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Research Article

Standardisation Of Marketed Herbal Fromulation Of Muscle And Joint Hrx Pain Relieving Oil

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Abstract

Forced degradation studies show the chemical behavior of the molecule which in turn helps in the development of formulation and package. A forced degradation study is an essential step in the design of a regulatory compliant stability program for both drug substances and products, and formalized as a regulatory requirement in ICH Guideline Q1A in 1993. Forced degradation is a degradation of new drug substance and drug product at conditions more severe than accelerated conditions. It is required to demonstrate specificity of stability indicating methods and also provides an insight into degradation pathways and degradation products of the drug substance and helps in elucidation of the structure of the degradation products. Thus, this review discusses the current trends in performance of forced degradation studies by providing a strategy for conducting studies on degradation mechanisms.

1. Introduction

Standardization of drug means confirmation of its identity and determination of its quality and purity and detection of nature of adulterant by various parameters like morphological, microscopical, physical, chemical and biological observations[2]. In the present era, market of all commodities has become global. Health has been of utmost importance since ancient times for the mankind. Market of health-related products has been active and these products are manufactured at different parts of the world and sold all over. Standardization is necessary to make sure the availability of a uniform product in all parts of the world. Standardization assures a consistently stronger product with guaranteed constituents[3]. WHO collaborates and assists health ministries in establishing mechanisms for the introduction of traditional plant medicines into primary healthcare programs, in assessing safety and efficacy, in ensuring adequate supplies, and in the quality control of raw and processed materials[4]. Herbal formulations in general can be standardized schematically as to formulate the medicament using raw materials collected from different localities and a comparative chemical efficacy of different batches of formulation is to be observed[5]. Through various analytical techniques like TLC, HPLC and HPTLC we can ascertain the presence of these compounds in plants and also quantify them. HPTLC offers many advantages over other chromatographic techniques such as unsurpassed flexibility (esp. stationary and mobile phase), choice of detection, user friendly, rapid and cost effective. Thus, HPTLC is most widely used at industrial level for routine analysis of herbal Medicines. In recent years, plant derived products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics and are available in health food shops and pharmacies over the counter as self medication or also as drugs prescribed in the non-allopathic systems. Herbal medicines widely used in health-care in both developed and developing countries are complex chemical mixtures prepared from plants and are limited in their effectiveness because they are poorly absorbed when taken orally[7] .According to an estimate of the World Health Organization (WHO), about 80% of the world population still uses

herbs and other traditional medicines for their primary health care needs. Herbal formulations have reached widespread acceptability as therapeutic agents for diabetics, arthritics, liver diseases, cough remedies, memory enhancers and adopt gens. As per WHO definition, there are three kinds of herbal medicines: raw plant material, processed plant material and medicinal. Herbal drugs regulations in India as well as an overview of regulatory status of herbal medicine in USA, China, Australia, Brazil, Canada and Germany has been reported. According to WHO guidelines, an herbal product needs to be standardized with respect to safety before releasing it into the market. The drug undertaken[16-17]for the study is Betasitosterol and Eugenol in Marketed formulation (HRX) from Baidyanath Life Sciences Pvt. Ltd Nagpur. Betasitosterol [Figure 1] Chemically is 17-(5-Ethyl-6-methylheptan-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1*H*cyclopenta [*a*] phenanthren-3-ol. And it is used in treatment of elevated blood cholesterol levels also used in prostatic hyperplasia. While eugenol [Figure 2] chemically is 4-Allyl-2-methoxyphenol and it is used as analgesic, biocides and antiseptic. The review of literature[8-15] has reported that very few work on the standardisation of the above phytoconstituents of the herbal formulation has been carried out so the present work is undertaken with the following objectives to study the physiochemical parameters of oil and to generate a valid data of standardisation on the herbal formulation.

