u> , Hahnemannian Gleanings 1978 Nov;45(11): 510-511 |
| Munshi GK, <u><i>Identification and standardization of homeopathic liquid formulation drugs by TLC and UV spectrophotometry</i></u> , Hahnemann Glean 1984 Sep;51(9):375-7 | Varma PN, Vikramaditya, <u><i>Study of crystals and sublimates. One of the bases for identification and standardisation of homeopathic drugs</i></u> , Hahnemannian Gleanings 1974 Dec;41(12): 548-563 |
| Varma PN, Lohar DR, Ram H, <u><i>Phytochemical studies leading to identification of homeopathic drugs</i></u> , Hahnemannian Gleanings 1981 Feb;48(2): 93-94 | Jolliffe GH, Jolliffe GO, Smith NB, <u><i>Identification of homeopathic mother tinctures</i></u> , Mid Homoeopath Res Grp Newslet. 1982 Aug;(8): 4-9 |
| Varma PN, Saxens VK, Satsangi AK, <u><i>Identification of amino acids in Avena sativa as an additional standard in statutory control of tincture</i></u> , Hahnemannian Gleanings 1979 Feb;46(2): 75-76, | Varma PN, Lohar DR, Hariram, <u><i>The chromatographic studies for differential identification of homeopathic drugs of asclepias species</i></u> , Glean 1983 Jan;50(1):44-7 |
| | <u><i>Standardising homeopathic pharmacy</i></u> , Homoeopath Res Grp Newsletter 1980 Feb;(3): 14 |

Example monographs:

2. INORGANIC SOURCE

A good example of a monograph for an inorganic remedy is Mercury metal known homeopathically as *Mercurius vivus*. Again what follows is taken from the *German Homeopathic Pharmacopoeia*.

Mercurius vivus (Hydrargyrum metallicum)

Hg At.wt. 200.6

Mercury containing not less than 99.5 and not more than 100.5 per cent of Hg.

CHARACTERISTICS

Silvery white liquid that breaks up into small globules if rubbed into paper, not leaving a metallic trace; boils at about 357 °C, relative density about 13.5.

IDENTIFICATION

Test solution: Heat 0.1 g with a mixture of 1 ml of water and 1 ml of nitric acid *R* until dissolved and until the nitrous gases have disappeared. Dilute with sufficient water to produce 10 ml. The test solution yields identity reaction a) for mercury (Eur.P.).

ASSAY FOR PURITY

Appearance: The surface is lustrous and the substance is easily poured from a clean dry glass vessel, leaving no residue adhering to the glass.

Acid-insoluble material: 4.0 g dissolves to give a clear solution in a mixture of 5 ml of water and 5 ml of nitric acid *R* heated gently on a water bath.

ASSAY

Transfer about 0.15 g, accurately weighed, to a 250 ml conical flask, add 1 ml of nitric acid *R* and heat gently on a water bath until dissolved. Leave the solution on the water bath until no more nitrous gases evolve. Add 50 ml of water and 0.05 ml of methyl orange solution *R* and neutralise with dilute sodium hydroxide solution *R*. Add 10.0 ml of 0.1 M sodium EDTA solution and leave to stand for 5 minutes. Add 5 ml of buffer solution pH 10.9 *R*, 100 ml of water and 0.1 g of eriochrome black T mixed indicator *R* and titrate with 0.1 M zinc sulphate solution until the colour changes to red. Add 2 g of potassium iodide to the titrated solution; the solution turns green. Titrate again with 0.1 M zinc sulphate solution until the colour changes to red. 1 ml of 0.1 M zinc sulphate solution in the second titration is equivalent to 20.06 mg of Hg.

PREPARATIONS

The 1st decimal trituration contains not less than 9.5 and not more than 10.5 per cent of Hg.

MANUFACTURE

Trituration by Method 6.

CHARACTERISTICS

The 1st decimal trituration is a grey powder

IDENTIFICATION

Test solution: Suspend 2.00 g of the 1st decimal trituration, accurately weighed, in 15 ml of water in a centrifuge glass and centrifuge. Remove the supernatant liquid with a pipette. Add 10 ml of water to the residue, shake and centrifuge again. Repeat the process three more times. Gently heat the residue in a mixture of 2 ml of water and 2 ml of nitric acid *R* on a water bath until dissolved and until the nitrous gases have disappeared. When cold, transfer to a 25 ml graduated flask, washing with water, and make up to the mark with water. The test solution yields the identity reaction for the substance.

ASSAY

To assay the 1st decimal trituration use 15.0 ml of the test solution. The method is that given for assay of the substance.

