



# Need for Standardization of Drug Strength of Homoeopathic Mother Tinctures

Barve R<sup>1\*</sup> and Kulkarni S<sup>2</sup>

<sup>1</sup>Guest Professor, Dept. of Repertory, CMP Homoeopathic Medical College, India

<sup>2</sup>Senior Pharmaceutical Consultant and Researcher, India

**\*Corresponding author:** Rajesh Barve, Guest Professor, Dept. of Repertory, CMP Homoeopathic Medical College, Vileparle west, Mumbai, India, Email: rsbarve@yahoo.co.in

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## Abstract

Standardization of homoeopathic finished products is a need of hour, especially when new regulations and G.M.P. standards are being implemented. Mother tincture is a basic substance from which higher potencies are prepared in Homoeopathy. Standardization of higher potencies is difficult as quantity of original drug is very difficult to trace, but at tincture level it is possible. One such criteria for standardization is drug strength. Purpose of this work is to verify the actual drug strength of finished product (mother tincture), and to compare with postulated drug strength as per pharmacopeia.

**Keywords:** Homoeopathic Mother Tincture; Drug Strength; H.P.I. (Homoeopathic Pharmacopeia of India)

## Introduction

Drug strength of a tincture plays important role in efficacy of tincture and accuracy of subsequent higher potencies. Mother tincture is basic drug substance commonly prepared from vegetable, animal, mineral source using Hydro Alcoholic mixture as vehicle, amount of vehicle is decided by moisture content in vegetable source. H.P.I. (Homoeopathic Pharmacopeia of India) states, mother tincture are preparations containing soluble ingredients of the drug substance in alcohol. Drug strength of a tincture means power or strength of a drug [1]. i.e. amount of drug substance in proportion of its solvent, it indicates the amount of drug content in the medicinal preparation. In India homoeopathy mother tinctures are prepared with drug strength of either 1/10 or 1/100, as directed by HPI. Where as in old Hahnemannian method drug strength use to vary according to class of mother tincture e.g.

**Class I** it is  $\frac{1}{2}$

**Class II** :  $\frac{1}{2}$

**Class III:**  $\frac{1}{6}$

**Class IV:**  $\frac{1}{10}$  [2].

Drug strength 1/10 means in 10 parts of drug, one part is original drug substance and nine parts is vehicle. i.e. in 100 ml of tincture amount of drug present should be 10 grams and in 1000 ml of tincture the drug should be 100 grams. as per H.P.I. H.P.I. has tried to standardize the drug strength of most of the tinctures to 1/10 by stating appropriate proportion of drug substance and amount of water and alcohol to be taken to prepare 1000 ml of tincture. Homoeopathic tincture is hydro alcoholic mixture with the drug substance. e.g. for a tincture prepared from plant kingdom it is a mixture of plant or plant product with alcohol and water. Plant will contain cell wall debris, Cellulose, saponins, tannins, trace elements, minerals, tissue matrix, alkaloids. Some of these may be

soluble or insoluble. Solubility of drug substance varies in different proportions of water and alcohol.

## Material and Methods

Two Mother Tinctures namely

- Holarrhena antidysentrica
- Nicotina tabacum

No	Name of Drug	Postulated Drug Strength by H.P.I.	Drug Amount	Alcohol 91%	Water
1	Holarrhena Antidysentrica	10-Jan	100 gm powder	600 ml	500 ml
2	Nicotina Tabacum	10-Jan	100 gm powder	824 ml	200 ml

**Table 1:** Indicates that to prepare Holarrhena Antidysentrica tincture.

To prepare Homoeopathic Tincture, specified amount of vehicle ( water + alcohol ) is added to 100 grams of drug powder by percolation or maceration method which is filtered after 8 days to get required tincture which is assumed to have drug strength 1/10 as per H.P.I. Ideally 1000 ml of tincture should have 100 gms of drug (soluble+insoluble) substance.

To have drug strength 1/10. Actual amount of drug present in tincture was calculated in this study by weighing the amount of residue left after the filtration. Amount of drug taken to prepare tincture -Residue filtered = amount of drug present in tincture.

