

The Kolisko Validation™ Method:

Improving the Quality Control of Homeopathically Potentized OTC Drugs

Ross Rentea MD, Mark Kamsler MD

Summary:

We describe a standardized biological test, the Kolisko Validation™ method, which allows validation i.e. verification of effective activity of homeopathically potentized substances.

Only potentized substances that have been proven active in the biological (living) model are then included in the finished products that become commercially available.

Potencies that are no different in their effectiveness than the untreated control medium are eliminated from further use.

To our knowledge this is the first time that such an objective, statistically analyzable “Potency Validation” test is included in the quality control process of manufacturing of homeopathic/anthroposophic products. This could constitute an additional step in assuring the consumer that the product containing an ultra-high dilution is not “just water or just sugar pills”.

Additionally, the Kolisko Validation™ test allows a more objective interpretation of the potencies of each substance (is a potency a low or high potency, etc.)

It is hoped that ultimately the resulting potency validated homeopathic/anthroposophic medications will emerge as clinically more effective.



Figure 1 Kolisko Validation Curve for Silicea 6x

Introduction

Homeopathically potentized remedies are manufactured worldwide.

By and large the manufacturers abide by GMP (good manufacturing practices) regulations, which dictate minimal sanitary conditions in the work place, truthful labeling, etc.

The main pivotal point though, the essential potentizing process, is more difficult to quality control. From a certain point forward this stepwise process of dilution and agitation results in a product that has purportedly no molecules of the original substance left and yet it is supposed to have a therapeutic effect. It is this characteristic that causes the scientific community to call homeopathic remedies “implausible” and doubt their effectiveness.

To repeat, the potentizing or dynamizing process involves two crucial steps. One is the dilution of the original substance as such - usually done in 1:10 proportion (denoted as D or X potencies) or 1:100 proportions (the so called C potencies) and more. The second step is an agitation of the dilution for a predetermined time before one proceeds to the next step. Both steps together convey a new quality to the thus treated medium, a quality that was not there before.

When the stepwise process has gone beyond 23 steps one reaches the so called Avogadro’s limit, which essentially postulates that there are no more molecules of the original substance left in the medium. These potencies are then called either high potencies or ultra-high dilutions. That these preparations can still exert an appreciable effect on biological systems, let alone be therapeutically useful, is indeed a difficult “pill” to swallow for the conventional science not willing to accept this new paradigm.

One would expect then that a considerable effort had been put forth to show that the final potency of a substance that goes into a final product is indeed effective and different than just the originating medium – water or alcohol. The more exacting companies try to make the potentizing process as such more reliable by, for example, having two co-workers observe each other during the potentizing process to ensure that “no corners are cut”, etc.

However, currently, there is no uniformly applied quality control test at the end of the manufacturing chain to demonstrate that the potentizing process was indeed successful. Due to whatever reason – a wrong flick of the wrist, an insufficient length of agitation time for that particular substance, etc. – that special “potency quality” may not have been achieved.

How can that be remedied?

To state the obvious, how do I know that I am not getting “just water” or, if the remedy comes as pellets, how do I know that I am not getting “just sugar pills?” How do I know that the potentizing process was truly successful?

And then there is a second question that should be considered.

Traditionally the following potencies have been selected for common use: the 6th, 15th, 30th, 200th, 1M, and so on. These include low potencies, ex. 6x, and high ones like the 200C. Are these though the best, the most efficacious? Why not 7x or 8x? Why not 199C? Manufacturing expediency or tradition is no substitute for actual best choice. How can we find the most efficacious potency?

We propose that the model developed in the pioneering work of R. Steiner and L. Kolisko could help with both quandaries.

Rudolf Steiner, Ph.D. (1861-1925) and Lily Kolisko (1889-1976)

The answer was given by Rudolf Steiner already in the 1920's. In a reply to a question from his student Lily Kolisko about a method for finding the most appropriate potency of a substance that was to be given as a remedy against hoof and mouth disease in cows he suggested to her: Let wheat seeds germinate under the influence of a series of potencies of that substance. The response of the seeds to the various potencies will result in an overall curve showing the "vitalizing process", or lack of it, created by specific potencies on the seedlings. This, he added, would not only be valid for the plant but also for the animal organism.

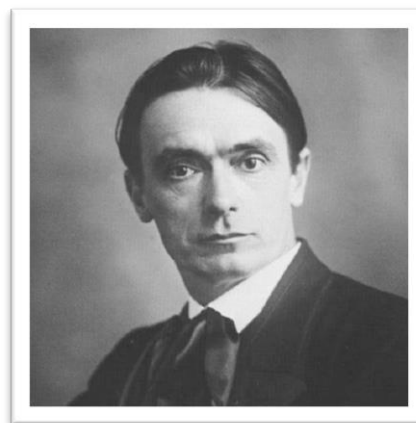


Figure 2. Rudolf Steiner

He further characterized the resulting curves in a lecture he gave on 3.31.1920 (Steiner):

"(In the series of potencies ...) you will reach a Null point. Beyond that the opposite effects (of the test substance in the first zone) appear. But this is not all; the further path leads to another Null point for these opposite effects. Passing the second Null, you will come to a higher form of efficiency, tending in the same direction as the first sequence but of quite a different nature. **It would be valuable and appropriate to plot out the different effects of potencies in curves of this special manner.**" According to R. Steiner the curve for the first



2 zones can be seen on the paper but an accurate representation of the 3rd zone would need to show the curve coming out of the plane of the paper at 90 degrees.

Figure 3. Lily Kolisko

Based on these insights Kolisko proceeded to do the work that led to germination curves of potencies. She pursued this project essentially lifelong!

She let wheat seeds germinate for a number of days in separate containers watering them with either water as control or with increasing potencies of a particular substance. (In general 1x to 60x; many experiments however to 600x!) Below are samples of findings from one of her early experiments (Kolisko). (Here: potencies D17 and 18-no response; D19 and D20-big response; 21 again low, and so on.)

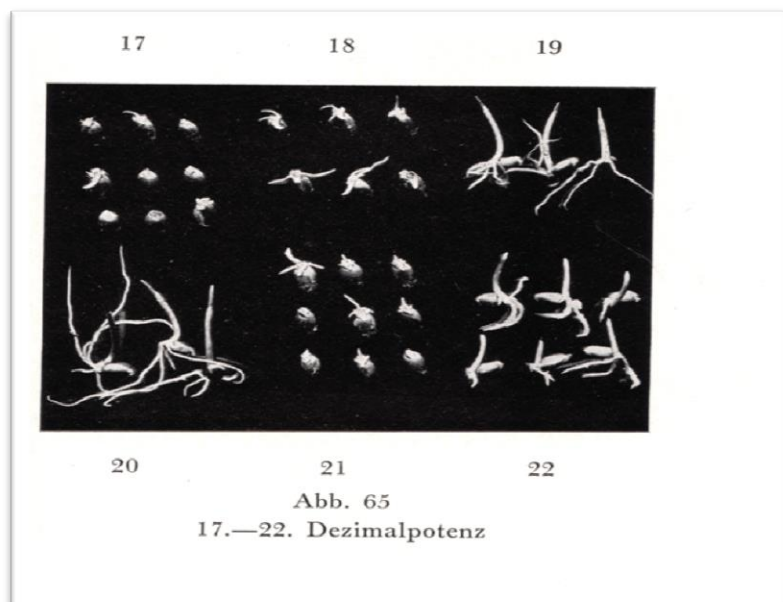


Figure 4. Wheat germination with potencies D17-D22. Note the alternating enhancement of growth of the seeds (the “vitalizing effect”) by the various potencies. (Kolisko)

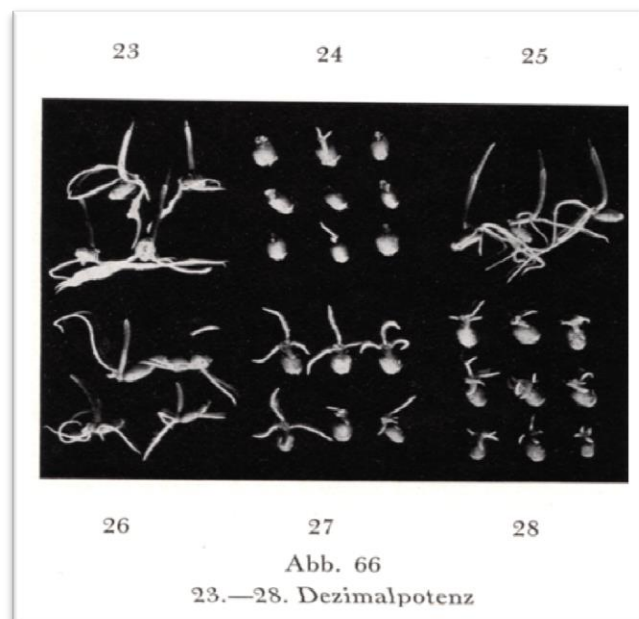


Figure 5. Wheat germination with potencies D23-D28. Note the alternating enhancement of growth of the seeds (the “vitalizing effect”) by the various potencies. (Kolisko)

The value of her work consists in demonstrating for the first time that sequential potencies increase and decrease in effectiveness in a rhythmical semi sinusoidal manner.

