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Assessment of frequently accessible homeopathic mother tinctures for their pharmacopoeal specifications in Pakistan

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The homeopathic system of medicine has attained ample attentiveness being one of the premium systems of cure accessible to mankind, and lingers to hold the awareness of remedial publications and the correspondence at the same time. The foremost superlative of cure is swift, undeviating refurbishment of health or inhibitive of the disease in its entire scope, most trustworthy and non detrimental way. The probable means of their accomplishments seem conflicting by way of conformist procedural deliberation and the investigation corroboration for which leftovers are arguable. Mother tinctures are liquid preparation ensuing from the extraction of an appropriate source that is, animal substance material with alcohol or water mixture within a specific ratio. Adverse events taking place during homeopathic treatment are seldom accredited to the homeopathic medicine itself. Nevertheless, sanctuary appraisal should also deem possible impurities of the source material or contagion and failures of good manufacturing practice. This is the first study conducted in Pakistan to appraise the physical and chemical parameters of five frequently accessible mother tinctures that is, *Aconitum napellus*, *Arnica montana*, *Bryonia alba*, *Atropa belladonna* and *Matricaria chamomilla*, and manufactured by five confined leading companies by employing customary methodology for the following specifications that is, alcohol contents, weight/ml, specific gravity and pH. Most of the parameters of mother tinctures comply with German Homoeopathic Pharmacopoeia and manufacturers own specifications. There is dire need to enact law to control the sale, manufacture, storage and export of complementary and alternative medicines at earliest possible time in true letter and spirit, along with the adaptation of good manufacturing practice (GMP), quality control (QC) and quality assurance (QA) guideline.

Key words: Mother tinctures, *Aconitum napellus*, *Arnica montana*, *Bryonia alba*, *Atropa belladonna*, *Matricaria chamomilla*, pharmacopoeal specifications.

INTRODUCTION

Medicinal plants have been manipulated over a period of time in the cure of ailments due to the pharmacological prospective and organic commotion of the compounds inside the plant (Ceiśla and Waksmundzka-Hojnos, 2009), and also represents a foundation of unprocessed materials for both contemporary and conventional types of medicine that is, Homoeopathy, Unani, Chinese and Ayurvedic medicine (Bandaranayake, 2006). There has been a substantial awareness worldwide in Traditional medicine/ Complementary and Alternative Medicine (TCAM) particularly in herbal products over the last few decades

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(World Health Organization (WHO), 2001) and virtually half of the population currently often customize some form of complementary and alternative medicine (CAM) (Bodeker and Ong, 2005).

The homeopathic system of medicine is one of the premium systems of cure accessible to mankind. The premier superlative of cure is swift, moderate and undeviating refurbishment of health or confiscation and inhibitive of the disease in its entire scope, in the unswerving, most reliable and most not detrimental way, on easily ample principles (www.nchpakistan.com). The National regulatory scaffold and the place of homeopathy within the health care system diverge from country to country, but the use of homeopathic medicines, mostly as non prescription medicines, is emerging in numerous parts of the world. The literal size of the homeopathic medicines market in cost-effective term is not well known but sales data divulge that homeopathic medicines represent a noteworthy part of medical economics (WHO, 2009).

A mother tincture is a liquid preparation ensuing from the extraction of a suitable source, namely plant or animal substance material with alcohol or water mixture within a specific ratio (Banerjee, 2002). They have widespread restorative account and as the prominence of wellbeing is fetching a wide-reaching tendency, homeopathic provisions are becoming progressively more accepted. Nevertheless (Pande and Pathak, 2006). Homeopathic mother tinctures, rarely and in amalgamations, contains a lots of figures of compounds in composite matrices in which no solitary vigorous component is accountable for the over all effectiveness. This creates a confrontation in establishing excellent run principles for unprocessed materials and equivalence of refined herbal drugs, ensuing in anecdotal values for these provisions internationally (Chitlange, 2008). Its standardization is usually done by assorted physical, chemical and chromatographic specifications.

As the international costs of mother tinctures have begun to escalate due to assorted factors, the use of local manufacturers has become an imperative source option. A need therefore has arisen to frequently assess whether there is a difference in quality between locally and internationally feigned mother tinctures and whether the quality of the local and international manufactured homoeopathic mother tinctures comply with the standard stipulated by the Homoeopathic Pharmacopoeias (Lee et al., 2007).

