
Method for the production of a plant-based medicament

The present invention relates to a method for the production of a plant-based medicament which contains *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*, *Carvi fructus*, *Mellissae folium*, *Angelicae radix*, *Liquiritiae radix*, *Cardui mariae fructus* and *Chelidonii herba* in the form of alcoholic extracts, and a medicament produced by this method, and its use.

Iberogast is a plant-based medicament (herbal combination preparation, phytopharmaceutical product), which is used for the treatment of functional dyspepsia and in gastrointestinal multitarget therapy. It has both a tonus-increasing effect in relaxed smooth musculature and also has a spasmolytic effect in paroxysmal states of the smooth musculature. The active pharmaceutical ingredients of this phytopharmaceutical product are preparations of fresh plants and herbal drugs, (dried plants or parts of plants) as ethanolic, liquid extracts. Iberogast contains extracts of *Iberis amara* (bitter candytuft), *Menthae piperitae folium* (peppermint leaves), *Matricariae flos* (chamomile flowers), *Carvi fructus* (caraway fruit), *Mellissae folium* (lemon balm leaves), *Angelicae radix* (angelica root), *Liquiritiae radix* (liquorice root), *Cardui mariae fructus* (milk thistle fruit) and *Chelidonii herba* (celandine).

European Patent EP 0550 703 B1 already describes a plant-based medicament with a limited number of 6 extracts.

Iberogast itself, which comprises 9 extracts, is a medicament which has been well-established for years. The pharmaceutical quality of the extracts has a decisive influence on the effectiveness and harmlessness of herbal medicaments. In addition to complying with specifications of the initial drugs in accordance with the pharmacopeia, the reproducibility of the production processes (validation) is the essential prerequisite for the high standard as German and European phytopharmaceutical product. Based on the new guidelines, which also apply to herbal medicaments in relation to the respective European regulations, there is an obligation to be consistent with the information regarding content which is declared for the respective medicament. Deviation from this information may only be $\pm 5\%$ of the declared content of the ingredients which determine effectiveness (lead substance, active marker or analytical marker substance).

It has proved to be problematic to obtain a constant effective substance content in the finished medicament Iberogast and to obtain a consistent, reproducible quality. Corresponding investigations with regard to the pharmaceutical development indicated precipitations/crystal formation in the extract of angelica root, which led to inhomogeneities in the production batch and consequently led to unacceptable fluctuations of the osthol content (lead substance). On the one hand, the recovery rate of the osthol content increased in the first weeks after the first analysis in clear-filtered solutions, and on the other hand

the total content decreased in production batches in accordance with the sediment formation.

It was therefore an object of the present invention to make possible a constant effective substance content in the finished medicament with a consistent, reproducible quality in the final package over a longer period of time.

This problem was solved by a method for the production of a plant-based medicament as disclosed herein.

According to one aspect, there is provided a method for the production of a plant-based medicament which contains *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*, *Carvi fructus*, *Melissae folium*, *Angelicae radix*, *Liquiritiae radix*, *Cardui mariae fructus* and *Chelidonii herba* in the form of alcoholic extracts, characterized in that in a first step a) *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in a volume ratio of 1:6 to 3:1 and subsequently in at least one further step the mixture of step a) is mixed together with the extracts of the further ingredients or mixtures containing them, which are produced separately and if applicable additionally contain *Liquiritiae radix*.

According to another aspect, there is provided a plant-based medicament produced according to a method as defined above.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above for the treatment of disorders of the gastrointestinal tract.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above for the treatment of functional dyspepsia.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above to inhibit gastric juice production.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above for the treatment of ulcers.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above as an anti-inflammatory and/or anti-phlogistic.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above as an antioxidant and/or radical scavenger.

According to yet another aspect, there is provided the use of a plant-based medicament as defined above as modulator of gastrointestinal mobility.