Limit test of the 4x

Suspend 1.0 g of the 4th decimal trituration in 10 ml of a solution containing 5 g of sodium chloride *R* and 5 mg of sodium lauryl sulphate in 100 ml, and heat gently on a water bath until the lactose has dissolved; centrifuge. Discard the supernatant liquid, add 10 ml of the above solution of sodium chloride and sodium lauryl sulphate and centrifuge again. Repeat the process twice more. Dissolve the residue in 0.1 ml of hydrochloric acid *R* and 0.1 ml of nitric acid *R* by heating gently on a water bath at about 50 °C. Transfer the solution to a 25 ml graduated flask, washing the centrifuge glass with water, and make up to the mark with water.

Transfer 1.0 ml of the resulting solution to a test tube with ground glass stopper containing 0.1 ml of dithizone solution *R* and shake vigorously.

Add 5.0 ml of chloroform *R* and shake vigorously. When the phases have separated the lower phase is green and not grey or orange.

STORAGE

Protected from light. Store with great care.

Notes on mineral monograph example

The testing methods for inorganic substances is a little easier than for plants as the starting material is less variable and has accompanying data from the chemical manufacturer although this has to be independently verified. The assay is a standard trituration method and is also used to verify the 1x if the decimal scale is prepared. Method 6 is the trituration method described in the GHP as *'divide the vehicle (lactose) into three parts for a short period in a porcelain mortar. Add the basic drug material and triturate for 6 minutes, scrape for 4 minutes with a porcelain spatula, triturate for a further 6 minutes, scrape down again for 4 minutes, add the second part of the vehicle and continue as above. Finally add the third part and proceed as before. The minimum time required for the whole process will thus be 1 hour. The same method is followed for subsequent dilutions'*

The duration and intensity of trituration should be such that the resulting particle size of the drug in the 1x or 1c should be below 10 microns at 80% level; no particle should be more than 50 microns. Notice that a limit test to test verify the dilution level at 4x (i.e. 2c) is included.

Journal references on inorganic remedies

Munshi GK, *Identification of homeopathic inorganic drugs by T.L.C.*
Glean 1983 Oct;50(10):450-1

Huttenrauch R, Fricke S, *Molecular galenical evaluation of the conventional handling of solids in homeopathy* (German),
Pharmazie 1985 Feb;40(2):129-30

Your notes on mineral monograph

Example monographs:**3. ANIMAL SOURCE**

A good example of a monograph for an animal remedy is that of Apis and the following is a translation from the French Pharmacopoeia.

Apis Mellifica

The drug *Apis mellifica* consists of the whole animal *Apis mellifica* L. Only the worker bees are used.

DESCRIPTION OF THE DRUG

Apis mellifica L. is a slightly pubescent brown insect, 12 to 20 mm long.

Observed from the front, the triangular head has a short pair of bent antennae in twelve articles, a pair of reniform compound eyes, and three ocelli in a triangle at the top. The mouth, situated in the lower portion, is composed of mouthparts, of the licking type.

The thorax is formed of three segments. On the upper portion, two pairs of uneven membranous wings are anchored; they are of the same length as the body and are held horizontal when at rest. They are linked, two by two, by chitinous hooks, and are marked by a scant number of veins.

On the lower surface of the thorax, three pairs of legs are anchored. The posterior pair of legs has combs and baskets, or scoops, on the tibia; bristles on the tarsus.

The striped pedunculate abdomen is formed of twelve rings of which only six are visible. It is terminated by a poisonous barbed sting.

IDENTIFICATION

The drug presents the above-described macroscopic characteristics.

TINCTURE

The mother tincture of *Apis mellifica* is prepared at the ethanol content of 65 percent V/V, from the whole animal *Apis mellifica* L., according to the preparation technique for mother tinctures of zoological origin.

CHARACTERISTICS

Pale yellow coloured liquid, with a faint odour and taste.

IDENTIFICATION

A. Add 1 ml of cupri-tartaric solution R to 1 ml of the mother tincture. Bring to a boil. A rust-coloured precipitate is formed.

B. Add a few crystals of ninhydrin R to 1 ml of the mother tincture. Bring to a boil. A purple-blue colour appears.

C. Add 10 ml of water to 1 ml of the mother tincture. Examine the mixture under ultraviolet light at 365 nm. It shows a light blue fluorescence.

TEST

Ethanol content (V.5.3.1). The ethanol content is between 60 and 70 percent V/V.

Dry residue. The dry residue is more than or equal to 0.25 percent.

Chromatography. Examine by thin-layer chromatography (V.6.20.2) using silica gel G R as the coating substance.

