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Stability and expiry date evaluation of homoeopathic mother tincture

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Abstract

Expiry date and stability testing is relatively new concept in homoeopathy. There is lack of scientific data regarding evaluation of expiry date of homoeopathic tinctures and potencies. This is a preliminary work in that direction, where we have tried to develop standard methodology for stability testing . Nicotiana Tabacumtincture(77% alcohol) is subjected to various tests as per W.H.O. and I.C.H. guidelines and introduced new criteria of evaluating biological efficacy by in vitro culture studies for the samples which are 5-10 year old.

The term 'shelf life' is used to indicate the time period in which an active ingredient A.P.I.(active pharmacological ingredient) of F.P.P.(finished pharmaceutical product) is expected to remain within the approved stability specifications, provided that it is stored under the conditions defined on the container label.

Till 2009 there was no concept of expiry date for Homoeopathic Tinctures and Potencies in India. In modern medicine (allopathic) every drug is labeled with shelf- life or expiry date as alkaloid or active ingredient of drug will undergo degradation with time and environmental factors.

After AYUSH guidelines, which in a way are dependent on W.H.O. and I.C.H. guidelines, It is now mandatory to write date of expiry for homoeopathic tinctures and potencies. Drug and Cosmetic Rule, schedule –M states that shelf life for Homoeopathic tincture and Potencies should not be more than 60 months (5 years). This is a blanket date of expiry for all Homoeopathic potencies and tinctures irrespective of their source and nature of the drug. This evaluation is not based on actual study of shelf life of individual drug.

Homoeopathic tinctures and potencies are prepared from plant, animal and mineral kingdom mainly. Mineral or metal based remedy cannot expect to have same shelf life as that from plant or animal source. Within plant kingdom also tinctures are prepared from alcohol concentration varying from 35% to 80%. Tincture prepared from 35% ethanol can't expect to have same stability and expiry date as that which is from 80% ethanol. This 5 year expiry date evaluation is empirical. No detailed scientific study is available about stability or expiry date of individual drug potency or tincture.

This paper is to primarily find effect of environmental factors like light, temperature, moisture etc. on homoeopathic medicines as per guidelines given by W.H.O. and I.C.H. and evaluate the effect of storage for longer time on homoeopathic tincture at room temperature. For this work Nicotiana Tabacum tincture (77% alcohol) was used and physiochemical and in vitro biological studies were carried out for first time in this preliminary study of stability and expiry date evaluation of homoeopathic tincture.

Like homoeopathy, for Ayurvedic system of medicine also AYUSH has set guidelines for stability and expiry date. Govt .notification in 2005 and later modified in 2009. Rule 161 B displays list of expiry dates for ayurvedic products. (ASU products)

E.g. Gutica -3 years, churna -2 years etc. however for Asavas and Aristas (which are alcoholic extracts) there is no expiry date. Asavas and Aristas have much less ethanol content when compared with homoeopathic tinctures and potencies.

Hence actual evaluation of stability and expiry date of each type of homoeopathic drug and tincture is necessary, which is the purpose of this primary work.

Biography

Dr. Rajesh Barve is a medical practitioner by profession. After completing his M.D. in Homeopathy, he is working as Head, Repertory Department of Virar Homeopathic Medical College, Maharashtra and runs his clinic in Mumbai.

Dr. Barve's main interest is to use herbal medicines in the nanoparticles size in alcohol medium to treat the patients. He has published several original peer reviewed papers and contributed his work in the book chapters of international repute. He is also on the Editorial board of Homeopathic journal of medicine.