In other words, this problem is solved by a method for the production of a plant-based medicament which contains *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*,

Carvi fructus, Mellissae folium, Angelicae radix, Liquiritiae radix, Cardui mariae fructus and Chelidonii herba in the form of alcoholic extracts, wherein in a first step a) Angelicae radix extract and Liquiritiae radix extract are mixed together in a volume ratio of 1:6 to 3:1 and then in at least one further step the mixture of step a) is added together with the extracts of the further ingredients or mixtures containing them, which are produced separately and if applicable once again contain Liquiritiae radix.

With the background of the problem which is posed, a range of process methods and also analytical methods were investigated or specifically developed. In particular, the volatile components of the drugs with etheric oils and the precipitations/crystal formation in the extract of angelica root led to non-reproducible quality fluctuations. Surprisingly, only the use of a production method as disclosed herein emerged as being effective. A crucial factor here is the sequence of additions of the individual drug

extracts. A preferred variant of the method according to the invention for the production of a plant-based medicament is characterized in that in a step b) a mixture is produced containing extracts of *Matricariae flos*, *Iberis amara* and *Carvi fructus*, the mixture of step a) is added to this and in a step c) extracts of *Cardui mariae fructus*, *Menthae piperitae folium*, *Melissae folium* and *Chelidonii herba* are added. Step a) is as defined above, i.e. *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in a volume ratio of 1:6 to 3:1.

It is to be assumed that the saponins of the liquorice extract stabilize the osthol in the angelica extract and that they subsequently emulsify the etheric oils of the predominantly oleiferous drugs (chamomile, *Iberis amara* and caraway). In addition, it is presumed that the mucilaginous drugs such as milk thistle prevent the sedimentation (milk thistle, mint, lemon balm). The mixing sequence (addition sequence) prevents the formation of crystals of the ingredients (secondary plant substances) of the herb extracts. The crystal formation affects the batch homogeneity. Therefore, the addition sequence according to the invention ensures a reproducible production of the product.

In each case, single extracts are used. Compared with multiple extracts, the mixture of single extracts has the advantage that for the respective drugs and fresh plants, optimum extractants and extraction conditions can be selected, and the ingredients which determine the effectiveness or are pharmaceutically relevant are thus present in a good yield. The transition rates of the ingredients and those of the extractive substance yields of

the drug which is used are traceable, which is of great importance for the analysis.

Preferably, in the method according to the invention for the production of a plant-based medicament, mixtures containing extracts of *Menthae piperitae folium*, *Carvi fructus* and *Melissae folium*; *Cardui mariae fructus* and *Matricariae flos*; and *Iberis amara* and *Chelidonii herba* are produced separately.

In particular, it is preferred that *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in step a) in a volume ratio of 1:2 to 2:1. In a particularly preferred embodiment of the method according to the invention, *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in step a) in a volume ratio of 1:1.

Proceeding from the initial mixing of *Angelicae radix* extract and *Liquiritiae radix* extract in step a), different variants of the further mixture have surprisingly proved to be particularly suitable.

A preferred embodiment of the production method according to the invention is based on the fact that in a step b) the mixture of step a) is mixed together with a mixture containing extracts of *Menthae piperitae folium*, *Carvi fructus* and *Melissae folium*, in a step c) a mixture containing extracts of *Cardui mariae fructus* and *Matricariae flos* is added and in a step d) the addition takes place of a mixture containing extracts of *Iberis amara* and *Chelidonii herba*.

A likewise preferred embodiment is characterized in that in a step b) the mixture of step a) is mixed together with a mixture containing extracts of *Menthae piperitae folium*, *Carvi fructus* and *Melissae folium*, in a step e) a mixture containing extract of *Cardui mariae fructus* and *Matricariae flos* with a mixture containing extracts of *Iberis amara* and *Chelidonii herba* are mixed together and in a step f) the mixtures of steps b) and e) are mixed together.

Based on an initial mixture of *Angelicae radix* extract and *Liquiritiae radix* extract in step a) in a volume ratio of 1:6 to 3:1, it has likewise proved to be preferred to additionally add a particular proportion of the *Liquiritiae radix* extract in a later step. Accordingly, a preferred embodiment of the present invention is characterized in that the mixture containing *Menthae piperitae folium* extract, *Carvi fructus* extract and *Melissae folium* extract additionally contains *Liquiritiae radix* extract. It is particularly preferred here if the mixture containing *Menthae piperitae folium* extract, *Carvi fructus* extract and *Melissae folium* extract additionally contains *Liquiritiae radix* extract, wherein the volume of the containing *Liquiritiae radix* extract is in the ratio 1:1 to the volume of *Liquiritiae radix* extract contained in the mixture of *Angelicae radix* extract and *Liquiritiae radix* extract from step a).