Figure 1: Chemical structure of Betsitosterol

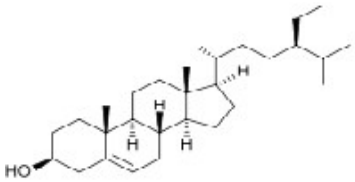
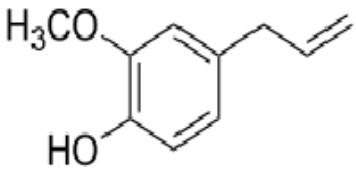


Figure 2: Chemical structure of Eugenol



2. Experimentals

2.1 Materials and Methods: All the methods performed as per the WHO guidelines.

2.2 Apparatus: Round bottom flask, Pipette, Burette, Conical flask, Iodine flask, Reflux condenser, Water bath, Measuring Cylinder, Glass beads, pyncometer.

2.3 Chemicals: Potassium Hydroxide, Ethanol, Ether Phenolphthalein, Carbon tetrachloride, Iodine monochloride, Potassium iodide, sodium thiosulphates, Hydrochloric acid, starch.

2.4 Physiochemical Parameters:

2.4.1Acid Value: Dissolve about 10.0 g of the substance under examination, accurately weighed, in 50 ml of a mixture of equal volumes of ethanol (95 per cent) and ether, previously neutralized with 0.1 M potassium hydroxide to phenolphthalein solution. Connect the flask with a reflux condenser and warm slowly, with frequent shaking, until the sample dissolves. Add 1 ml of phenolphthalein solution and titrate with 0.1 Mpotassium hydroxide until the solution remains faintly pink after shaking for 30 seconds. Calculate the acid value from the expression.

$$\text{Acid value} = 5.61\ n/w$$

Where,

n = the number of ml of 0.1 M potassium hydroxide required;

w = the weight, in g, of the substance.

2.4.2 Iodine Value: Determined from wijus method. Place an accurately weighed quantity of the substance under examination in a dry 500-ml iodine flask, add 10.0 ml of carbon tetrachloride and dissolve. Add 20 ml of iodine monochloride solution insert the stopper and allow standing in the dark at a temperature between 15º and 25º for 30 minutes. Place 15.0 ml of potassium iodide solution in the cup top, carefully remove the stopper, rinse the stopper and the sides of the flask with 100 .0ml of water, shake and titrate with 0.1 M sodium thiosulphate using starch solution, added towards the end of the titration, as indicator. Repeat the operation without the substance under examination and note the number of ml required (b). Calculate the iodine value from the expression

$$\text{Iodine value} = 1.269\ (b - a)/w$$

Where,

w = weight, in g, of the substance.

2.4.3 Peroxide Value: Weigh accurately about 5 g of the substance under examination, transfer to a 250.0 mL glass-stoppered conical flask, add 30.0 ml of a mixture of 3 volumes of glacial acetic acid and 2 volumes of chloroform, swirl until dissolved and add 0.5 ml of saturated potassium iodide solution. Allow to stand for exactly 1 minute, with occasional shaking, add 30.0 ml of water and titrate gradually, with continuous and vigorous shaking, with 0.01 M sodium thiosulphate

until the yellow colour almost disappears. Add 0.5 ml of starch solution and continue the titration, shaking vigorously until the blue color just disappears (a ml). Perform a blank determination omitting the substance under examination (b ml). The volume of 0.01 M sodium thiosulphate in the blank determination must not exceed 0.1 ml. Calculate the peroxide value from the expression

$$\text{Peroxide value} = 10\,(a - b)/w$$

2.4.4 Refractive Index: The refractive index is measured at $20^{O} + 0.5^{O}C$.First clean the prism of Refractometer by using water and acetone. Calibrate the apparatus against distilled water which has a refractive index of 1.3325 at $25^{O}C$.Dry the prism and apply the sample of which refractive index is to be find out.