When at a later time several of her germination potency curves were looked at cumulatively, the semi sinusoidal pattern emerged even more clearly. (Fig. 6)

Kolisko herself believed that every substance has its own completely characteristic “signature” curve and that it would be of extreme importance for every doctor to know the curve of every remedy as naturally as they would know the appearance and signature of every plant and

mineral. To increase accuracy she would have welcomed, she said, a cumulating of several experiments of the same substance with the same potencies. In the case shown below several of her experiments, but with different metal salts, were put together by a later researcher (Junker) in order to emphasize the rhythmical phenomenon. She did not see the complete value in that. In retrospect, however, one can wonder if such a curve done with a high number of different substances and different plant seeds would not reveal a “universal curve” that would begin to explain more fully the mystery of this rhythmical phenomenon.

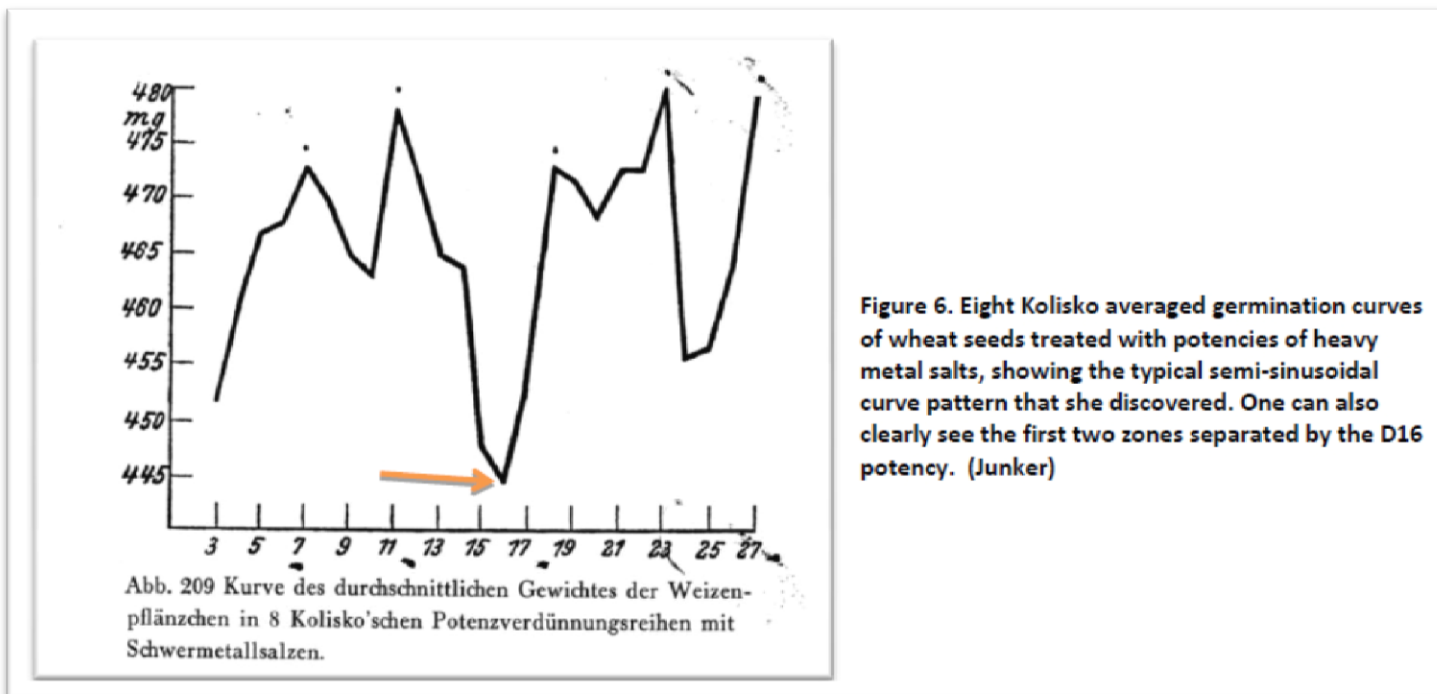


Figure 6. Eight Kolisko averaged germination curves of wheat seeds treated with potencies of heavy metal salts, showing the typical semi-sinusoidal curve pattern that she discovered. One can also clearly see the first two zones separated by the D16 potency. (Junker)

She also observed the influence of potencies in other plant models, such as f. ex. gladiolas. One can see the same patterns as described above in the actual plants- some potencies inhibit the growth, some accelerate it – but the most important point is that the pattern is not a linear one. Clearly some potencies are more “vitalizing” on the plant than others.

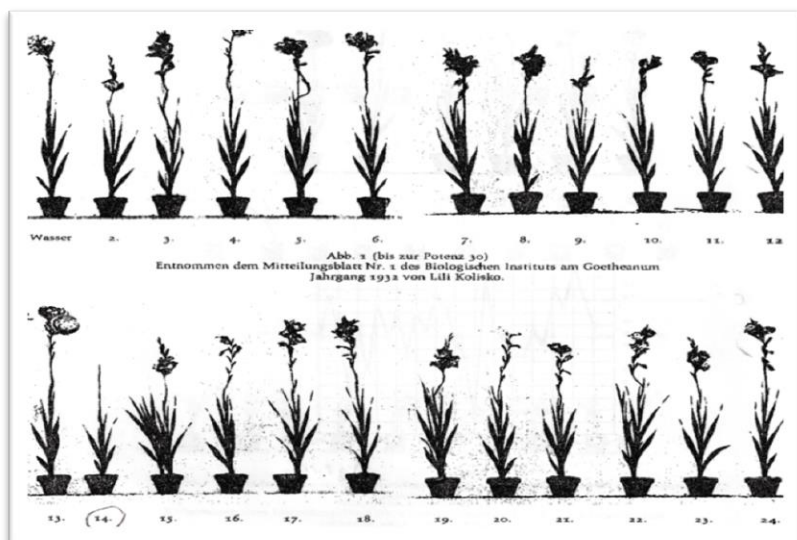
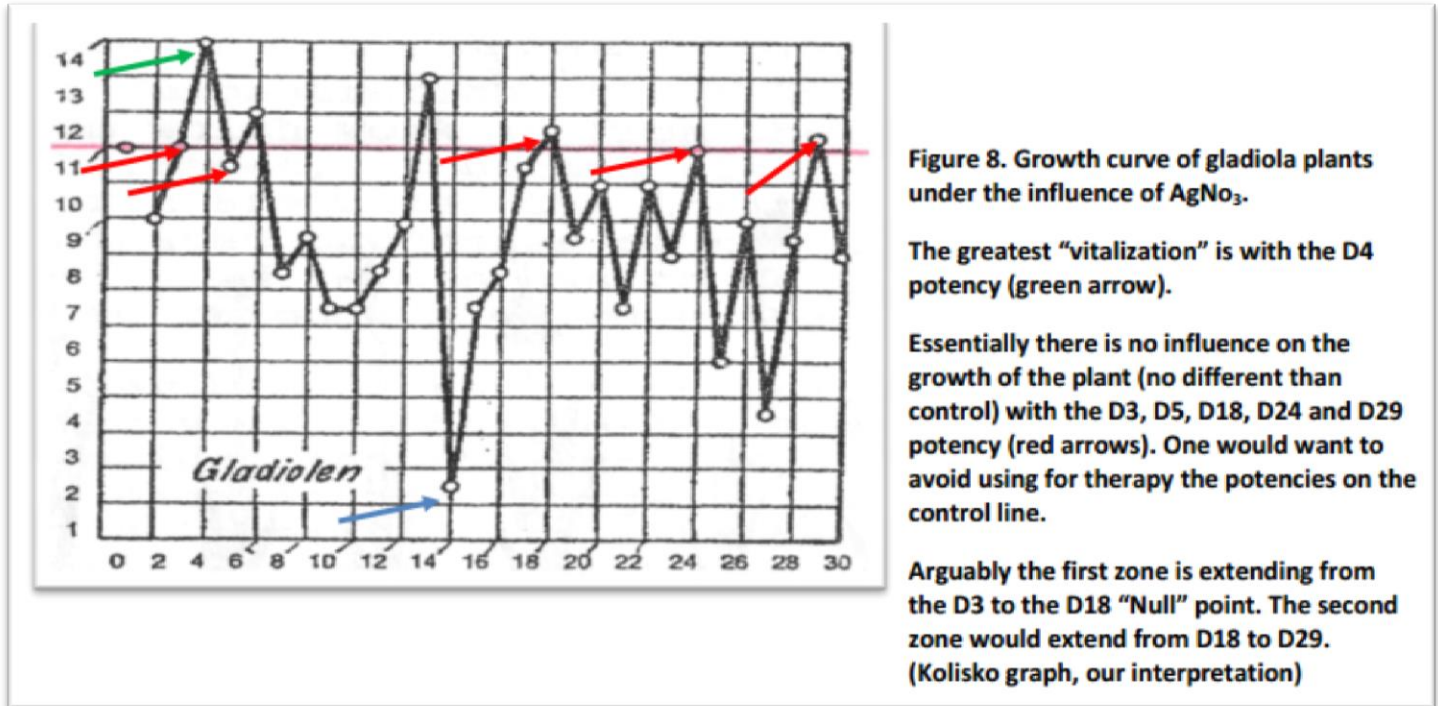


Figure 6. Kolisko gladiolas experiment. Some potencies are “vitalizing” the plant enhancing the flowering process; other potencies suppress the flowering, and have a “drying out” effect. (Kolisko)

From these observations she made the curves representing the growth (length) of the plants under the influence of the potencies. Below is the example of the gladiolas experiment from above (Fig. 7) potentized with AgNO_3 :



Rudolf Steiner gave Kolisko specific indications that helped understanding and interpreting these curves. Let's use this particular curve as an example. First we notice that there are three so called Null points (red arrows) -one at D3, D18 and one at D29. They delineate two regions. According to R. Steiner the first region between the first potency and the first Null point contains the potencies that would be considered to belong to the so called low potencies. The second region has the higher potencies. R. Steiner considered these two first regions to be the most significant and the ones with greatest correlation to the human organization. Notice that we did not pick D5 and D24. This is a matter of interpretation but it seems to us that those points are part of the process of that zone and not a true "turning" point, "Null point".

