



## Comparing 2 ways of manufacturing for Habbe Zahab (Aloe pill): Traditional and modern method

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### ABSTRACT

*Habbe Zahab (HZ) is a one of the most prescribed medications in Traditional Persian medicine (TPM). HZ is categorized as purgative. According to traditional texts, most purgative pills expire within 2-3 months of production, so it is better to make them just before use. To further investigate its durability, HZ pills were produced by two different methods, traditional and industrial, and its durability was assessed after 1 year. Our results showed that, HZ pills that were produced by traditional method can be used within 6 months of production while HZ tablets that were produced by industrial method can be used within 2 years.*

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### INTRODUCTION

In TPM, laxatives can only precipitate waste excretion from intestines, but purgatives can eliminate waste products from other parts of the body and passed them through intestines, such as phlegm from lungs, black bile from the spleen. HZ eliminates waste products from brain, eyes and digestive system. Thus, it's prescribed in diseases arising from these organs. It is so effective and useful but unfortunately has a very short expiration date (2-3 months) and due to its short durability, it is not suitable for mass production [1-4]. So, in this study, we decided to produce it by two different methods (traditional and industrial method) and compared the results.

### MATERIALS AND METHOD

HZ contains 7 components. All of them were purchased from Tehran/Iran herbal market and approved by expert herbalist. Mastic (*Pistacia lantiscus* L.) was not approved by herbalist, so it was purchased from New Delhi/India was used in formulary after expert approval [5-6].

Table 1-Ingredients of formulation

Common name	Scientific name	Part used	amount
Aloe	<i>Aloe vera</i> (L.) Burm.f.	latex	60 g
Myrobalan	<i>Terminalia chebula</i> Retz.	fruit	30 g
Mastic	<i>Pistacia lantiscus</i> L.	gum resin	9 g
Damask rose	<i>Rosa damascene</i>	petals	15 g
Saffron	<i>Crocus sativus</i> L.	stigmas	9 g
Tragacanth	<i>Astragalus gssypinus</i> Fisch.	gum	9 g
Scammony	<i>Convolvulus scammonia</i> L.	resin	9 g

### Method of preparation

Scammony needs to be modified before using:

Traditional method: A cube of an apple was cut and some of its flesh was vacated. Then it was filled with scammony and white sesame was poured around the scammony. The apple cube back to its place and the apple was covered in dough (made by flour and water) and put in the oven at 80 °C for 3 hours to cook. The scammony was brought out of apple and after some hours was completely dried.

Industrial method: Scammony was smashed and put in a pot filled with apple juice. The mixture was boiled gently for 20 min. Then it was filtered and completely dried.

Making pills:

Traditional method:

Part1: Aloe, myrobalan and rose petals were grounded separately and passed through sieve no.100 then mixed together.

Part2: other ingredients were passed through sieve no.40 separately and dissolved in rosewater. The last ingredient must be Tragacanth. After getting a semisolid homogenized mucilage, little by little mixed powder of part 1 added to the mucilage and by the end made round pills by hands. According to the texts these pills should be in the size of Pease or bigger (about 320 mg) and let them dried in shadow.

Industrial method: All ingredients were grounded separately and passed through sieve no.100. Wet granulations were made by rosewater, and after drying again were sieved and pressed as 320 mg tablets. For optimizing the flow and resolving adhesion problem we added 4% of magnesium stearate and 3% of starch.

### Physio-chemical analysis

We used long term stability control (1year) for both productions. Samples were analyzed for organoleptic virtues, total ash, acid insoluble ash, loss of drying, hardness and disintegration time.

### HPLC

Aloe is the major component of HZ (more than 40%). So we used HPLC to detect aloin as aloe standardization marker.

Well chrom 2000 HPLC (Knauer company), Maxi-star k-1000 pump at 590 nm, Erospher 100 C18 column (25 cm length and 4 mm diameter) were used. The standard of aloin was bought from Roth, Germany.

Standard solutions in 75,100,300,500,1000ppm concentrations were prepared by adding ethanol to draw calibration curve.