The high impending inconsistency of chemical composition of the plant material implicated in the construct of homeopathic mother tinctures renders both their quality control and assurance a noteworthy confront (Pande and Pathak, 2006). Homeopathic medicines or their stocks/mother tinctures are prepared from natural or synthetic sources that are referenced in pharmacopoeial monographs or other renowned documents. Numerous factors have been reported to manipulate the excellence of homoeopathic mother tinctures, and countless specifications must be met when assessing the worth of these products (Bandaranayake, 2006).

Not considering imponderabilia, the source materials for homeopathic medicines may consist of plant material such as: roots, stems, leaves, flowers, bark, pollen, lichen, moss, ferns and algae; microorganisms such as: fungi, bacteria, viruses and plant parasites; animal materials such as: whole animals, animal organs, tissues, secretions, cell lines, toxins, nosodes, blood products; human materials such as: tissues, secretions, cell lines; and endogenous molecules such as hormones, minerals and chemicals. Furthermore, the quantity of starting material present in homeopathic medicines may depend on the method of preparation.

Safety issues may crop up if these differences in method of preparation are abandoned. For example, an assessment of the "identically" entitled pharmacopoeial monographs on *Aconitum napellus* in different pharmacopoeias that is, the Pharmacopoeia française (Phf), the German Homeopathic Pharmacopoeia (GHP), the Homoeopathic Pharmacopeia of the United States (HPUS) and the Homoeopathic Pharmacopoeia of India (HPI) reveals substantial differences (Table 1). *Aconitum napellus* 1X = 1DH prepared according to the German Homeopathic Pharmacopoeia is closer to *A. napellus* mother tincture than to the 1X = 1DH, both prepared according to the Pharmacopoeia francaise (WHO, 2009).

Diverse customs in the utilization of homoeopathic and anthroposophic analysis and altering levels of proficiency along with the dogmatic powers inside the European unification have executed in altering principles of appraisal (Schultz et al., 2011). Quality assurance for herbal starting materials is based on the knowledge about their origins, as well as their pharmacognosic identification and assessment. The studies had shown that the thin layered chromatography (TLC) fingerprints of different mother tincture batches may show wide variation. This raises the question of whether additional quality characteristics should be considered in order to ensure a constant and uniform level of quality. For this purpose, it seems particularly appropriate to use the concept of marker substances, as in the field of Herbal medicinal products if this concept were to be applied to mother tinctures. The fortitude of a specific marker substance, or group of maker substance, would have to be added to the current range of quality characteristics. In this context, however, it is important to note that the current knowledge about characteristic constituents of plants has for the most part been gained from studies of dried plant materials (Hager et al., 2006).

Adverse events taking place during homeopathic treatment are rarely accredited to the homeopathic medicine itself. However, safety assessment should also consider possible impurities of the source material or contamination and failures of good manufacturing practice. Furthermore, because many homeopathic medicines can be

Table 1. The monographs on *Aconitum napellus* in four pharmacopoeias.

Characteristic	Pharmacopoeia Française (Phf)	German Homeopathic Pharmacopoeia (GHP)	Homoeopathic pharmacopeia of the United States (HPUS)	Homoeopathic pharmacopoeia of India (HPI)
Alkaloid content expressed in aconitine in the mother tincture	0.02–0.05%	0.08–0.16%	0.025–0.075%	Not described (approx. 0.03%)
Ratio of mother tincture to diluents for obtention of 1X = 1DH	1:9	1:4	1:1	Mother tincture = 1X
Percentage of the mother tincture in the 1DH dilution	10%	20%	100%	100%
Content expressed in aconitine in 1X = 1DH	0.002–0.005%	0.016–0.032 %	0.025–0.075%	N/A

medicines can be purchased as non-prescription medicines in community pharmacies and health stores, without consultation with a healthcare provider, it has become increasingly important to provide sufficient and accessible information on such medicines. Although homeopathic medicines are generally assumed to be benign, the level of authorization, appropriate labeling and quality assurance should take into consideration its extensive use, also within vulnerable populations such as the elderly, pregnant women and children.

In recent years, there have been a number of calls on WHO to support efforts to regulate the safety of homeopathic medicines (WHO, 2009). Throughout the precedent few decades, the manipulation of homoeopathic preparations and herbal medicines in the industrial world has turn into a trendy and exceedingly demanded form of therapeutic management, which has been expedited by fewer rigorous systems than other medications (WHO, 2009c). Even though the majority of trustworthy manufacturers of homoeopathic mother tinctures point toward the charisma of vigorous components on the labels of unvarying products, methodical methods have mottled extensively (Gower, 2009).