Apply to a plate, in a 10 mm band, 30 microlitres of the mother tincture. Develop over a path of 10 cm using a mixture of 63 volumes of ethanol R and 17 volumes of water. Allow the plate to dry in air.

When examined under ultraviolet light at 365 nm, the chromatogram generally shows four or five blue-tinted bands between R_f 0.60 and 0.90.

Spray the plate with ninhydrin solution R and heat at 100-105°C for 10 mm. When examined in daylight, the chromatogram shows a series of six to eight purplish-pink bands between R_f 0.35 and 0.90.

Spray a second chromatogram prepared under the same conditions with phtalic aniline solution R, then heat at 100 - 105°C for 10 mm. When examined in daylight, the chromatogram shows an ochre-tinted brown band at about R_f 0.80.

Notes on animal monograph example

The verification of source material for animals is similar to that for plants although the absence of pathogens has to be verified to ensure the animal is not diseased. Identification of the species has to be well supported and details of collection and immediate processing as required for plants. The identification tests are also similar to those used for plants and chromatography is the standard procedure.

The technique for mother tinctures of zoological origin, in the Fr.Hom.P, uses the dry weight calculation but recommends all animal tinctures be a 1/20 drug strength. A sample animal, or animals, are tested for loss on drying and sufficient ethanol and water are added to give the required volume and concentration in the final tincture. This is similar to the HPUS methodology. The animals parts are chopped finely and the 10 day maceration is shaken daily before filtering, leaving it to stand and filtering again before use.

The 1c is prepared by diluting 20 parts tincture with 80 parts of ethanol 65%.

The German method for Apis uses a 1/10 method using 62% ethanol and in this case the 1c is of identical strength whichever pharmacopoeia is used.

Journal Articles on Pharmacopoeia treatment of Apis

Baker WP, Baker CP, [Apiotherapy, apis, apium venenum, homeopathic pharmacopoeias](#), J Am Inst Homeopath 1982 Mar;75(1): 7-10

Similar tincture methods, as the above, are used for other animal remedies such as Vespa (wasp), The Tarentula spiders, Cantharis (Spanish Fly) and Blatta Orientalis (Cockroach).

Journal articles on pharmacopoeia

McCrae WR, *On proposed British homeopathic pharmacopoeia* (L),
Br Homoeopath J 1945 35: 65

Leeser O, *Report on new British homeopathic pharmacopoeia*,
Br Homoeopath J 1943 33: 102-128

Leeser O, *Towards a new British pharmacopoeia*,
Br Homoeopath J 1937 27: 96

Ainsworth JB, *Homeopathic pharmacopoeia*,
Br Homoeopath J 1987 76: 199

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Br Homoeopath J 1944 34: 114

Menou J, *La matiere medicale aussi...*,
Cah Group Hahnemann Doct P Schmidt 1987;24(3):109-10

Broese R, *German homeopathic pharmacopoeia and manufacturing of homeopathic medicaments*,
De Natura Rerum 1989 Feb;3(1):12-8, English summary

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Int J Vet Homoeopath 1988 Nov;3(2):8-18

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Homeopath 1980 Dec;73(4): 9-10

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J Am Inst Homeopath 1968 Apr-Jun;61(4-6): 111-115

Ainsworth J, *Homeopathic pharmacopoeia. What are the problems*,
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Baker WP, *Progress on the Homeopathic Pharmacopoeia*,
J Am Inst Homeopath 1980 Dec;73(4): 6-8

Good Manufacturing Practice

The manufacturing of homeopathic medicines requires the same stringent controls and environmental conditions as any other drug manufacturer. Segregated areas of operation are required for potentising, medicating and assembling. Temperature regulation, pest control and standard operating procedures for literally every activity, including cleaning, are necessary and a high level of hygiene is required at all times with white coats and hats ever present. Regular MCA inspections take place every two years to ensure standards are kept up and procedures are followed.

The principles of quality assurance are ensured by a quality control laboratory and manager with a qualified person on hand for final releasing of finished products. The principles of batch numbering, quarantine and release are strictly adhered to for every component associated with remedy manufacture from tincture and raw materials to labels and packaging. Retained sampling, complaint revision and an efficient product recall system is also required.

Introducing a range of remedies onto the market is a long and expensive affair with much data to compile for each individual substance as described above. Once the tincture has been made, and passed, potentisation is carried out with constant double checking of batch numbers of components (i.e. tinctures, ethanol, tablets and pillules) and verification that each step of the dilution and succussion has been completed.