Importantly, notice that D4 (green arrow) potency has the most effect on the growth of the plant, in a sense it is "excitatory", while D14 (blue arrow) is the most "inhibitory potency on the growth forces.

Question: If one would want to choose a high potency for therapy would one want to pick the D24, the D29, or even the customarily chosen D30 potency? No, because they have essentially no more influence on the vitality of the biological system than the water control! A better choice would be D27 (brown arrow) with a clearly active inhibitory effect.

Another example: Hyacinth growth curve under the influence of AgNO_3 potencies.

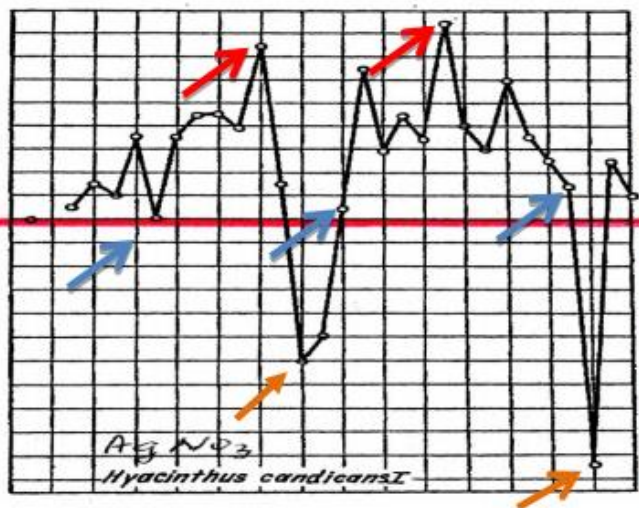


Figure 9.

Hyacinth growth curve under the influence of AgNO_3 potencies.

Most vitalizing caused by the D12 and the D21 potencies (red). The zones are separated by the three blue arrows. Highest excitatory potencies are D12 and D21 (red arrows). The inhibitory potencies are D14 and D28 (brown arrows)

In the present case the worst potencies to pick for therapy, for a final product, would be the ones that do not affect the growth of the plant any more than the water control does: D7, D16, and D26 (blue arrows). (Kolisko graph, our interpretation)

One can see the zones in other of her wheat germination curves (An Astragalus experiment depicted below in Fig. 10). The first region corresponds to the low potencies, potencies which in turn would be used for an effect proceeding from the metabolic system; the second region would represent more the middle potencies and influence the organism primarily starting from the rhythmical, heart lung system; the third region would be more the high potencies as such, going over the nervous- sense system.

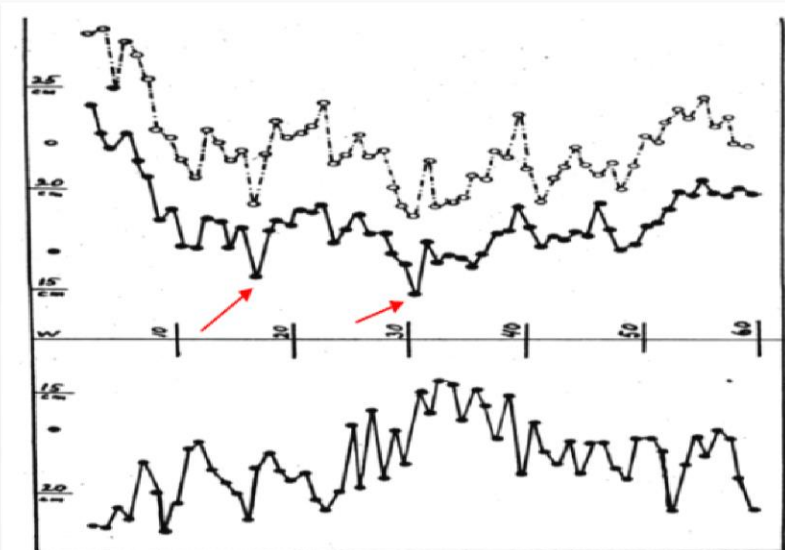


Figure 10. Wheat germination with astragalus potencies.

The upper most curves represent the leaves of the sprouts. The lowest curve represents the root length. The zones are (arrows): 1st from D2-D17; the 2nd from D18-D30; the 3rd from D31-to end of curve. (Kolisko graph, our interpretation)

It had been L. Kolisko's intention to develop this method to a high degree of reliability such that **the method could be used for the making of highest quality potentized remedies**. This system would allow the choice of the most efficacious potency in the range desired and if that potency would be the one used for a remedy one could have some proof that an active potency went into the product. Unfortunately even though she devoted her life to this dream she could never obtain the close enough cooperation of doctors that would work with her to bridge the gap from biological testing to manufacturing and clinical practice.

Her plant germination methods, demonstrating in the research laboratory the effect of homeopathic potencies, became over the decades the model for a wealth of subsequent research (Daems; Husemann, 2011) and last but not least, of course, the template for our own so called Kolisko Validation™ quality control tests. Later the validity of her work was occasionally questioned because of the lack of solid statistical analysis but one should not forget that she was nevertheless the trailblazer and pioneer who inspired the subsequent generations.

Today the plant germination technique is generally accepted among credible researchers (Baumgartner et al.; Bellavite et al.; Betti L et al.; Bonamin; Fisher; Husemann, 1992; Scherr et al.) as a solidly recognized model for the study of homeopathic processes. However, to the present, as far as we know, none of the in vitro plant models – or similar- have been used in the sense desired by Kolisko, and pursued by us, as a practical tool for quality control in the manufacturing process of ultra-high diluted medicines.

Following is a description of our testing procedure. We have developed a new relatively simple (albeit very labor intensive) protocol for a germination based model that we use to accomplish the stated purpose of demonstrating that the final potency going into a final OTC homeopathic/anthroposophic remedy is indeed active and can influence a biological system. To overcome the above stated weakness in the Kolisko experiments our method uses a statistical validation.

We are calling our test the Kolisko Validation™.

Methods

Materials

Wheat seeds: Hard Red Winter Wheat biodynamically grown without pesticides or herbicides. They were carefully selected for consistency and to eliminate seeds with damage or other visible defects.

Agitation Machine: Boekel Scientific-- Wrist-O-Matic Shaker®. This ensures that all agitations between the dilution steps are performed identically without person fatigue, irrespective of the number of potencies prepared.

Petri Dishes: Polypropylene, 100mm

Filter Paper: Whatman #1 Qualitative Circles 90mm

Location: The tests are done in a room monitored for temperature and humidity consistency. The room is used exclusively for this purpose.

Lights: Phillips Natural Light, T8, 32W, 48", Simulates Full Spectrum, 2850 Lumens, Color Rendering Index 82, Color Temperature 5000K. Lights are on for one hour before and after sunrise and sunset each day of the experiment. At other times the room is dark and undisturbed.

Shelving: Stainless Steel Wire Rack Shelving, 48" x 18", NSF

Preparation of potencies: The test substance is either a native mineral or herb or the mother tincture of the herb depending on the requirements necessary to elicit the highest characteristic of the material or to comply with the homeopathic pharmacopeia. The material then is diluted in a 1:10 proportion with distilled water or mixed in the same ratio with lactose monohydrate. The 1:10 dilution is then rhythmically agitated for 2 ½ minutes (plant material) or 4 ½ minutes (mineral material) and is designated as 1x (same as a D1 notation). The material in powder form is triturated (mixed) the same amount of time except for the first three powder steps which are triturated from 20 minutes to one hour. The process is then repeated as many times as necessary to produce all potencies desired. The 30th dilution thus would be called the 30x potency (D 30, 10⁻³⁰, log 30).

After the testing procedure (described below) the potency that has "passed satisfactorily" and that is desired for a finished product is transferred to globules of pharmaceutical grade sucrose (from non-GMO sugar cane).



Figure 7. The Wrist O Matic Shaker Agitation Machine. It creates a vortex and shakes the dilution vertically at the same time at approx. 200 times per minute depending on the setting chosen.



Figure 8. 10 individual seeds are placed in each Petri dish for germination.

Testing Procedure

We were guided by Kolisko's original work but developed a protocol that allowed a faster and more reproducible processing in a one week cycle.

