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STABILITY STUDY FOR ARGEMONE MEXICANA

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Abstract: *Argemone mexicana* is an erect, prickly, annual herb, in India it is introduced and naturalized and occur as wasteland weed in almost every part of India. The plant (sap) is used as an antidote to snake bite; in skin diseases, scabies, in eye infections and corneal ulcers. The plant and the root also find use as a diuretic, purgative, laxative, expectorant, for application on wounds; in skin diseases. The root bark powder of *Argemone mexicana* is used a good hepatoprotectant as it repairs liver dysfunction. The stability is aimed at assuring that the drug/drug product remains within specifications established to ensure its identity, strength, quality and purity. It can be interpreted as length of time under specific conditions and storage that a product will remain within the pre-defined limits for all its important characteristics. Each ingredient, whether therapeutically active or inactive, in a dosage form can affect stability. Environmental factors such as temperature, light, air (specifically oxygen, carbon dioxide and water vapours) and humidity can affect stability. Similarly, such factors as particle size, pH, the properties of water and other solvents employed the nature of container and the presence of other chemicals resulting from contamination or from the intentional mixing of different products can influence stability. From observations of CHNS analysis, TGA, DTG, DSC technique and HPTLC analysis of samples it was found that Alupoly is a good container closure for to store Root Bark Powder of *Argemone mexicana L*. The phytochemical corresponding to R_f-value 0.05 of Root Bark Powder of *Argemone mexicana L*. is stable at control temperature in alupoly and HDPE container closure. These results clearly indicate that there was no change in phytochemicals at accelerated conditions.

Keywords: Liver tonic, ingredients, TGA, DSC, HPTLC, pH

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INTRODUCTION

Historically there has always been evidence of concern on the part of pharmaceutical practitioners and the pharmacist, that the drug during development and in the dispensed dosage form be stable. In early twentieth century in-compatibilities between drugs and excipients were quite obvious because of their interactions (e.g. aspirin and magnesium stearate which resulted in acetic acid). This was because formulation development was in its nascent stage. Quantitation was another issue, since the first half of the twentieth century quantitation of assays for such problems relied on some colour reactions and a colorimeter. The introduction of spectrophotometer on a commercial scale was a giant step forward in fifties and sixties, but specificity as still lacking. Such specificity was accomplished in a semi-quantitative manner by thin layer chromatography (TLC), since quite good separations were achieved by this method. Later quantitation by TLC was also achieved due to technological improvements. It was high performance liquid chromatography (HPLC), which proved to be suitable for detection of small amounts of impurities and decomposition products[1].

In early 1960s there was no requirement, as per USFDA regulation, to mention the expiry date on the label of the drug and it was manufacturers responsibility to assure that the product met the USP requirements at all times during the period in which it is sold. In 1975 the USP contained an expiry date clause, but never defined on what basis it should be calculated, and did not define terms in such a way those quantitative calculations could be made. Cartensen and Nelson in 1976 proposed terminology which could allow such calculations, and these were incorporated in 1987 USFDA guidelines as a basis for so-called confidence bound method. Later ICH (International conference on Harmonisation) guidelines on stability testing for drug substances and drug products were issued on 27th September 1993[2,3.]

Objective of Stability Testing:

Substances used as medicine are subject to decomposition resulting in loss of potency. The purpose of stability testing is to provide evidences on how the quantity and / or quality of a medicinal substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. Stability testing enables recommended storage conditions, retest periods and shelf lives for the drugs / drug products to be established[4].

Importance of Stability Testing:

Stability studies are important due to the following reasons

1. If decomposition takes place, insufficient active agent may be present to have the desired therapeutic effect.
2. The decomposition product may be detrimental to the patient.
3. The decomposition products may have a synergistic effect with the action of the drug and produce undesirable side effects.
4. To prevent the economic repercussions of marketing an unstable product. Since subsequent withdrawal and reformulation may lead to considerable financial loss.