The current study was conducted to appraise the physical and chemical parameters of five frequently accessible used mother tinctures that is, *Aconitum napellus*, *Arnica montana*, *Bryonia alba*, *Belladonna* and *Chamomila*, prepared by five local homeopathic pharmaceutical companies by employing standard methodology for following parameters that is, alcohol contents, weight/ml, specific gravity and pH. All of these mother tinctures are commonly used in different dilutions throughout the country for the cure of different diseases.

MATERIALS AND METHODS

Sample collection and physico-chemical properties assessment

Twenty five samples of mother tinctures were collected from various localities of the country that is, Islamabad, Rawalpindi, Lahore and the local market during August, 2011. All samples were stored at room temperature by employing WHO guidelines on good agricultural and collection practice (GACP) and FCP (Field collection practices) (WHO, 2003). Mother tinctures of conitum *A. napellus*, *A. montana*, *B. alba*, *Belladonna* and *Chamomila* manufacturered by four various leading homeopathic companies were purchased from open market and were analyzed for the following parameters by employing standard methodology (British Pharmacopoeia (BP), 1968).

1. Alcohol contents;
2. Weight/ml;
3. Specific gravity;
4. pH.

There are three methods given in BP (1968) and we had employed all three methods according to the need and requirement of parameters.

Method-I

Twenty five (25) ml of the preparation was measured in a graduated flask at 20°C, transfered to a flask of 500 to 800 ml capacity, the graduated flask was washed with 100 to 150 ml of water, and the washings added to the contents of the larger flask together with a little pumice powder. The flask was connected to a condenser by means of a suitable still-head, and distilled for at least 90 ml, into a 100 ml graduated flask. The distillate was brought to 20.0°C and diluted to 100 ml with water at the same temperature. The specific gravity was determined at 20.0°C and the refractive index of the solution at 20.0°C. And if by reference to the ethyl alcohol (Quadruple bulk) table, page 1280, the refractive index does not differ by more than 0.00007 (equivalence of 0.2 on the immersion refractive index does not differ by more than that corresponding to the specific gravity, the percentage of ethyl alcohol corresponding to the specific gravity is read off). If the refractive index differs by more than 0.00007 (equivalence of 0.2 on the immersion refract meter scale), 75 ml of the distillate is treated with powdered sodium chloride and light petroleum (boiling-range, 40 to 60°), as in Method II, distilled to about 70 ml, and the distillate to 75 ml. If the refractive index still does not correspond with the specific gravity, the distillate contains some impurity, and the specific gravity does not indicate the true proportion of ethyl alcohol. When the distillate contains steam-volatile substances other than alcohol (it will then usually be turbid or contain oily drops), Method III is applied. When steam violate-volatile acids are present, the solution is made alkaline with N/I sodium hydroxide, using solid phenolphthalein as indicator before the final distillation.

Method II

Twenty five (25) ml of the preparation was measured in a graduated flask at 20°C, transfered to a separator, the graduated flask washed with about 100 ml of water, the washings added to the contents of the separator with sufficient powder (boiling-range, 40 to 60°), and shaken vigorously for two to three minutes. The mixture was allowed to stand from 15 to 30 min and run power layer run into a distillation flask. The light petroleum was washed in the separator by shaking vigorously with about 25 ml of a saturated solution of sodium chloride, allowed to stand, and the washed liquor run into the first brine solution. Where the alcohol limits table directs a double separation, the brine solution was run into a second separator and shaken further with 100 ml of light petroleum (boiling-range, 40 to 60°) before transferring to the distillation flask. This is the second quantity of light petroleum with the washed liquor from the first washing. The mixed solutions were made alkaline with N/I sodium hydroxide using solid phenolphthalein as indicator, a little pumice powder was added, and together with 100 ml of water the solution was distilled 90 ml. The amount of ethyl alcohol was determined by Method I. The distillate was brought to 20.0°C and diluted to 100 ml with water at the same temperature.