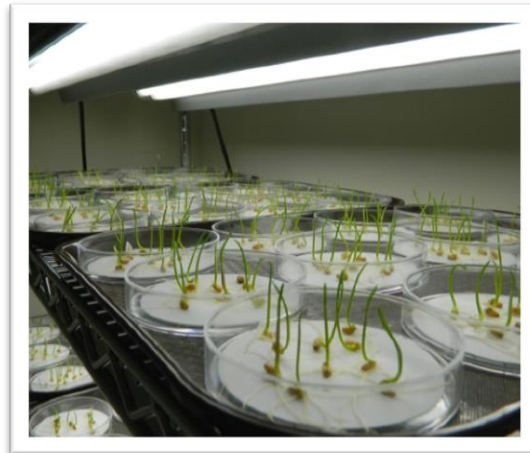


Figure 9. Petri dishes with germinating wheat seeds. They are placed on three racks that all have the same lighting, humidity and temperature.

Wheat seeds were allowed to germinate and grow for one week in Petri dishes. The seeds in the control dishes were watered with distilled water. The other dishes were given the corresponding potency. A complete experimental series plus its control were placed on a shelf. The same procedure was repeated two more times and the series with its control were placed on the additional two shelves. The test is thus run essentially three times simultaneously.

An actual protocol is given below:

1. Use water potencies made for the selected test potencies.
2. Prepare Petri dishes: 9 dishes for each potency level; one set for each of the indicated substances/potencies.

3. Seeds –
 - a. Select them,
 - b. Arrange Petri Dishes with bottom filter paper to have 9 dishes for each potency strength and 9 dishes for the control plates
 - c. Place 10 seeds in each Petri dish (open spine down)
 - d. Arrange dishes on shelves per protocol schema document.
4. Each Petri dish labeled for a specific substance and potency gets 2cc bottom filter/2cc top filter of the corresponding substance and potency bottle content. USE FRESH PIPETTE FOR EACH DIFFERENT POTENCY OR CONTROL.
5. Each Petri dish labeled for specific Control type gets 2cc bottom filter/2cc top filter of the corresponding Control type bottle content. USE FRESH PIPETTE FOR EACH DIFFERENT POTENCY OR CONTROL.
6. On day 4 at 1 pm remove top filter paper from all plates, add 2cc of the associated potency or control water and re-cover all dishes with top piece of the dish.
7. On day 7 at 6 am, remove the top plate of petri dish and leave open until weighing.
8. Weigh seeds/rootlets/shoots from each plate per protocol on day 7 at 9 am.

It is important to weigh the seedlings at the same time. All steps are people intensive.

The weights are recorded on a template and the curve generated is followed by a statistical analysis.

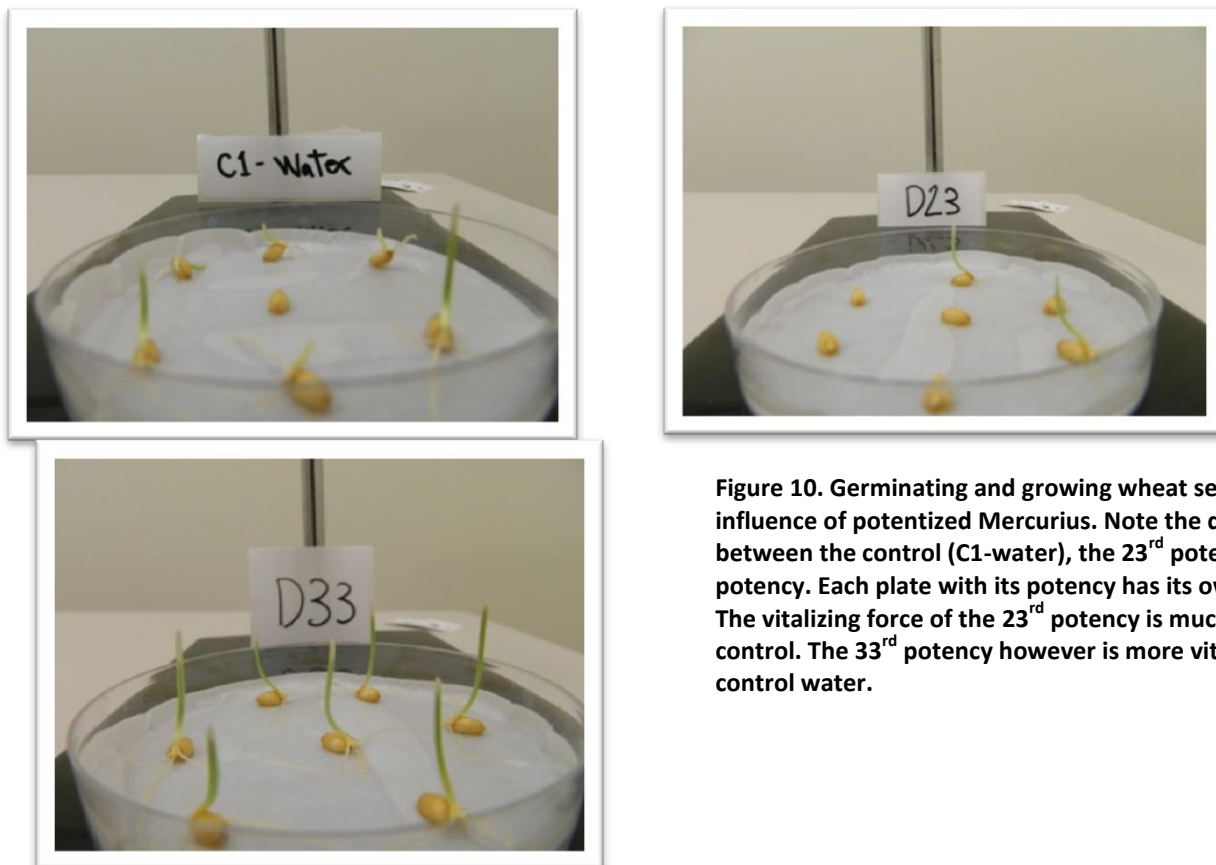


Figure 10. Germinating and growing wheat seeds under the influence of potentized Mercurius. Note the difference between the control (C1-water), the 23rd potency and the 33rd potency. Each plate with its potency has its own characteristic. The vitalizing force of the 23rd potency is much smaller than control. The 33rd potency however is more vitalizing than the control water.

Statistical analysis

We used as a biological marker the weight of the entire seedling (rootlets, seed and stalk). An arithmetic mean of all the seedlings in a group was obtained and the confidence interval for each group mean was calculated ($\pm 2 * SE$). In the beginning both parametric (classic Student's t test) and non-parametric (Mann-Whitney rank sum, U test) tests were performed to determine the significance level of the difference between the control group and the individual test groups. It became obvious soon though that the results of both parametric and non-parametric tests were nearly identical so that later only the classical Student's t-test was used and significance was accepted for a $p < 0.05$ (comparison of each test group against the control). The statement needs to be made, however, that acceptance of significance at the 95% level of confidence is an arbitrary tradition for which it can only be hoped that soon a revision will be found and generally accepted. Why would a $p < 0.05$ be significant but $p < 0.056$ not be? Nevertheless, we have adopted the more stringent requirements in order to avoid additional criticism.

Results/Interpretation

Carbo Germination Curve leading to the Carbo 6x and 30x remedy

The test with the Carbo betulae (birch charcoal) is a good example for a number of the principles at work here.

Carbo is a commonly used homeopathic and anthroposophic remedy. Carbo potencies D4 to D80 were made. It is usually recommended in anthroposophical circles as either as 6x (low potency) or 30x (high potency). Homeopaths tend to look at the 30x as being low and consider high potencies in the 200 (mostly C not X) to 1M. (The designations D and X are used interchangeably. The Europeans denote dilutions of 1:10 more like D, for decimal, the US prefers X).

Wheat seeds were then germinated as described in the methods section above and a curve obtained as seen below (Table 1). The three zones of low, middle and high potencies are delineated by the Null points D14, D30, and D51.

The maximal points are at D7, D21 and D38 (red arrows). These maximal points indicate the potencies that “vitalize” the growth of the seedlings the most. In scientific terms this would be termed more properly evidence of an acceleration of growth but the term vitality is more comprehensive and is preferred by us.

Based on the above considerations we would want to make from this batch a D7 remedy to have the best influence via the metabolic system (low potency); a D21 for the so called medium potency to affect directly the rhythmical system of the heart and lungs; and the D38 for a so called high potency that would work directly over the nerve-sense system. These potencies are statistically significantly different from the control group. (Surprisingly enough the commonly used potency of D30 appears here as a Null point with not much difference to simple water. Would that be the best “high potency” to pick for clinical use?) Remember that these potencies (this curve) are such only for this time, this date, this batch, under that particular constellation. But this thought is important because it is this particular potency from this particular batch that will go into the finished product.



Table 1

Wheat Growth Mean Weights Under the Influence of Carbo Potencies D4 – D80

	Control	D6	D7	D10	D21	D26	D30	D38	D45
Mean (%)	0	25.58	32.81	-42.11	64.71	-30.70	-2.79	62.2	-8.98
C.I. (%)	± 21.25	± 20.3	± 19.68	± 15.78	± 20.71	± 22.32	± 18.35	± 18.36	± 26.61
P		N. S.	P<0.03	P<0.002	P<0.001	P<0.05	N. S.	P<0.001	N. S.

Legend

N (number of seedlings) = 90/potency

P values are expressing the comparison between potency test groups and control;

N. S. =not significant;

p<0.05 significant;

p<0.001 highly significant.

CI = Confidence Interval = ± 2SE

Standardized to 0% control.