Five types of stability studies generally recognised are Chemical, Physical, Microbiological, Therapeutic and Toxicological stability

Factors Affecting Stability:

Each ingredient, whether therapeutically active or inactive, in a dosage form can affect stability. Environmental factors such as temperature, light, air (specifically oxygen, carbon dioxide and water vapours) and humidity can affect stability. Similarly, such factors as particle size, pH, the properties of water and other solvents employed the nature of container and the presence of other chemicals resulting from contamination or from the intentional mixing of different products can influence stability.

Storage Conditions:

The length of the studies and the storage conditions should be sufficient to cover storage, shipment and subsequent use. Application of the same storage conditions as tested on the drug product will facilitate comparative review and assessment. Other storage conditions are allowable if justified. These are Temperature, Humidity, Accelerated conditions, Expiry Date etc.

Experimental:

The whole plant powder of root bark of *Argemone mexicana* was used for the stability studies. The changes in the quality of the product may occur due to the interactions between the formulated biotechnological / biological product and container / closure, which determine the effects of the container / closure on product quality. Generally, the herbal products or formulations are packed in:

1. Airtight aluminium foil coated inside with good quality polyethylene layer.
2. High-density polyethylene container.
3. Glass bottles with rubber cork.
4. Sealed plastic bags (transparent).

The plant powder was packed in two sets of the above-mentioned containers. One set of containers was kept in an incubator maintained at storage temperature i.e. 25 °C ± 2 °C / 60% RH ± 5%. This served as control sample. Another set of containers was kept in an oven maintained at accelerated temperature i.e. 40 °C ± 2 °C / 75% RH ± 5%.

The samples were removed from both control and accelerated storage temperature conditions. These samples were analysed by HPTLC for their phytochemical content, at zero days, one, two and three months.

The samples in different containers were extracted as per the sample preparation procedure explained in the section HPTLC fingerprint of *Argemone mexicana* L. Toluene and Ethyl acetate in the volume ratio of 8 : 2 respectively, was the best solvent system for optimum resolution of the phytochemical constituents obtained in the plant extract Marker(root bark powder)

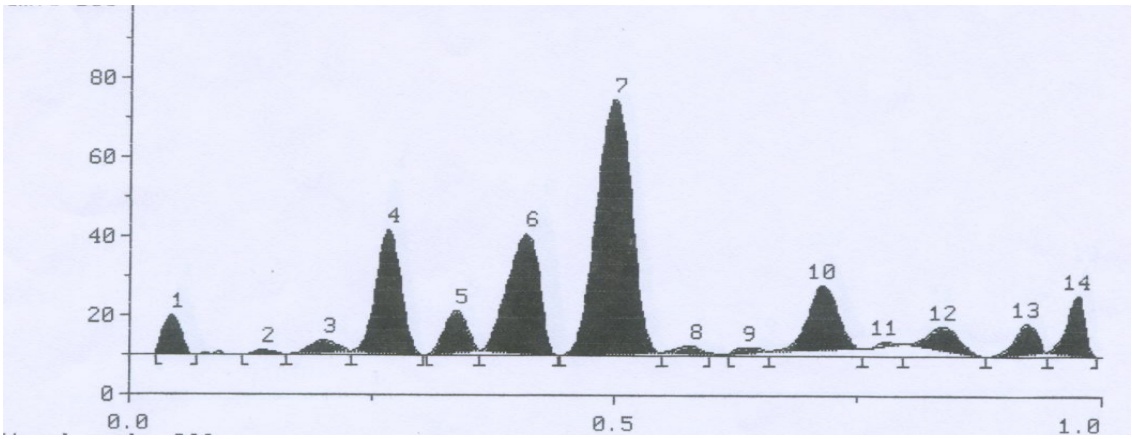

Fig.1: Typical HPTLC Chromatogram for Root Bark powder of *A. mexicana* .