There are some basic rules which apply when potentising or medicating on a large or small scale. One remedy should be prepared or handled at a time with a cleaning procedure done between large batches. Glassware should never be reused and it is usual to have disposable tubes for potentising. Diluents or unmedicated tablets should always be introduced first, into a new bottle or tube, before adding the potency. A medicated vessel should never be brought close to an inert diluent or tablet dispenser. Combinations of remedies in potency must be made using disposable tubes to transport and mix the potencies to avoid contamination of the stored potency bottles.

It is usual to make a large quantity of the potency to be used for medication e.g. 30c. or of the potency before i.e. 29c so that a one step dilution and succussion can be done each time a bulk medication prepared. Validation of uniform medication must be carried out and can be done using dyes, such as cochineal, or by ethanol content tests of tablets and pillules. Loss on drying for each batch of medicated tablets is an on going everyday activity to ensure a consistent moisture content of the final product. The raw solid dosage form used must be routinely tested on arrival and the expiry date of a homeopathic medicine is based on the stability of the dosage form after medication. On going stability studies are required to justify the maximum expiry date which is usually 5 years. It is widely accepted, from the experience of homeopaths, that remedies stay active beyond 5 years if stored away from antidoting influences, but at present the 5 year limit is the maximum permitted.

After medication the assembling of remedies involves the use of production documents and double checking systems must be followed at all stages as there are no identification marks on homeopathic remedies. Filling and capping is carried out in a room separate from medication and free from contamination of possible adverse influences such as strong light, odours etc. Finally labelling and

packaging is completed in yet another area before the final release and retained sample is put away. Storage conditions of all products must be below 30°C in clean, dry and pest free areas.

Journal articles on quality control

Barthel P. Quality and posology: look at the sources. *Homoeopath Links*, 1996, Winter;9(4):184-185,

Barthel P. Quality standards and posology. Proc. 51st LMHI Congr., Capri, Italy, 1996, 96-97,

Vaid I. Trendsetters to statutory quality control of homeopathic medicines. *Homoeopath Heritage*, 1995, Mar;20(3):163-4

Zacharias CR. Contaminants in commercial homeopathic medicines: a spectroscopic determination. *Br Homoeopath J*, 1995, Apr;84(2):71-4,

Cook T. Quality control in homeopathic medicines. *Br Homoeopath J* 1978 67: 208

Boyd WE, Purity in potentizing (L), *Br Homoeopath J* 1933 23: 107

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Barthel P. Hahnemann's legacy - quality standards for homeopathic medicines. Proc. 49th LMHI Congress, New Delhi, 1995, 329-336,

Singh DM. Standardisation of homeopathic drugs: a pharmaceutical perspective. *CCRH Quarterly Bulletin*, 1995, ;17(1&2):25-26

Self Study & Parallel Reading

At home study pp 55-58 on quality control in your companion text: *Homeopathic Pharmacy*: S Kayne

Reference Textbooks

The Organon: S Hahnemann

Homeopathic Pharmacy: S Kayne, Churchill Livingstone

The Science of Homeopathy - George Vithoulkas

A Guide to the Methodologies of Homeopathy - Ian Watson

Homeopathy in Practice - Borland

The Complete Homeopathy Handbook - Miranda Castro

Homeopathic Pharmacy - Steven Kayne

Textbook on Homeopathic Pharmacy - DD Banerjee

Essential Theory Guide to Homeopathic Pharmacy - SK Banerjee

Synoptic Materia Medica - Frans Vermeulen

A treatise on homeopathic pharmacy_ Banerjee NK Sinha N. Calcutta, Salzer & Co, No year

Dictionary of Homeopathic Medicine. - ed. Jeremy Swayne

Other Reference Sources

Raj J. [Factors involved in the production of homeopathic drugs](#). CCRH Quarterly Bulletin, 1996, ;18(1&2):19-21

Summary checklist for WEEKS 3-6

Before proceeding to the next section check that you:

- know something of the history of pharmacopoeia development
- can name the three main reference pharmacopoeias
- understand which of Hahnemann's methods have changed significantly since *The Organon* ed. 6
- have an awareness of the issues surrounding standardisation particularly in tincture preparation
- be familiar with the most important methods of quality control in homeopathic manufacture

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Cookinham FH. [Influenza.](#) Homoeopath Heritage, 1996, May;21(5):265-271
Gilruth C. [A new view of the flu.](#) Homeopathy Today, 1996, Apr;16(4):14,16, Herzberger G Weiser M. [Homeopathic treatment of infections of various origins: a prospective study.](#) Biomed Ther, 1997, Oct;15(4):123-127,
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Answers to SAQs

6.2 *Answer: 1.7219 kg*