At this point two possibilities present themselves. Breaking with tradition one could simply proceed to make f. ex. a Carbo D7 (7x) as a low potency even though the commonly expected potency would be the 6x. In the future we might- and will- choose to go indeed with the potencies as seen, even though it may break with tradition, i.e. if D7 (7x) is more potent than D6 (6x) then pick 7x.

The second possibility is, however, to repeat the potentizing and germinating process on another day, starting from scratch, being under a different constellation, weather, etc, and see if one would get a D6 and/or a D30 potency that would be validly active.

We did do this and obtained the curves shown in the curves of Fig. 15

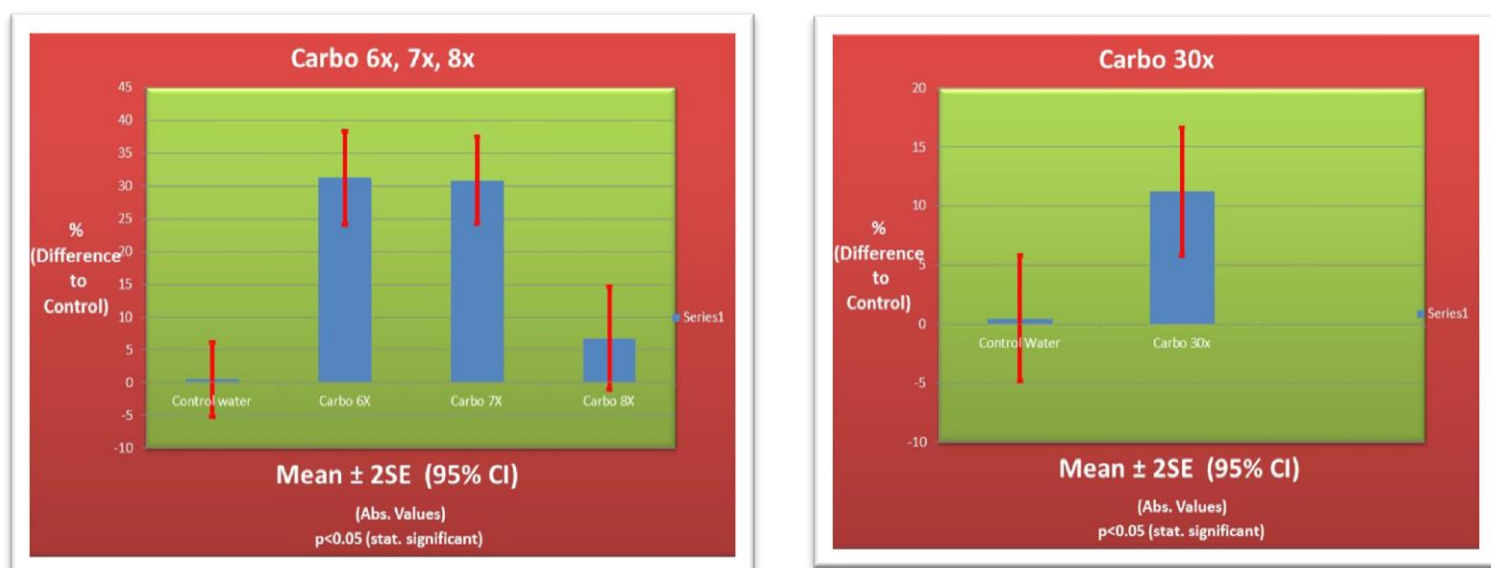


Figure 11. Germination of wheat seeds under the influence of Carbo potencies. Both Carbo 6x, 7x and 30x are significantly different, i. e. more vitalizing, than control. The Means are expressed here in absolute numbers.

Regarding the final products: We designate then all of our OTC homeopathic/anthroposophic remedies as having “Validated Potencies”, if they have been based on a curve proving that the potentizing process was successful, and statistically validated.

Why express our values in ABSOLUTE NUMBERS (all positive)?

As one can see from the long curve above (Table 1) some of the potencies are not stimulating the growth of the plant but rather are inhibiting it. The mean value of that group can be negative in relationship to control. The interpretation and application of this phenomenon is complicated and goes beyond the scope of this paper. Nevertheless, the difference to control can still be statistically significant. If the intention is mainly to point out that the difference between the test group and control is statistically significant then showing the means of both groups as positive visually facilitates the point – as shown in Fig. 15.

We have chosen this visual method to illustrate our “Validated” products on the web and other places in the non -specialist literature.

Other examples follow below. Once the desired potency is established as being statistically significantly different from control, i.e. it is biologically valuable and “Validated”, that potency is used to make the commercial product. The product is shown then in the catalog or online with the corresponding graph next to it.

Mercurius Vivus 30x™

When intending to make the remedy Mercurius 30x, following the general protocol, we first potentized mercury to the 30th potency. Subsequently, wheat seeds were germinated with water (control) and a comparable group with only the 30x mercury potency. The result showed a curve where the Mercurius 30x was clearly statistically significantly different from control (see Fig. 16 and data in Table2 further down). This potency was transferred to the globules and is the finished product.

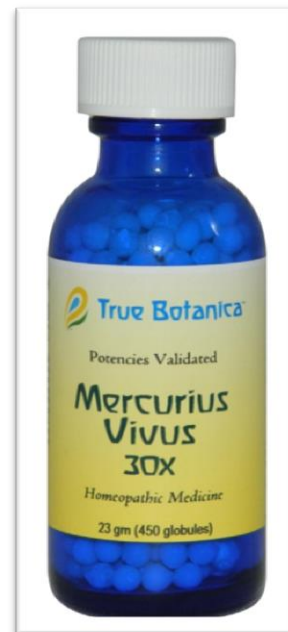
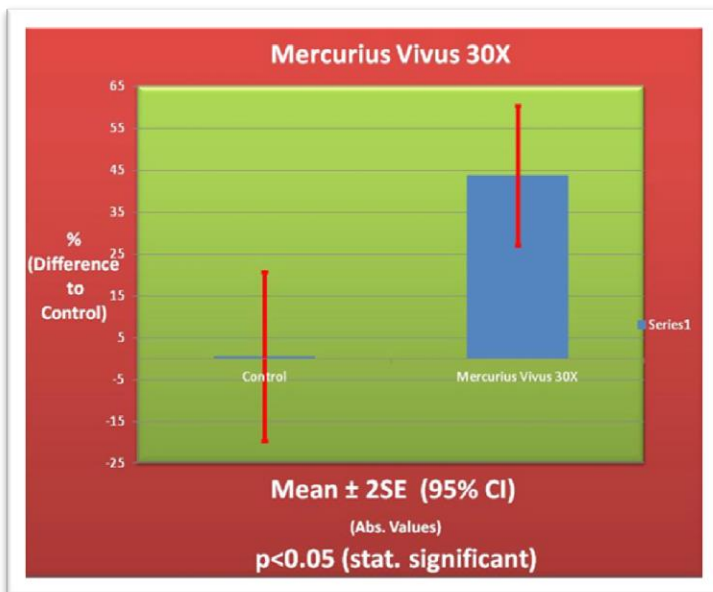


Figure 12. Mercurius Vivus 30x finished product based on the germination curve seen to the left.

Since the potency was verified as effective through the Kolisko Validation™ test the label carries now the notation “Potency Validated.”

Stannum metallicum 6x

Same process as described above:

The raw tin (Stannum) >>Potencies >> Germination of the wheat seeds with the potencies (and always control) >>Statistical analysis of the germination curve to show whether the desired potency-here 6x- is effective in the biological system >> Making of the finished product.

Since the potency was verified as effective through the Kolisko Validation™ test the label carries now the notation “Potency Validated.”

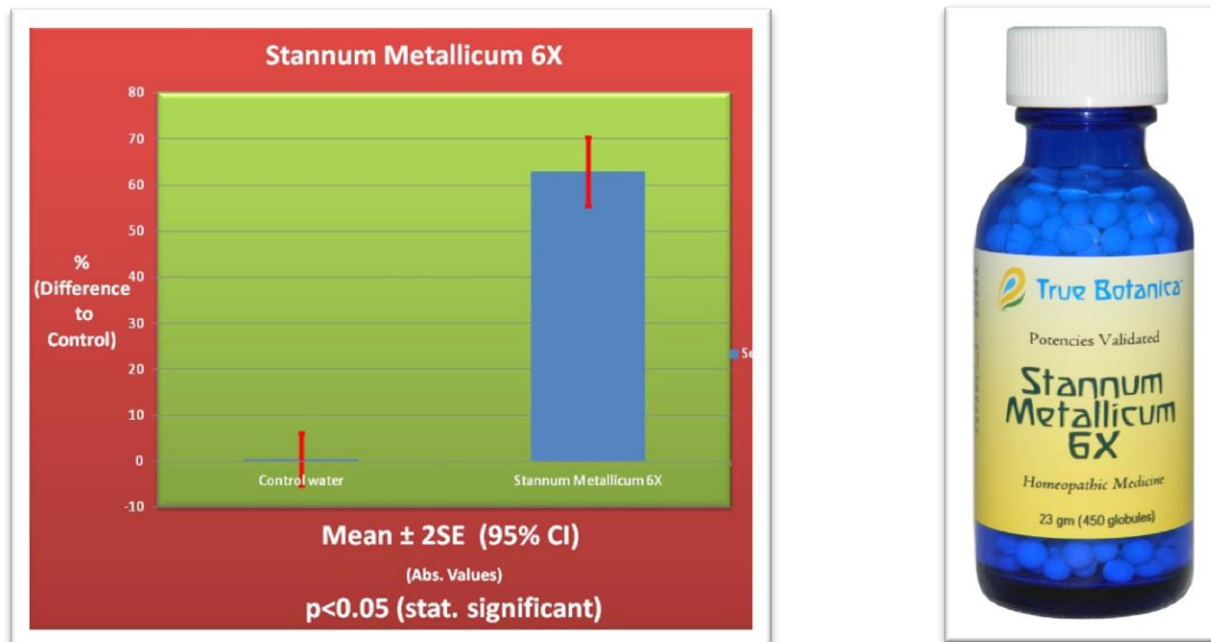


Figure 13. Stannum metallicum 6x finished product based on the germination curve seen to the left.