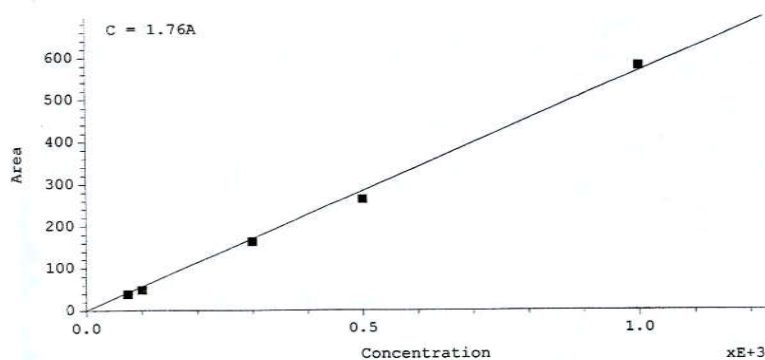
Sample preparing: 1 gr powder of each sample was soaked in ethanol. After filtering and making 10 ml solutions, they were injected to the device. Aloe was diluted 10 times more, pills and tablets 5 times more.

### Quality control

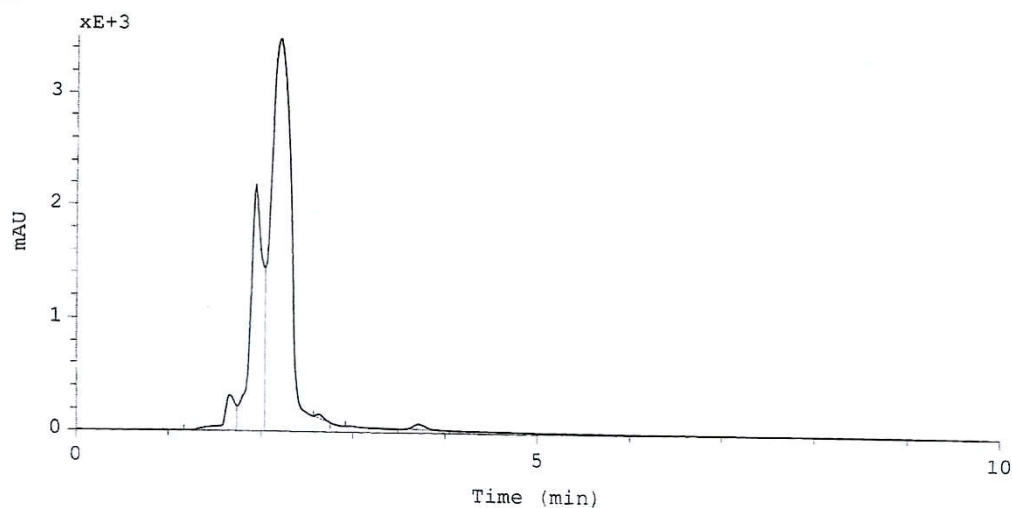
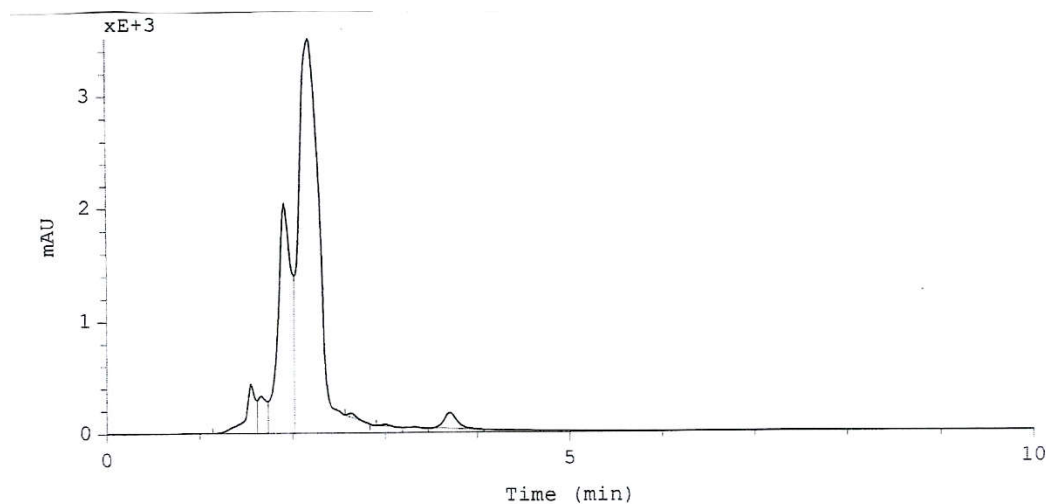
Microbial evaluation and measuring heavy metals and were performed by standard methods.