According to the invention, the production method is directed to the production of a plant-based medicament, which comprises

15 to 40 vol.% *Iberis amara*,

5 to 30 vol.% *Menthae piperitae folium*,

20 to 40 vol.% *Matricariae flos*,

10 to 30 vol.% Carvi fructus,
10 to 30 vol.% Melissae folium,
5 to 30 vol.% Angelicae radix,
10 to 30 vol.% Liquiritiae radix,
5 to 30 vol.% Cardui mariae fructus and
5 to 30 vol.% Chelidonii herba in the form of alcoholic
extracts. The method is preferably directed to the
production of a plant-based medicament, which comprises
15 vol.% Iberis amara,
5 vol.% Menthae piperitae folium,
20 vol.% Matricariae flos,
10 vol.% Carvi fructus,
10 vol.% Melissae folium,
10 vol.% Angelicae radix,
10 vol.% Liquiritiae radix,
10 vol.% Cardui mariae fructus and
10 vol.% Chelidonii herba in the form of alcoholic
extracts.

It is preferred to use extracts from fresh plants or drug
extracts. In particular, it is to be preferred if the
Iberis amara extract is a fresh plant extract of Iberis
amara totalis (flowers, leaves, stem and roots). The
harvesting of Iberis amara fresh plant with flowers,
leaves, stem, roots takes place at a time at which the
content of flavonoids has reached its optimum. Within the
framework of flavonoids, the glycosides of kaempferol are
particularly relevant as antiphlogistics. The extract of
the fresh plant contains, as the most important flavonoid,
kaempferol-3,4'-di-O- β -glucopyranoside-7-O- α -
rhamnopyranoside. The fresh plant preferably contains at
least 100 μ g/g flavonoids, in particular kaempferol-3,4'-

di-O- β -glucopyranoside-7-O- α -rhamnopyranoside. With regard to the *Iberis amara* fresh plant extract, it is preferred if this has a flavonoid content of kaempferol-3,4'-di-O- β -glucopyranoside-7-O- α -rhamnopyranoside of 0.05 to 0.2 mg/ml.

The plant material according to the invention additionally contains a limited content of cucurbitacins, in particular cucurbitacin I and E. The fresh plant preferably contains a content of cucurbitacin I of a maximum of 500 μ g/g and a content of cucurbitacin E of likewise a maximum of 500 μ g/g. Higher values are not desired, because after a certain threshold value, these substances have a side-effect potential. With regard to the extract, it is preferred that the *Iberis amara* extract is a fresh plant extract which has a content of cucurbitacins of 0 to 200 μ g/ml. It is particularly preferred here if the *Iberis amara* extract is a fresh plant extract which has a content of cucurbitacins of 35 to 185 μ g/ml. In particular, it is to be preferred that the *Iberis amara* extract is a fresh plant extract which has a content of cucurbitacin I of 0 to 100 μ g/ml and a content of cucurbitacin E of 0 to 100 μ g/ml.

As already mentioned, extracts from fresh plants or drug extracts can be used. Preferably, the method according to the invention is characterized in that the extracts of *Menthae piperitae folium*, *Matricariae flos*, *Carvi fructus*, *Melissae folium*, *Angelicae radix*, *Liquiritiae radix*, *Cardui mariae fructus* and *Chelidonii herba* are drug extracts.

With regard to the fresh plant extract of *Iberis amara totalis*, it is to be preferred that the ratio of macerated/percolated plant to the extract is between 1 gram : 10 ml (10 gram) and 1 gram : 1 ml (1 gram). In particular, it is preferred that with the fresh plant extract, the ratio of macerated/percolated plant to the extract is from 1 gram : 1.5 ml (1.5 gram) to 1 gram : 2.5 ml (2.5 gram).