The specific gravity was determined at 20.0°C, and the refractive index of the solution at 20.0°C, and if, by reference to the ethyl alcohol (Quadruple Bulk) table, page 1280, the refractive index does not differ by more than 0.00007 (equivalence of 0.2 on the immersion refractive index does not differ by more than correspond-ding to the specific gravity) the percentage of ethyl alcohol corresponding of the specific gravity is read off. If the refractive index differs by more than 0.00007 (equivalence of 0.2 on the immersion refract meter scale), 75 ml of the distillate is treated with powdered sodium chloride and light petroleum (boiling-range, 40 to 60°) as in Method II, distilled to about 70 ml and diluted to 75 ml. If the refractive index still does not correspond with the specific gravity, the distillate contains some impurity, and the specific gravity does not indicate the true proportion of ethyl alcohol. When the distillate contains steam-volatile substances other than alcohol (it will then usually be turbid or contain oily drops), Method III is applied. When steam violate-volatile acids are present, the solution is made alkaline with N/I sodium hydroxide, using solid phenolphthalein as indicator, before the final distillation.

Method III

Twenty five (25) ml of the preparation was measured in a graduated flask at 20°C, transfered to a flask of 500 to 800 ml capacity, washed with 100 to 150 ml of water with the washings added to the contents of the larger flask, and a little pumice powder finally added. The flask was connected to a condenser by means of a suitable still-head, and distilled to about 100 ml. The solution was transferred to a separator, and the amount of ethyl alcohol determined by Method II. Sufficient powdered sodium chloride was added and allowed to stand. The wash liquor was finally run into the first brine solution. Where the alcohol limits table directs a double separation, the brine solution was run into a second separator and shaken further with 100 ml of light petroleum (boiling-range, 40 to 60°) before transferring to the distillation flask. This second quantity of light petroleum was washed with the washing liquor from the first washing. The mixed solutions were made alkaline with N/I sodium hydroxide, using solid phenolphthalein as indicator, with pumice powder and 100 ml water added and distilled to 90 ml. The amount of ethyl alcohol was determined by Method I.

The distillate was brought to 20.0°C and diluted to 100 ml with water at the same temperature. The specific gravity at 20.0°C was determined, and the refractive index of the solution at 20.0°C also, and if by reference to the ethyl alcohol (Quadruple Bulk) table, page 1280, the refractive index does not differ by more than 0.00007 (an equivalence of 0.2 on the immersion refractive index does not differ by more than corresponding to the specific gravity), the percentage of ethyl alcohol corresponding to the specific gravity is read off. If the refractive index differs by more than 0.00007 (equivalence of 0.2 on the immersion refract meter scale), 75 ml of the distillate is treated with powdered sodium chloride and light petroleum (boiling range, 40 to 60°); as in Method II, about 70 ml was distillated and diluted to 75 ml.

If the refractive index still does not correspond with the specific gravity, the distillate contained some impurity, and the specific gravity does not indicate the true proportion of ethyl alcohol. When the distillate contains steam-volatile substances other than alcohol (it will then usually be turbid or contain oily drops), Method III is used. When steam violate-volatile acids are present, the solution was made alkaline with N/1 sodium hydroxide, using solid phenolphthalein as indicator before the final distillation (BP, 1968).

RESULTS

A total of 25 samples of commonly used mother tinctures of *A. napellus*, *A. montana*, *B. alba*, *Belladonna*, *Chamomila* manufactured by five different companies were unruffled from diverse places of the country that is, Islamabad, Rawalpindi, Lahore and physicochemical specifications that is, alcohol contents, weight/ml, specific gravity, pH were determined and analyzed statistically. Table 2 shows that alcohol content of *A. napellus* of five mother tinctures varies from 59.01 to 64.55% (Range 61 to 65%, standard deviation = 2.40), weight/ml varies from 0.859 to 0.884 g/ml (range = 0.890 to 0.925, SD = 0.00956). Specific gravity varies from 0.903 to 0.929 (range is 0.930 to 0.950 = according to GHP and SD = 0.00998) and pH varies from 5.06 to 6.099 (range = 5.0 to 7.0 and SD = 0.41367).

All ranges given in Table 1 are given by manufacturers except specific gravity which was not given by manufacturers and given in Germen Homeopathic Pharmacopoeia. Table 3 shows results of *A. montana* whose alcohol contents varies from 53.71 to 62.73% (range 57 to 61%) except of Rax Laboratories whose result is 83.11% with the range of 88 to 92%. Weight/ml varies from 0.788 to 0.884 (Range = 0.900 to 0.925, SD = 0.03857); specific gravity varies from 0.828 to 0.929 (range = 0.833 to 0.945 GHP, SD = 0.04108), pH varies from 5.060 to 6.099 (Range = 5.0 to 7.0, SD = 0.41367). Range of specific gravity is taken from GHP. Table 4 shows results of *B. Alba* whose alcohol contents varies from 51.94 to 57.28% (range 57 to 61%) except of BM Pvt. Ltd whose result is 55.48%, with the range of 60 to 70%.