No	Drug	Amount of Residue Filtered out	Actual Amount of Drug Present in 1000 Ml of Tincture
1	Holarrhena Antidysentrica	90 gms	10 gms
2	Nicotina Tabacum	83 gms	17 gms

**Table 2:** Indicates that after filtration of Holarrhena tincture.

Table 3 indicates as per H.P.I. postulated drug strength of both drugs should be 1/10(0.1) but in reality it is far less. For Holarrhena tincture it was observed to be 1/100 (0.010 ),

No	Name of Drug	Postulated Drug Strength According to Hpi	Actual Drug Strength Observed
1	Holarrhena Antidysentrica	1/10 (0.1)	1 /100 (0.010 )
2	Nicotina Tabacum	1/10 (0.1)	17 /1000 (0.017)

**Table 3:** Indicates as per H.P.I. postulated drug strength.

This difference in actual and assumptive drug strength is due to difference in amount of drug substance taken as raw

These were prepared according to the guidelines given in H.P.I. for the study as follows [3]. Table 1 indicates that to prepare Holarrhena Antidysentrica tincture of drug strength 1/10 we have to take 100 grams of Holarrhena Antidysentrica powder and to it add 600 ml of alcohol and 500 ml of distilled water. Similarly to prepare Nicotina Tabacum tincture of drug strength 1/10 we need to take 100 grams of tobacco powder and add 824 ml of alcohol and 200 ml of distilled water.

## Results

Table 2 indicates that after filtration of Holarrhena tincture almost 90 grams of undissolved powder is filtered out, meaning only 10 grams of drug substance is present in tincture instead of 100 grams and in Nicotina tabacum case only 17 grams of drug is retained in the tincture.

To have the drug strength of 1/ 10 = 0. 1. Amount of drug present in tincture should be 100 grams. Actual calculated drug strength of tincture (finished product) after filtration.

and for Nicotina it was 17/1000(0.017). As the study shows both of these tinctures do not have drug strength of 1/10 as postulated by H.P.I.

material and finished product. Amount of drug to be taken to prepare Holarrhena Antidysentrica tincture is 100 gms

(as per H.P.I.), but this is the amount out drug taken as raw material, and not the amount present in the tincture (finished product) after filtration. Drug strength should be calculated of finished product and not raw material. Drug strengths of (finished products) Holarrhena is 0.01 and Tabacum 0.017 respectively instead of theoretical 0.10. which is much less than postulated in H.P.I.

### Implications

According to H.P.I. tincture of assumptive drug strength 1/10 is taken as 1x potency (first decimal potency). Since dilution factor is 1/10. Further potencies are prepared assuming it is 1x or 1/10 dilution. For Holarrhena tincture actual drug strength observed is 1/100 instead of 1/10. i.e dilution factor of tincture is =2x (second decimal potency) instead of 1x hence all further potencies will be wrong. i.e. 2<sup>nd</sup> decimal dilution prepared from this tincture will have dilution 1/10000 instead of 1/1000 and so on. All further potencies will be inaccurate.

### Discussion and Conclusion

Practically it is not possible to get drug strength of 1/10 of finished product (Tincture After Filtration) unless drug is

100% soluble. As the solubility of each drug substance in hydro alcoholic mixture is not same and most of insoluble material is filtered out (again it depends on size of filter used). Hence though we are taking raw material 100 gm to start with, amount of actual drug left after filtration (finished product) is much less. Drug strength will vary depending on insoluble residue filtered out and extractive value of the substance. (Extractive Value of substance i.e. amount of soluble portion of the substance in a solvent.) When it is not possible to prepare tincture with 1/10 drug strength in most of cases it will be better to write actual drug strength of each tincture.

### References

1. (2016) Homoeopathic Pharmacopoeia of India 2016(38).
2. (2016) Homoeopathic Pharmacopoeia of India 1: 396-398.
3. (2016) Homoeopathic Pharmacopoeia of India 1(214): 306.