Natrium muriaticum 30x

Same process as described above:

The raw ingredient, here salt (Natrium mur.) >> Potencies >> Germination of the wheat seeds with the potencies (and always control) >> Statistical analysis of the germination curve to show whether the desired potency-here 30x- is effective in the biological system >> Making of the finished product.

Since the potency was verified as effective through the Kolisko Validation™ test the label carries now the notation “Potency Validated.”

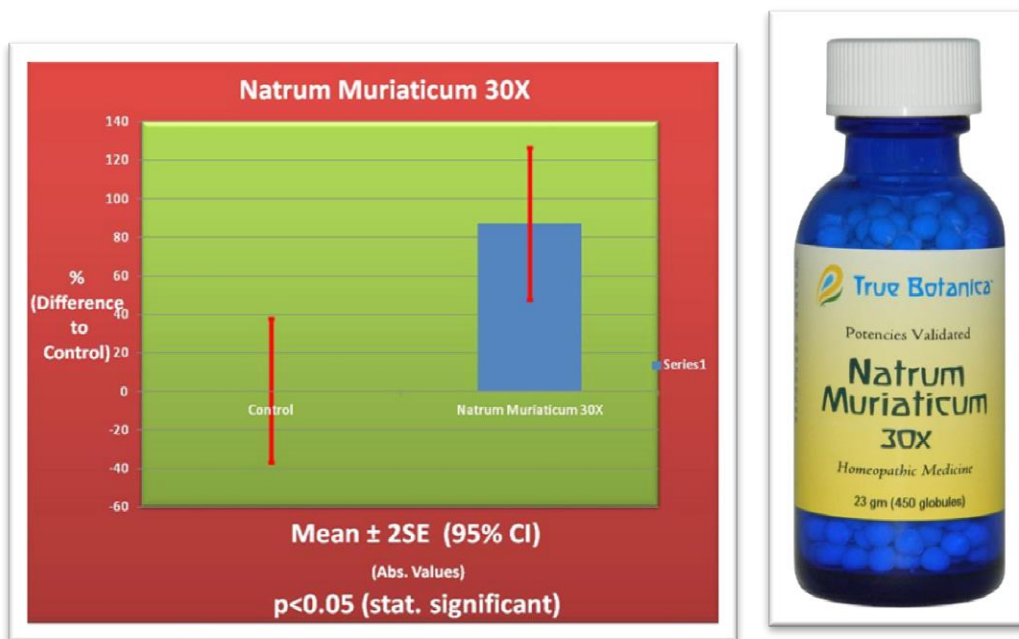


Figure 14. Natrium muriaticum 30x product based on the germination curve to the left

Summary of the Data leading to the corresponding above mentioned remedies.

-Carbo, Mercurius vivus, Stannum metallicum, Natrium muriaticum -

Table 2

**Wheat Growth: Mean Weight of Seedlings in 6 Test Curves
N = 90**

		Mean ± CI (%) (ABS. Values)	p
Carbo	Control	0 ± 5.7	
	6x	30.74 ± 7.12	p<0.001
Carbo	Control	0 ± 5.32	
	30x	11.72 ± 5.41	p<0.001
Mercurius	Control	0 ± 20.27	
	30x	43.21 ± 16.68	p<0.001
Stan. met.	Control	0 ± 5.66	
	6x	62.41 ± 7.42	p<0.001
Stan. met.	Control	0 ± 5.66	
	30x	58.65 ± 8.04	p<0.001
Nat. mur.	Control	0 ± 37.49	
	30x	87.22 ± 31	P<0.002

Legend

N (number of seedlings) = 90 for all series;

P values are expressing

the comparison between potency test groups and control;

p<0.05 significant; p<0.001 highly significant.

CI ± = Confidence Interval ± = ± 2SE

ABS = Absolute Values

Can this method be used to distinguish between similar commercial products?

We have begun taking the first steps into this direction.

Rudolf Steiner points out that every substance taken in by the digestive system will ultimately not just be metabolized in the conventional sense of the word but rather that it will be “homeopathized” or potentized in the organism to very high levels. An herbal mix f. ex. will be working in the body both as the substance as such as well as in the potentized form.

If one would subject a commercial product to the Kolisko Validation test one would ideally want

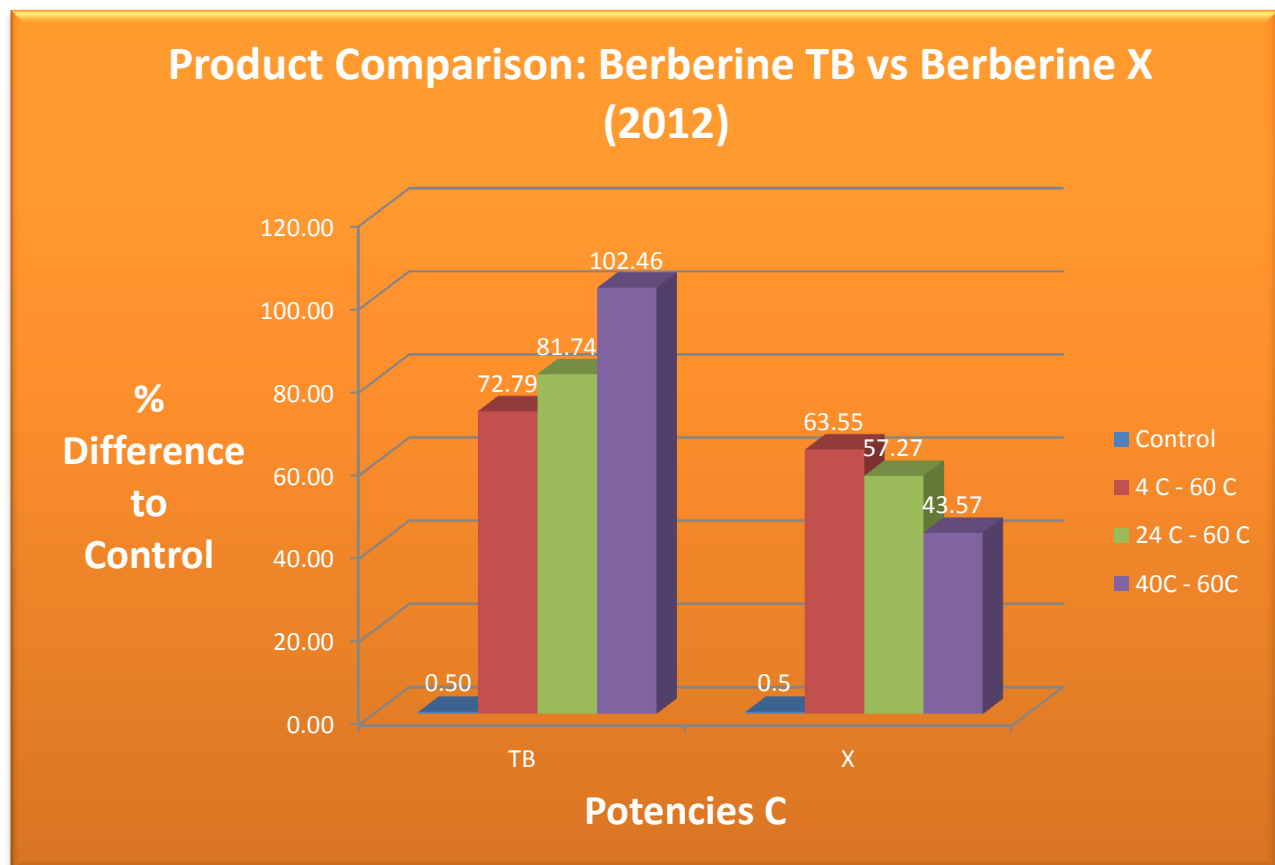


Fig. 19. Comparison between a True Botanica company Berberine product and a company X similar product. With increasing potencies the TB product is more and more active, while the company X product loses in strength.

to see how the higher potencies of that product behave. This consideration goes beyond the customarily tested physiologic response and since potencies above the 24th contain, by and large, no physical molecules the intrinsic life quality, the “etheric” value of the product could be assessed.

We tested this supposition by comparing the behavior of our Berberine Plus™ formula against a very similar berberine product of company X. As seen in the figure below the higher the

potencies are of the True Botanica formula the more active they are. By comparison the formula of company X are increasingly less active the higher the potencies go.

The experiment was repeated two years later with the same results.