Weight/ml varies from 0.870 to 0.892 (Range = 0.883 to 0.940, SD = 0.00953), specific gravity varies from 0.914 to 0.920 (range = 0.940 to 0.960 GHP, SD = 0.00249), pH varies from 5.932 to 6.939 (range = 5.5 to 8.3) except of BM Pvt. Ltd whose result is 5.959 with the range of 7.9 to 8.3. Table 5 shows results of *Belladonna* whose alcohol content varies from 36.63 to 53.71% with different ranges given by all companies. Weight/ml varies from

Table 2. Name of the drug (*A. napellus*).

Name of drug	Alcohol content (%)		Weight/ml (g/ml)		Specific gravity		pH		Manufacturer
	Observed value	Limit	Observed value	Limit	Observed value	Limit (GHP)	Observed value	Limit	
Aconitum napellus	59.01	61	0.8662	0.90	0.910	0.930-0.950	5.637	6.0	KL
Aconitum napellus	64.55	61-65	0.859	-	0.903	0.930-0.950	6.016	-	RL
Aconitum napellus	64.55	61-65	0.884	0.890-0.925	0.929	0.930-0.950	5.581	5.0-7.0	BM
Aconitum napellus	62.72	63	0.868	-	0.912	0.930-0.950	5.060	-	WH
Aconitum napellus	60.90	61-65	0.863	0.896-0.904	0.907	0.930-0.950	6.099	5.5-7.0	MH

*KL= Kamal Laboratories, Rawalpindi Pakistan; RL= Rax Laboratories, Homeopathic, Lahore Pakistan; BM= BM (private) Limited Lahore Pakistan; WH= Warsan homeopathic Laboratories, Lahore Pakistan; MH = Masood homeopathic Stores & Hospitals, Lahore, Pakistan.

Table 3. Name of the drug (*Arnica Montana*).

Name of drug	Alcohol content (%)		Weight/ml (g/ml)		Specific gravity		pH		Manufacturer
	Observed value	Limit	Observed value	Limit	Observed value	Limit (GHP)	Observed value	Limit	
Arnica montana	53.71	60	0.86	0.80	0.913	0.833-0.945	5.637	6.0	KL
Arnica montana	83.11	88-92	0.788	-	0.828	0.833-0.945	6.016	-	RL
Arnica montana	55.48	57-61	0.884	0.900.925	0.929	0.833-0.945	5.581	5.0-7.0	BM
Arnica montana	60.91	57-61	0.869	0.900-0.925	0.914	0.833-0.945	5.060	-	WH
Arnica montana	62.73	57-61	0.875	0.900-0.925	0.919	0.833-0.945	6.099	5.5-7.0	MH

*KL= Kamal Laboratories, Rawalpindi Pakistan; RL= Rax Laboratories, Homeopathic, Lahore Pakistan; BM= BM (private) Limited Lahore Pakistan; WH= Warsan homeopathic Laboratories, Lahore Pakistan; MH = Masood homeopathic Stores & Hospitals, Lahore, Pakistan.

Table 4. Name of the drug (*Bryonia alba*).

Name of drug	Alcohol contents (%)		Weight/ml (g/ml)		Specific gravity		pH		Manufacturer
	Observed value	Limit	Observed value	Limit	Observed value	Limits (GHP)	Observed value	Limit	
Bryonia alba	51.94	60	0.870	0.900	0.914	0.940-0.960	6.939	5.96	KL
Bryonia alba	57.28	57-61	0.870	-	0.914	0.940-0.960	6.282	-	RL
Bryonia alba	55.48	60-70	0.875	0.883-0.940	0.920	0.940-0.960	5.959	7.9-8.3	BM
Bryonia alba	53.71	57-61	0.892	0.983-0.940	0.916	0.940-0.960	5.612	5.5-6.5	WH
Bryonia alba	51.94	57-61	0.870	0.883-0.940	0.917	0.940-0.960	5.932	5.5-7.0	MH

*KL= Kamal Laboratories, Rawalpindi Pakistan; RL= Rax Laboratories, Homeopathic, Lahore Pakistan; BM= BM (private) Limited Lahore Pakistan; WH= Warsan homeopathic Laboratories, Lahore Pakistan; MH = Masood homeopathic Stores & Hospitals, Lahore, Pakistan.