Preferably, with the drug extracts the ratio of drugs to the extract is from 1 gram : 1 ml (1 gram) to 1 gram : 10 ml (10 gram). It is particularly preferred here if with the drug extracts the ratio of drugs to the extract is from 1 gram : 2 ml (2 gram) to 1 gram : 4 ml (4 gram). In a preferred embodiment, the ratio in the case of drug extracts of drugs to the extract is from 1 gram : 2.5 ml (2.5 gram) to 1 gram : 3.5 ml (3.5 gram).

The preferred extractant comprises water and aqueous ethanol with a concentration of 0.1 to 60 vol.% ethanol. Particularly preferably, the extractant comprises aqueous ethanol with a concentration of 30 to 50 vol.% ethanol. In a preferred embodiment, the extractant for the fresh plant extract is aqueous ethanol with a concentration of 50 vol.% ethanol and the extractant for the drug extracts is aqueous ethanol with a concentration of 30 vol.% ethanol.

The present invention also comprises a plant-based medicament which was produced by the method according to the invention.

Likewise, the present invention comprises the use of this plant-based medicament for the treatment of disorders of

the gastrointestinal tract, in particular for the treatment of functional dyspepsia.

Furthermore, the use of the plant-based medicament is preferred for the inhibition of gastric juice production, and the use for the treatment of ulcers.

The medicament is preferably used as an anti-inflammatory and/or anti-phlogistic. Likewise, the use as antioxidant and/or radical scavenger is preferred.

A further preferred use is constituted by the usage of the medicament according to the invention as a modulator of gastrointestinal mobility.

The crystal formation is significantly inhibited when the mixture sequence according to the invention is adhered to. Without adhering to this sequence, the content values for osthol lie far outside the permissible tolerance both in the angelica drug extract and also in the finished product, i.e. the recovery of the lead substance osthol did not lie in the range of 95 to 105% of the target value. The batches produced with adherence to the mixture sequence according to the invention no longer had any deviations. Likewise, it can be seen that when the sequence is adhered to, scarcely any crystal formation is to be observed. For example, Fig. 1 and 2 show the batch homogeneity with regard to the examined plant ingredient (osthol) with an arbitrary sequence (Fig. 1) and with the mixture sequence according to the invention of the individual herb extracts in accordance with Examples 1, 2 and 3 (Fig. 2). The examples 1, 2 and 3 according to the invention did not show any

appreciable differences, so that a separate representation was dispensed with.

The invention is further explained below with the aid of examples.

EXAMPLES

Production formula

Ingredients	Amount in g	Amount in ml
Drug extract of chamomile flowers (1 : 2 - 4)	1980	2000
Fresh plant extract of bitter candytuft (1 : 1.5 - 2.5)	1455	1500
Drug extract of caraway (1 : 2.5 - 3.5)	975	1000
Mixture of drug extract of liquorice root (1 : 2.5 - 3.5)	990	1000
Drug extract of angelica root (1 : 2.5 - 3.5)	990	1000
Drug extract of milk thistle fruit (1 : 2,5 - 3.5)	970	1000
Drug extract of peppermint leaves (1 : 2.5 - 3.5)	495	500
Drug extract of lemon balm leaves (1 : 2.5 - 3.5)	990	1000
Drug extract of celandine (1 : 2.5 - 3.5)	990	1000
Extractant for Iberis amara: ethanol 50% (V/V)		
Extractant for all other drug extracts: ethanol 30% (V/V)		

The individual ingredients must be mixed homogeneously before weighing. The ingredients are weighed in and mixed successively according to the production formula into high-grade steel and plastic containers.

Example 1 - Sequence A

Pre-mixture: A pre-mixture of liquorice root extract and angelica root extract is produced in the ratio 1 : 1. The ingredients are weighed in successively and mixed according to the production formula.

Final mixture: The ingredients peppermint leaf drug extract, caraway drug extract and lemon balm drug extract are mixed. The pre-mixture is then added to this. The ingredients chamomile drug extract and milk thistle drug extract, and also celandine drug extract and the fresh plant extract candytuft are weighed in to this. The extracts are mixed.