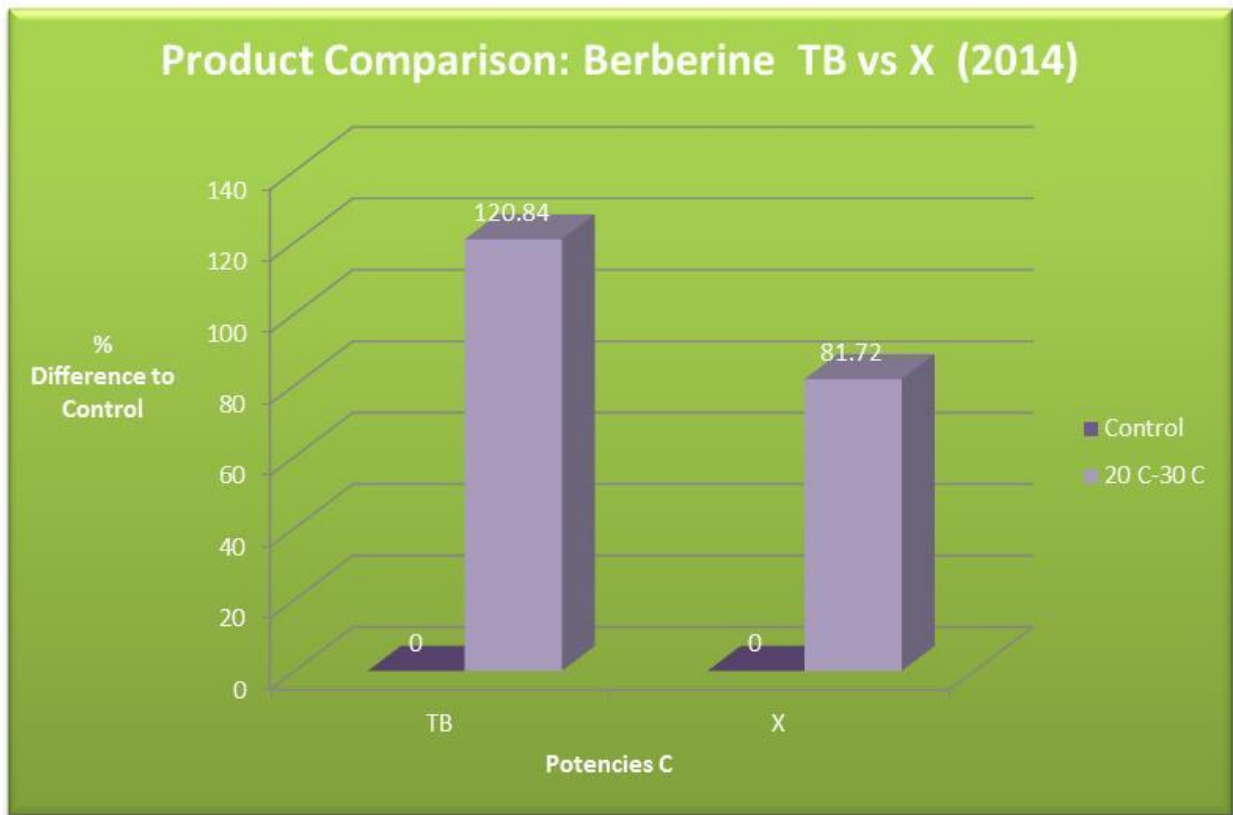


Fig. 20. The experiment from Fig. 19 done in 2012 was repeated two years later with essentially the same results: at the tested potency levels the TB berberine product was more active than the company X product.

Additional Examples for using the Kolisko Validation™ protocol as a quality control step in the manufacture of ultra-high diluted remedies

We want to illustrate here concrete examples where the Kolisko Validation test resulted in either the need to repeat the potentizing process in order to get a validly active potency; or the need to choose another closely related potency if after repeated attempts the desired potency could not be “validated” but a potency close to it was the actually active one.

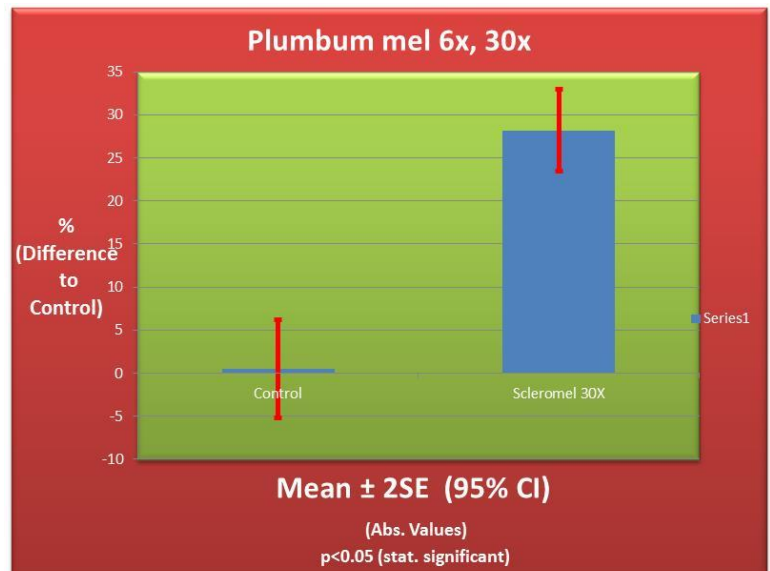
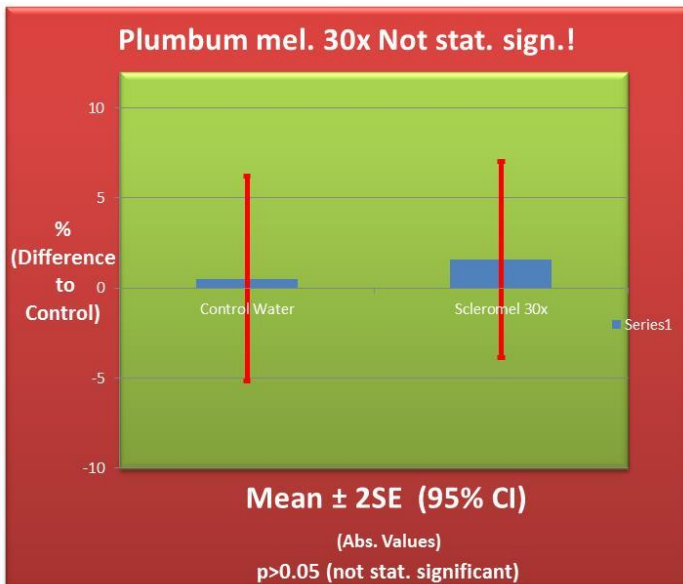
1. **Plumbum Mel. 30x** – The formula mix consisting of Plumbum, honey and sugar was originally called Scleromel now re-labeled as Plumbum Mel.

As Fig. 21 shows, the first potentizing process resulted in a 30x potency that was not satisfactory. A second potency prepared on a different day, under different constellations, perhaps different weather, etc, resulted in a potency that was highly effective in affecting the life force – in a statistically highly significant manner.

This was utilized for the commercial product Plumbum Mel. 30x™



Fig. 21 First attempt to obtain active 30 x potency failed. Second attempt successful. The 30x potency used in the commercially available product was statistically highly significantly different from the water control.



2. Same reasoning as above is evident in the steps taken to get to the Antimonium Crudum 6x product. (The words Antimonium and stibium are used interchangeably.)

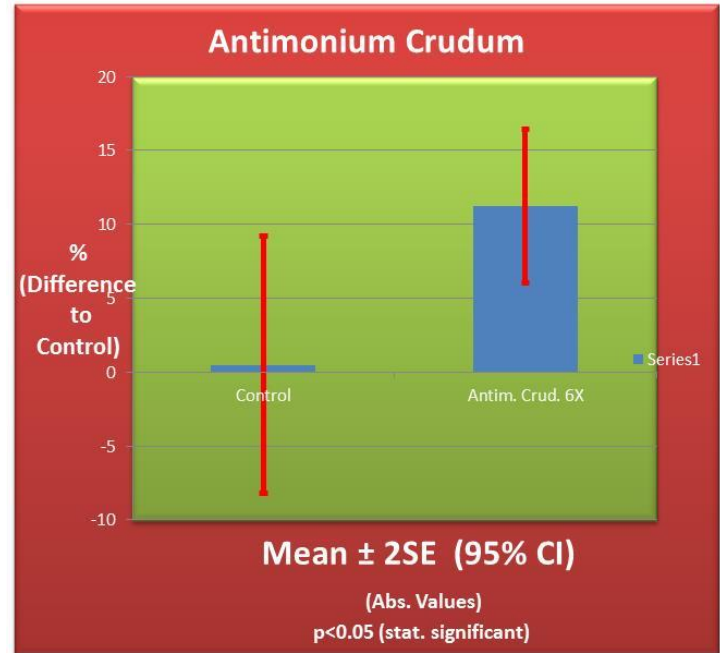
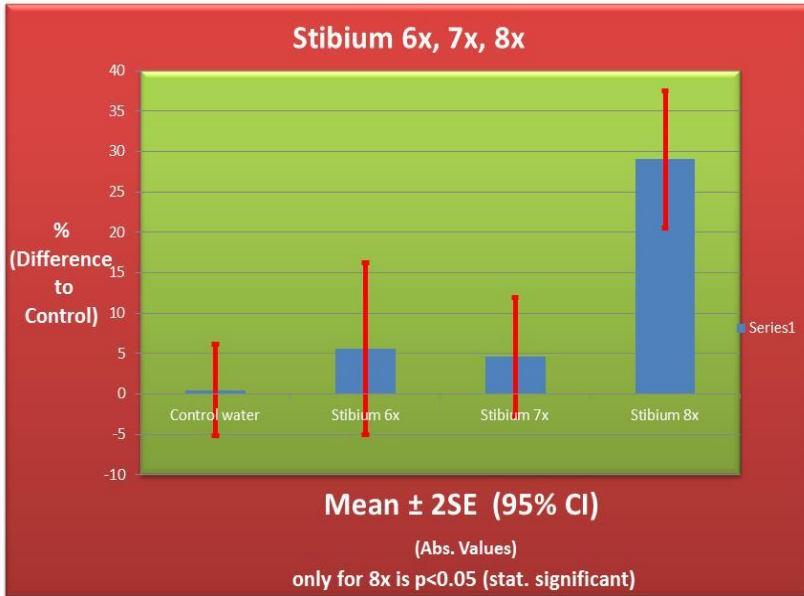


Fig. 22.