Table 1: Details of HPTLC Chromatogram Figure 1

Peak No.	Rf	Area Under The Peak	%
1	0.05	144.4	3.08
2	0.14	20.8	0.44
3	0.20	66.9	1.43
4	0.27	630.4	13.46
5	0.34	193.7	4.14
6	0.41	790.7	16.88
7	0.50	1849.6	39.49
8	0.58	35.4	0.76
9	0.63	28.4	0.61
10	0.71	403.4	8.61
11	0.78	15.1	0.32
12	0.84	153.9	3.29
13	0.92	136.1	2.91
14	0.98	215.1	4.59

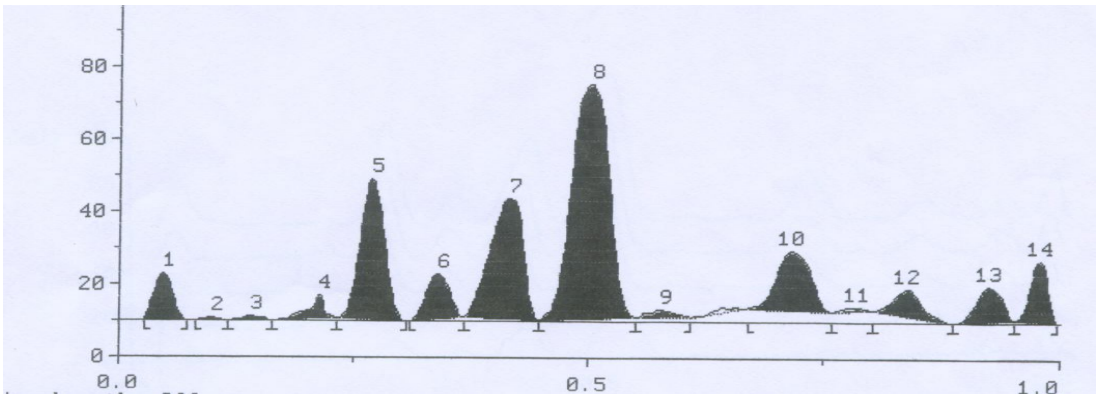

Fig. 2: Typical HPTLC Chromatogram for Root Bark powder of *A. mexicana*

Table 2: Details of HPTLC Chromatogram Fig 2

Peak No.	Rf	Area Under The Peak	%
1	0.05	205.8	3.75
2	0.10	10.2	0.19
3	0.14	21.0	0.38
4	0.21	81.6	1.49
5	0.27	788..7	14.37
6	0.34	246.3	4.49
7	0.42	931.5	16.98
8	0.50	2047.6	37.32
9	0.58	46.2	0.84
10	0.72	468.2	8.53
11	0.79	19.1	0.35
12	0.84	175.1	3.19
13	0.93	205.6	3.75
14	0.98	240.3	4.38

The peak at Rf value 0.5 was selected for the stability study, as that is the major phytochemical constituent as seen from the figure 1 and 2 which shows maximum area under the curve.

The Chromatographic Parameters used are as follows.

PARAMETER: DESCRIPTION

Stationary Phase : HPTLC Silica gel 60 F_{254} Pre-coated Plates.

Solvent : Methanol.

Spotting Volume : 6 and 8 micro-liter.

Mobile Phase : Toluene-Ethyl acetate (8:2)

Developing Mode : CAMAG Twin Trough Chamber.

Sample applicator : CAMAG LINOMATE IV.

Scanning Mode: CAMAG TLC SCANNER II equipped with Cats 3.0 version software.

Lamp: Deuterium.

Wavelength: 336 nm (UV).

Conclusion

Alupoly is a good container closure for Root Bark Powder of *Argemone mexicana* L. The major phytochemical corresponding to Rf-value around 0.05 of Root Bark Powder of *Argemone mexicana* L. was found to be more stable at accelerated temperature as compared to with control temperature, for all container closures. The root bark powder shows stability with reference to phytoconstituents up to three years as the pattern of peaks is found to be constant.

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