Example 2 - Sequence B

Pre-mixture: Angelica root extract and liquorice root extract are mixed 1 : 1.

Final mixture: The ingredients peppermint leaf drug extract, caraway drug extract and lemon balm drug extract are mixed. Added to this mixture is the mixture of angelica root extract and liquorice root extract. A mixture of milk thistle fruit drug extract and chamomile drug extract is produced separately with a mixture of celandine drug extract and fresh plant extract candytuft. The mixtures are finally mixed together.

Example 3 - Sequence C

Pre-mixture: A pre-mixture of liquorice root extract and angelica root extract is produced in the ratio 1 : 2 (1 part : 2 parts). The ingredients are weighed in successively and mixed according to the production formula.

Final mixture: A further part of liquorice root extract is mixed together with peppermint leaf drug extract, lemon balm leaf drug extract and caraway drug extract. The obtained mixture is mixed with the pre-mixture. Chamomile drug extract and milk thistle drug extract and also fresh plant extract candytuft and celandine drug extract are then added.

The obtained solutions of Examples 1, 2 and 3 are stored in high-grade steel or plastic tanks at room temperature (15 - 25°C) for at least 14 days (including the storing and retrieval days).

The osthol content was determined with regard to samples which were produced according to the mixture sequences of Examples 1, 2 and 3. A comparison was made with samples which were based on an arbitrary mixture sequence of the individual herb extracts. The results of the measurements are displayed in Figures 1 (arbitrary mixture sequence, without pre-mixture) and 2 (mixture sequences according to the invention). As can be seen from Fig. 2, the mixture sequence prevents the formation of crystals of the ingredients (secondary plant substances) of the herb extracts.

The crystal formation was examined microscopically, wherein the measurements took place after 2 and respectively 6 weeks' storage. The results are displayed in Tables 1 and 2.

Table 1: 2 weeks' storage at room temperature

Example 1	Example 2	Example 3
Sediment light, dark, powdery; supernatant colloidal, very turbid; uniform particles of approx. 2 μm , isolated small crystals up to 2 μm	Sediment thin, dark, powdery; supernatant colloidal, very turbid; uniform particles of approx. 2 μm , partly agglomerated; isolated small crystals approx. 1 μm	Sediment thin, dark, powdery; supernatant colloidal, very turbid; uniform particles of approx. 2 μm , a few agglomerated; small crystals

Table 2 : 6 weeks' storage at room temperature

Example 1	Example 2	Example 3
Sediment light, dark, powdery; supernatant colloidal, slightly turbid; sediment of uniform particles, connected in a gel-like manner, of approx. 2 μm , several small crystals up to 4 μm	Sediment light, dark, powdery; supernatant colloidal, slightly turbid; uniform particles of approx. 2 μm , partly agglomerated in a mucous-like manner, isolated small crystals approx. 1 μm , a few up to 2 μm	Sediment light, dark, powdery; supernatant weakly colloidal, scarcely turbid; uniform particles of approx. 2 μm , a few agglomerated, several quite small crystals 1 μm , a few needles up to 2 μm

Claims

1. Method for the production of a plant-based medicament which contains *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*, *Carvi fructus*, *Melissae folium*, *Angelicae radix*, *Liquiritiae radix*, *Cardui mariae fructus* and *Chelidonii herba* in the form of alcoholic extracts, characterized in that in a first step a) *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in a volume ratio of 1:6 to 3:1 and subsequently in at least one further step the mixture of step a) is mixed together with the extracts of the further ingredients or mixtures containing them, which are produced separately and if applicable additionally contain *Liquiritiae radix*.
2. Method for the production of a plant-based medicament according to Claim 1, characterized in that in a step b) a mixture containing extracts of *Matricariae flos*, *Iberis amara* and *Carvi fructus* is produced, the mixture of step a) is added thereto and in a step c) extracts of *Cardui mariae fructus*, *Menthae piperitae folium*, *Mellissae folium* and *Chelidonii herba* are added.
3. Method for the production of a plant-based medicament according to Claim 1 or 2, characterized in that mixtures containing extracts of *Menthae piperitae folium*, *Carvi fructus* and *Melissae folium*; *Cardui mariae fructus* and *Matricariae flos*; and *Iberis amara* and *Chelidonii herba* are produced separately.