In the first process 6x is not significantly different from the water control. However, 8x is.

We could have chosen the 8x as the potency to be used for the commercial remedy but chose instead to repeat the procedure. Under the new condition the 6x potency was satisfactory and could thus constitute the basis for the remedy.



3. In the making of a low potency Chamomilla remedy repeated attempts to obtain a valid 6x failed and we ultimately decide to offer instead a 7x remedy: still a low potency but with a potency proven to significantly affect the life forces.

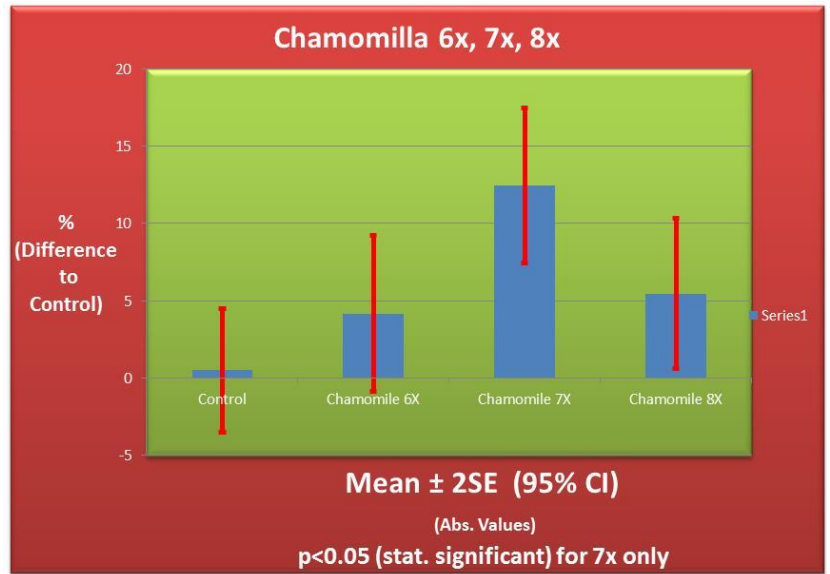
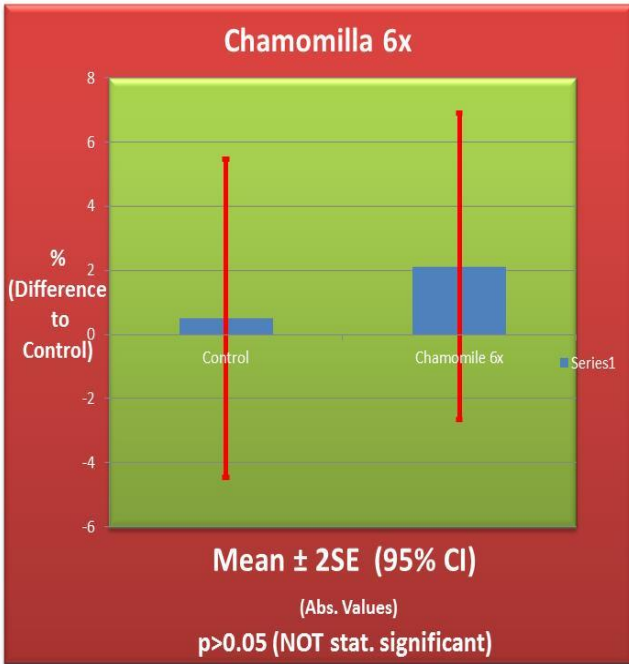


Fig. 23

One can see two tests.

On both, the 6x potency is not significantly different from the water control.

However, in the second test the 7x is significantly different from water and was thus chosen to go into the final remedy.



Discussion

The efficacy of homeopathic remedies has been a controversial topic from the beginning. (Bellavite, et al.). In spite of literally thousands of clinical reports from physicians –reports which have been disregarded as “anecdotal”-, in spite of dozens of clinical studies and several well documented meta-analyses (Vallance), the homeopathic/anthroposophic remedy is still suspected to be “only a placebo.” Over the last decades, innumerable in vitro studies on plants, cell cultures, animals and in a physico-chemical setting (Endler, et al.; Taddei-Ferretti) have gone a long way to demonstrate that potentized substances will have a demonstrable effect even at ultra-high dilutions.

Nevertheless, homeopathic remedies are often ineffective. May one possible reason be that the remedy itself given in that instance was not containing an “active” potency?

Methods such as ours could go a long way toward establishing an additional quality control step in the manufacture of homeopathic/anthroposophic remedies.

Our model, once it was put in place, could easily be executed on a weekly basis. The biological material needed, the wheat seeds, are available in nearly unlimited supply. The wheat seeds, especially at this stage in their development, are very sensitive to growth influences and most importantly they seem to be reacting surprisingly well to a multitude of potentized substances that they were exposed to, not only to a selected few.

To summarize, the overall sequence of testing that we have chosen is as follows:

1. Since customarily the 6x and 30x potencies are asked for, we do first a germination test that contains a control plus a 6x and a 30x potency. If they are significantly different from control the final product is made from those potencies.
2. If no stat. significant results can be obtained, a new series with 6x, 7x, 8x, 29x, 30x, 31x is made to see if the more active potencies might be f. ex. the 8x for a low potency instead of the typical 6x. Same with a potency around 30.
3. If still no positive results can be obtained, the entire series of 4x-33x or higher is made to see if the active potencies would be a completely unexpected different potency.
4. Alternatively, if the 6x or 30x potencies are not validated we may decide to start from scratch with a fresh batch of potencies and repeat the germination with this new batch. If we then have a statistically significant result for the 6x or 30x potencies we will make the final product.

This distinguishes our products from other companies' products in that you can be sure our products always show activity (even if it means discarding a batch) whereas for the others one cannot be sure.

The question may of course arise, and legitimately so, if this is a completely reliable system by which to judge the efficacy of a potency. Undoubtedly the model will be further developed, but no second step can ever be made until the first one is dared. Besides, if for centuries homeopathic remedies were made with no assurance whatsoever that they were indeed active then this modest attempt can only be an improvement.

Overall then, the present set up can help with at least some of these aspects:

1. Distinguishing in a series of potencies of the same substance which one of those potencies is most active;
2. Ensuring that only an active potency (one that has been shown to have an effect on a biological system) finds its way into a commercial preparation;
3. Allowing further research in the influence of constellations, weather, human subtle energies, technological influences, etc., on potencies.

Conclusion

Currently, the choice of potency to be given to a patient as part of the clinical/therapeutic process is largely based on tradition. The choice is so imprecise that homeopaths of renown are considering the choice of the potency to be nearly irrelevant. In their eyes the choice of the substance is everything. This attitude is not entirely unjustified even though due to the advances in anthroposophic medicine understanding the meaning of the potencies has been considerably more refined.

Even more heavily, however, weighs the fact that no proof/effort/method is currently in place to demonstrate that the final product that reaches the consumer has indeed a potency that is different from “just water.”

As repeatedly presented in this paper, Rudolf Steiner and Lily Kolisko inaugurated a method- the seed germination curves- which allow an objective/visual understanding of the quality of the potencies and an objective/ visual proof of which potencies are actively affecting the vitalizing process of the biological system. This takes the understanding of the potencies out of a theoretical or “mystical” realm.

Their initial “curve” experiments have been repeated in variations over the last decades and their basic initial ideas are recognized nowadays as valid models with corresponding statistical tools that can be utilized in research for the understanding of homeopathic dilutions.

Unfortunately the practical power of any of these models has never been tested in the practical applications relating to therapy or manufacturing – possibly relating to their labor intensiveness, possibly relating to the reluctance to acknowledge that basic life forces are shared on a primordial level by the Human and the Plant alike and thus a simple “wheat seed” has after all an enormous predictive power.

True Botanica™ is introducing now a wheat germinating test that while based on the original Steiner/Kolisko research, is, however, more standardized, reproducible and statistically analyzable than the original version and calls it the **Kolisko Validation™ test**.

Only those potencies that have been proven effective are then included in the final products that reach the consumer. Potencies whose effectiveness is no better than the control are never utilized.

Once a potency is verified as effective through the Kolisko Validation™ test an OTC product made with that potency will then carry the notation “Potency Validated” on the label.

Verifying the final potency is a crucial step that should be present in the quality control process of all manufacturing of homeopathic/anthroposophic OTC remedies.

It is hoped that this process will greatly increase the effectiveness of the homeopathic and anthroposophic remedies.

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