Table 5. Name of the drug (*Belladonna*)

Name of drug	Alcohol contents (%)		Weight/ml (g/ml)		Specific gravity		pH		Manufacturer
	Observed value	Limit	Observed value	Limit	Observed value	Limit (GHP)	Observed value	Limit	
Belladonna	36.63	45	0.789	0.928	0.829	0.932-0.947	6.492	6.75	KL
Belladonna	45.02	47-51	0.887	-	0.932	0.932-0.947	6.323	-	RL
Belladonna	53.71	45-55	0.911	0.900-0.960	0.957	0.932-0.947	6.131	5.0-6.5	BM
Belladonna	43.32	41-45	0.910	0.926-0.948	0.956	0.932-0.947	6.130	6.0-7.0	WH
Belladonna	45.02	41-45	0.904	0.926-0.948	0.950	0.932-0.947	6.143	6.4-7.0	MH

*KL= Kamal Laboratories, Rawalpindi Pakistan; RL= Rax Laboratories, Homeopathic, Lahore Pakistan; BM= BM (private) Limited Lahore Pakistan; WH= Warsan homeopathic Laboratories, Lahore Pakistan; MH = Masood homeopathic Stores & Hospitals, Lahore, Pakistan.

Table 6. Name of the drug (*Chamomilla*).

Name of drug	Alcohol contents (%)		Weight/ml (g/ml)		Specific gravity		pH		Manufacturer
	Observed value	Limit	Observed value	Limit	Observed value	Limit (GHP)	Observed value	Limit	
Chamomilla	39.95	45	0.894l	0.924	0.941	0.900-0.920	5.339	5.5	KL
Chamomilla	62.72	67-71	0.859	-	0.902	0.900-0.920	6.023	-	RL
Chamomilla	45.02	45-55	0.894	0.920-0.960	0.940	0.900-0.920	5.394	5.5-6.5	BM
Chamomilla	46.73	47-51	0.970	0.910-0.940	0.953	0.900-0.920	5.400	5.5-6.5	WH
Chamomilla	51.94	47-51	0.891	0.910-0.940	0.937	0.900-0.920	6.275	5.5-6.5	MH

*KL= Kamal Laboratories, Rawalpindi Pakistan; RL= Rax Laboratories, Homeopathic, Lahore Pakistan; BM= BM (private) Limited Lahore Pakistan; WH= Warsan homeopathic Laboratories, Lahore Pakistan; MH = Masood homeopathic Stores & Hospitals, Lahore, Pakistan.

0.789 to 0.911 (range = 0.900 to 0.960, SD = 0.05188), specific gravity varies from 0.829 to 0.957 (range = 0.932 to 0.947 GHP, SD = 0.05449), pH varies from 6.130 to 6.492 (different ranges given by all manufacturers).

Table 6 shows results of Chamomilla whose alcohol content varies from 39.95 to 62.72% with different ranges given by all companies. Weight/ml varies from 0.859 to 0.970 (range =0.910 to 0.960) except of BM Pvt. Ltd whose result is 0.894 with the range of 0.920 to 0.960, specific gravity varies from 0.902 to 0.953 (range = 0.900 to 0.920 GHP, SD = 0.01922) and pH varies from 5.339 to 6.275 (range = 5.5 to 6.5).

DISCUSSION

Homeopathic medicine continues to catch the attention of medical journals and the media as a well-liked form of complementary medicine (CM) whose anticipated mechanism of action seems irreconcilable with conventional technical thought and the research substantiation which remains contentious. Categorization of the prelude matter is guaranteed by the eminence of homoeopathic mother tinctures, the industrialized procedure and the exploratory distinctiveness construed in the treatise (Biber et al., 2009). Very little data is available on the quality of homoeopathic medicines as there is no law to regulate the complementary and alternative system of medicines (CAM) and is self regulatory. The most frequently

used but famous forms of CAM is homeopathy. Extremely diluted preparations of substances that cause symptoms in healthy individuals are used to kindle remedial reactions in patients who demonstrate analogous symptoms when sick (Jonas and Jacobs, 1996).