4. Method for the production of a plant-based medicament according to any of Claims 1 to 3, characterized in that *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in step a) in a volume ratio of 1:2 to 2:1.
5. Method for the production of a plant-based medicament according to any of Claims 1 to 4, characterized in that *Angelicae radix* extract and *Liquiritiae radix* extract are mixed together in step a) in a volume ratio of 1:1.
6. Method for the production of a plant-based medicament according to any of Claims 1 to 5, characterized in that in a step b) the mixture of step a) is mixed together with a mixture containing extracts of *Menthae piperitae folium*, *Carvi fructus* and *Melissae folium*, in a step c) a mixture containing extracts of *Cardui mariae fructus* and *Matricariae flos* is added and in a step d) the addition of a mixture containing extracts of *Iberis amara* and *Chelidonii herba* takes place.
7. Method for the production of a plant-based medicament according to any of Claims 1 to 6, characterized in that in a step b) the mixture of step a) is mixed together with a mixture containing extracts of *Menthae piperitae folium*, *Carvi fructus* and *Melissae folium*, in a step e) a mixture containing extract of *Cardui mariae fructus* and *Matricariae flos* with a mixture containing extracts of *Iberis amara* and *Chelidonii herba* are mixed together and in a step f) the mixtures of the steps b) and e) are mixed together.

8. Method for the production of a plant-based medicament according to any of Claims 1 to 7, characterized in that the mixture containing *Menthae piperitae folium* extract, *Carvi fructus* extract and *Melissae folium* extract additionally contains *Liquiritiae radix* extract.
9. Method for the production of a plant-based medicament according to any of Claims 1 to 8, characterized in that the mixture containing *Menthae piperitae folium* extract, *Carvi fructus* extract and *Melissae folium* extract additionally contains *Liquiritiae radix* extract, wherein the volume of the containing *Liquiritiae radix* extract is in the ratio 1:1 to the volume of *Liquiritiae radix* extract contained in the mixture of *Angelicae radix* extract and *Liquiritiae radix* extract of step a).
10. Method for the production of a plant-based medicament according to any of Claims 1 to 9, which comprises
 - 15 to 40 vol.% *Iberis amara*,
 - 5 to 30 vol.% *Menthae piperitae folium*,
 - 20 to 40 vol.% *Matricariae flos*,
 - 10 to 30 vol.% *Carvi fructus*,
 - 10 to 30 vol.% *Melissae folium*,
 - 5 to 30 vol.% *Angelicae radix*,
 - 10 to 30 vol.% *Liquiritiae radix*,
 - 5 to 30 vol.% *Cardui mariae fructus* and
 - 5 to 30 vol.% *Chelidonii herba*in the form of alcoholic extracts.
11. Method for the production of a plant-based medicament according to any of Claims 1 to 10, which comprises

15 vol.% *Iberis amara*,
5 vol.% *Menthae piperitae* folium,
20 vol.% *Matricariae* flos,
10 vol.% *Carvi* fructus,
10 vol.% *Melissae* folium,
10 vol.% *Angelicae* radix,
10 vol.% *Liquiritiae* radix,
10 vol.% *Cardui mariae* fructus and
10 vol.% *Chelidonii* herba
in the form of alcoholic extracts.

12. Method for the production of a plant-based medicament according to any of Claims 1 to 11, characterized in that extracts of fresh plants or drug extracts are used.
13. Method for the production of a plant-based medicament according to any of Claims 1 to 12, characterized in that the *Iberis amara* extract is a fresh plant extract of *Iberis amara* totalis (flowers, leaves, stem and roots).
14. Method for the production of a plant-based medicament according to any of Claims 1 to 13, characterized in that the *Iberis amara* extract is a fresh plant extract which has a flavonoid content of 0.05 to 0.2 mg/ml.
15. Method for the production of a plant-based medicament according to any of Claims 1 to 14, characterized in that the *Iberis amara* extract is a fresh plant extract which has a content of cucurbitacins of 0 to 200 µg/ml.