### Results

Aloin standard calibration curve and chart



	Concentration.	Area	Height	Ret time
1	75	38.348	229.278	2.317
2	100	48.727	309.715	2.325
3	300	163.184	1016.277	2.283
4	500	263.952	1626.006	2.275
5	1000	579.780	2445.006	2.290

**HZ pills curve****HZ tablets curve****Physio-chemical tests**

Test	HZ pills	HZ tablets
Loss of Drying (LOD)	8 %	3.5 %
Total Ash	3.56 %	3.67 %
Acid Insoluble Ash	1.33 %	1.26 %
Tablet Disintegration time	120 min	100 min
Dimensions Tablet	8 mm	10 mm
Hardness	4.8 kg/cm <sup>2</sup>	6.2 kg/cm <sup>2</sup>
Weight	325 mg	318 mg
Aloin	87.48mg/g	89.76 mg/g

**Microbial tests**

Microbial tests	HZ pills	HZ tablets	Limits
Total aerobic microbial count per g	5×10 <sup>3</sup>	2×10 <sup>3</sup>	10 <sup>5</sup> cfu/g
Total number of yeast and fungi per g	3×10 <sup>2</sup>	3×10 <sup>2</sup>	10 <sup>4</sup> cfu/g
Bile tolerant gram negative bacteria	3×10 <sup>3</sup>	2×10 <sup>3</sup>	10 <sup>4</sup> cfu/g
E. coli	N.D	Not detected	0
Salmonella	N.D	Not detected	0

**Heavy metals tests**

Parameter	Results	WHO & FDA limits
Pb	0.71	10 ppm
As	Less than 0.05	10 ppm
Hg	Less than 0.05	1 ppm
Cd	0.023	0.30 ppm

**Stability tests**

Item	Time (month)							
	HZ pills				HZ tablets			
	0	3	6	12	0	3	6	12
Description	Brown round pills with good smell and bitter taste	Confirmed	Confirmed	Become yellowish brown	Brown round tablets with light dotted, good smell, very bitter taste	Confirmed	Confirmed	Confirmed
Disintegration time (min)	120	150	225	365	100	105	110	125
Hardness (kg/cm <sup>2</sup> )	4.8	6.3	7.3	7.9	6.2	6.5	6.9	7.1
LOD (%)	8	5	3.6	2.4	3.5	3.5	3.3	3.2
Weight variation (%)	< 7.5 %	Confirmed	Confirmed	Confirmed	< 7.5 %	Confirmed	Confirmed	Confirmed
Alion (mg/g)	87.48	84.64	79	66.48	89.76	89	87.5	84.9

**CONCLUSIONS**

Our results show that pills manufactured by industrial method were more durable compared to traditional method. Aloin remained about 95% (94.6%) after 1 year compared to traditional pills which decreased to 76% during this period. Physical characters, LOD and hardness were better preserved in pills manufactured by industrial method.

One of the most important factors was disintegration time, which showed great variations between these 2 methods.

According to the traditional texts, these kinds of purgative pills that contain aloe eliminate waste product from brain, called "shibyar" (means night friendly pills). These pills should be taken at bed time, to have time to disintegrate and dissolve gradually. In this way, they are more effective and will not induce vomiting (because of large dose that should be taken).

By USP, maximum disintegration time for simple tablets is 30 min unless it has special monograph.

We did not change this parameter for USP general rule, to gain the optimum efficacy of medicine in clinic, but tried keeping it stable with low variation and suggest making a new monograph for this product and similar traditional medicines which follow the same rule.

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