2.4.5 Saponification Value: About 2.0 g of the substance under examination, accurately weighed, into a 200.0mL flask of borosilicate glass fitted with a reflux condenser. Add 25.0 ml of 0.5 M ethanolic potassium hydroxide and a little pumice powder and boil under reflux on a water-bath for 30 minutes. Add 1 ml of phenolphthalein solution and titrate immediately with 0.5 M hydrochloric acid (a ml). Perform a blank determination omitting the substance under examination (b ml). Calculate the saponification value from the expression

$$\text{Saponification value} = 28.05\,(b - a)/w$$

2.4.6 Weight per Milliliter: Select a thoroughly clean and dry pycnometer. Calibrate the pycnometer by filling it with recently boiled and cooled water at 25º and weighing the contents. Assuming that the weight of 1.0 ml of water at 25º when weighed in air of density 0.0012 g per ml is 0.99602 g, calculate the capacity of the pycnometer (Ordinary deviations in the density of air from the value given do not affect the result of a determination significantly). Adjust the temperature of the substance under examination, to about 20º and fill the pycnometer with it. Adjust the temperature of the filled pycnometer to 25º, remove any excess of the substance and weigh. Subtract the tare weight of the pycnometer from the filled weight of the pycnometer. Determine the weight per milliliter by dividing the weight in air, in g, of the quantity of liquid which fills the pycnometer at the specified temperature, by the capacity expressed in ml, of the pycnometer at the same temperature. Then calculate the weight per milliliter by following formula

Figure 3: Formulae to calculate the weight per milliliter

$$\text{Capacity} = \frac{\text{Weight of water}}{0.99602} = 24.2058 \text{ ml}$$

$$\text{Wt/ml} = \frac{\text{Weight of sample}}{\text{Capacity}}$$

3. Results and Discussion

3.1 Description of Oil:

Table 1: Results of preliminary description of oil formulation

Colour	Brownish yellow
Odour	Aromatic
Consistency	Viscous

3.2 Physiochemical properties:

3.2.1 Acid Value:

Table 2: Results of acid value evaluation

Sr. No.	Weight of Substance	Final Reading
1	10.108	7

Limit – 2-4

Result: The Acid value was found to be 3.61.

3.2.2 Iodine Value:

Table 3: Results of Iodine value evaluation

Sr. No	Weight of Substance	Blank Reading	Sample Reading	Final Reading
1	0.15609	33.7	25.2	8.5

Limit: - 97-105

Result: The Iodine value was found to be 102.57

3.2.3 Peroxide Value:

Table 4: Results of peroxide value evaluation

Sr. No.	Weight of Substance	Blank Reading	Sample Reading	Final Reading
1	50.0219	0.1	0.9	0.8

Limit: 2-3

Result: The peroxide value was found to be 2.5

3.2.4 Refractive Index:

Limit -1.4645-1.4695

Observation: The refractive index was found to be 1.4695

3.2.5 Saponification Value:

Table 5: Results of Saponification value evaluation

Sr. No.	Weight of Substance	Blank Reading	Sample Reading	Final Reading
1	2.0205	22.5	8.4	14.1

Limit: - 189-194

Result: The saponification value was found to be 193.47

3.2.6 Weight per Milliliter:

Table 6: Results of weight per milliliter evaluation

Sr.No.	DETAILS	OBSERVATION
1	Weight of empty pycnometer	23.44
2	Weight of empty pycnometer + water	47.55
3	Weight of empty pycnometer + sample	45.89
4	Weight of water	24.1
5	Weight of sample	22.45
6	Capacity	24.21

Limit: .0.919-0.934

Observation: The wt/ml was found to be 0.927 gm/mL.

4. Conclusion

All the standardisation procedures adopted as per the WHO guidelines. All the results found were accurate and specific. Therefore all the above parameters can be used for the routine quality control. Also the developed data of standerdisation can also be used for the further formulation developments using similar plant materials. Also the developed data of standerdisation parameters also serve as tool of authenticity. Therefore such standardisation procedures should be routinely employed.

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