16. Method for the production of a plant-based medicament according to any of Claims 1 to 15, characterized in that the *Iberis amara* extract is a fresh plant extract which has a content of cucurbitacins of 35 to 185 µg/ml.
17. Method for the production of a plant-based medicament according to any of Claims 1 to 16, characterized in that the *Iberis amara* extract is a fresh plant extract which has a content of cucurbitacin I of 0 to 100 µg/ml and a content of cucurbitacin E of 0 to 100 µg/ml.
18. Method for the production of a plant-based medicament according to any of Claims 1 to 17, characterized in that the extracts of *Menthae piperitae* folium, *Matricariae* flos, *Carvi* fructus, *Melissae* folium, *Angelicae* radix, *Liquiritiae* radix, *Cardui mariae* fructus and *Chelidonii* herba are drug extracts.
19. Method for the production of a plant-based medicament according to any of Claims 1 to 18, characterized in that in the fresh plant extract, the ratio of macerated/percolated plant to the extract is between 1 gram : 10 ml (10 gram) and 1 gram : 1 ml (1 gram).
20. Method for the production of a plant-based medicament according to any of Claims 1 to 19, characterized in that in the fresh plant extract, the ratio of macerated/percolated plant to the extract is from 1 gram : 1.5 ml (1.5 gram) to 1 gram : 2.5 ml (2.5 gram).

21. Method for the production of a plant-based medicament according to any of Claims 1 to 20, characterized in that in the drug extract, the ratio of drugs to the extract is from 1 gram : 1 ml (1 gram) to 1 gram : 10 ml (10 gram).
22. Method for the production of a plant-based medicament according to any of Claims 1 to 21, characterized in that in the drug extract, the ratio of drugs to the extract is 1 gram : 2 ml (2 gram) to 1 gram : 4 ml (4 gram).
23. Method for the production of a plant-based medicament according to any of Claims 1 to 22, characterized in that in the drug extract, the ratio of drugs to the extract is from 1 gram : 2.5 ml (2.5 gram) to 1 gram : 3.5 ml (3.5 gram).
24. Method for the production of a plant-based medicament according to any of Claims 1 to 23, characterized in that the extractant comprises water and aqueous ethanol with a concentration of 0.1 to 60 vol.% ethanol.
25. Method for the production of a plant-based medicament according to any of Claims 1 to 24, characterized in that the extractant comprises aqueous ethanol with a concentration of 30 to 50 vol.%.
26. Method for the production of a plant-based medicament according to any of Claims 1 to 25, characterized in that the extractant for the fresh plant extract is

aqueous ethanol with a concentration of 50 vol.% ethanol, and the extractant for the drug extracts is aqueous ethanol with a concentration of 30 vol.% ethanol.

27. Plant-based medicament produced according to a method in accordance with Claims 1 to 26.
28. Use of a plant-based medicament according to Claim 27 for the treatment of disorders of the gastrointestinal tract.
29. Use of a plant-based medicament according to Claim 27 or 28 for the treatment of functional dyspepsia.
30. Use of a plant-based medicament according to Claim 27 or 28 to inhibit gastric juice production.
31. Use of a plant-based medicament according to Claim 27 or 28 for the treatment of ulcers.
32. Use of a plant-based medicament according to Claim 27 or 28 as an anti-inflammatory and/or anti-phlogistic.
33. Use of a plant-based medicament according to Claim 27 or 28 as an antioxidant and/or radical scavenger.
34. Use of a plant-based medicament according to Claim 27 or 28 as modulator of gastrointestinal mobility.

ABSTRACT

The present invention relates to a method for the production of a plant-based medicament which contains Iberis amara, Menthae piperitae folium, Matricariae flos, Carvi fructus, Melissa folium, Angelicae radix, Liquiritiae radix, Cardui mariae fructus and Chelidonii herba in the form of alcoholic extracts and a medicament produced according to this method, and its use.