Currently, the only quantitative method described in HAB monographs is the fortitude of dry residue, except in those cases where the mother tincture contains toxic compounds. By distinction, the French Pharmacopoeia monographs often include the grit of a marker substance or group determination. Probing for the marker substances in mother tinctures is complicated. Research on plant constituents described in literature was for the most part performed on dried plant materials. These findings cannot be applied to fresh plants in general. This is most likely due to certain factors such as post harvest enzymatic process caused by disruption of the cellular compartmentation (Biber et al., 2009). Our analysis has shown variation in results of all samples of five manufacturers. All samples have their own limits of all parameters even all are from ISO 9001:2008 certified companies.

Generally, the eminence of the elected homoeopathic mother tinctures feigned globally abides by the excellence values deposit by the GHP and GMP. An assortment of samples of the nearby contrived homoeopathic mother tinctures complied with the standards of the GHP and GMP, although others are futile to attain this customary eminence (Scheepmaker, 2010). The quality of source materials and of the excipients used in the manufacture of homeopathic medicines is imperative. Homeopathic medicines may utilize material from problematic sources, the use of which is constrained in conventional medicine: nosodes comprise dilutions of pathogenic organs or tissues; causative agents such as bacteria, fungi, ova, parasites, virus particles, and yeast; disease products, excretions or secretions. All materials of animal or human origin are at risk of containing pathogenic agents. Homeopathic medicines may be based on toxic source materials from animals or plants, while others, particularly in their fresh form are prone to degradation processes or microbiological contamination (WHO, 2009).

Today, quantitative determinations present the analytical state of knowledge for herbal preparations as well. However, for homoeopathic mother tinctures of plant, it is attributed that the whole preparation is considered to present the active substance and in addition, there is no affiliation between dose and effect. For these reasons, quality cannot be proscribed based on one individual active constituent only. Unswerving quality primarily has to be assured by careful control of the starting material and by constancy of the traditional manufacturing process. Analogous to other herbal preparations it could be possible to select certain markers for quality control of homoeopathic mother tinctures made from plants in mother tinctures containing strong acting or toxic compounds, the contents of these substances have to be checked anyway for reasons of medicinal product safety (Directive, 2001/83/EC).

Plant materials may be tainted with pesticides and heavy metals. The content of toxic constituents in plant materials may vary considerably. Good manufacturing practice (GMP) guidelines covering the manufacturing process, premises, personnel, packaging and labeling apply to homeopathic medicines as well as to conventional pharmaceuticals. Failure to apply GMP may lead to major quality and safety concerns such as misidentification, impurity of starting material, cross-contamination or incidental contamination. The unique characteristics of the manufacturing of homeopathic medicines have a number of specific implications and demand specially qualified and experienced personnel. These have to handle toxic materials, particularly fresh ones that are prone to degradation processes and microbial contamination; and homeopathic medicines derived from animals or human sources. The properties of homeopathic medi-cines can be compromised by accidental or intentional contamination of source materials, excipients or diluents, or by the vessel or bottle in which the dilution is made. Because definitions may vary between pharmacopoeias, and because of the wide range of processing techniques and manufacturing methods in the various pharmaco-poeias, the final homeopathic products may show marked variability (WHO, 2009).

In Europe, there are two official homoeopathic pharmacopoeias regulating production and quality parameters of homoeopathic medicinal products based on one years of experience, the German Homoeopathic pharmacopoeia and the homoeopathic part of the French Pharmacopoeia. The current therapeutic use of homoeopathic medicinal products in Europe is based on the quality stipulated in these pharmacopoeias. Today at the European level, monographs on homoeopathic preparations are integrated step by step into the European pharmacopoeia (Ph. Eur). Replacing National requirements in addition, the European legislative had recently taken up a section on quality of homoeopathic medicinal products of the first time (Directive 2001/83/EC). The dearth of momentous regulations concerning the quality of CAM in South Africa contributes to this challenge (Gqaleni et al., 2007).

The Drug Control and Traditional Medicines Division of National Institute of Health, Islamabad in collaboration with WHO has organized number of seminars and workshops to educate the stakeholders of traditional medicines sector to adapt and implement current good manufacturing practices, quality control and quality assurance guidelines for herbal medicines and has also developed few booklets as well (Hussain et al., 2011; Shaikh et al., 2009). There is a dire need to implement these recommendations which had emanated from these activities. The present study should be extended to other commonly used homoeopathic medicines which will in turn form the basis of homeopathic pharmacopoeia.

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