

STANDARD OPERATING PROCEDURE AND PHYSICO-CHEMICAL EVALUATION OF *SHUNTHYADI* EYE DROPS - AN AYURVEDIC EYE DROPS FORMULATION

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ABSTRACT

Shunthyadi eye drops contain drugs like cow *Ghee*, *Sunthi* (*Zingiber officinale*), *Saindhava lavana* (rock salt), which are claimed to be effective in *Shushkakshipaka* (Dry eye syndrome). The present paper highlights preparation of eye drops, physico-chemical study of the different parameters and HPTLC of *Shunthyadi* eye drops.

KEYWORDS: *Shunthyadi* eye *Shushkakshipaka* drops.

INTRODUCTION

Acharya shushruta has suggested that *Sunthi* rubbed over a stone-slab with *Ghee* and breast-milk is recommended as an *Anjana* (collyrium) in *Suskakshipaka*.^[1] *Acharya shushruta* also states that *Vasa* of aquatic animals mixed with little quantity of powdered *Sunthi* and *Saindhava* salt should be applied to the eyes as an *Anjana* (collyrium) in

Suskakshipaka.^[2] According to *Acharya Charaka* "if eye is affected with *vata* an external application of soft extract(*Bidalaka*) may be prepared by making paste of *sunthi* and *Saindhava* with the supernatant part of *ghee* is useful.^[3]" Thus it is evident from the above references that *sunthi* and *Saindhava* have effect on *vatika* eye diseases like *Suskakshipaka*. Thus an eye drop has been planned with *Sunthi* and *Saindhava*. *Vasa* which gets hardened in room temperature, and not accepted by some Hindu communities was not found suitable for

the base of the eye drops. Hence *Ghrita manda* was selected as the base. For the convenience of the patients *aschyotan* was selected instead of *Bidalaka* and *Anjana* because eye drops have the advantage that it is more liked by the patients than other *kriya kalpas* since it is easy to use.

INGREDIENTS OF *SHUNTHYADI* EYE DROPS (*ANUBHOOTA*)

Sr No	Name of Ingredients	Botanical name	Ratio
1	<i>Go Ghrita</i>	-	1 part
2	<i>Shunthi</i>	<i>Zingiber officinale</i>	1/16 part
3	<i>Saindhava lavana</i>	-	1/16 part

MATERIAL AND METHODS

COLLECTION OF THE DRUG

Go Ghrita was purchased from the local cowshed. Rest ingredients were collected from the Pharmacy of IPGT & RA, Jamnagar, India. It was prepared according to *Ghrita paka* method. So before describing *Shunthyadi* eye drop preparation general overview of *Sneha kalpana* is furnished below.

PREPARATION OF THE EYE DROP (Plate 1)

Eye drop is prepared in *Ghrita paka* method, as mentioned in literature. *Sunthi* and *Saindhava lavana* were made into *kalka* form by adding sufficient water. This *kalka* was added to *Ghrita* and to this mixture water was added. The ratio of *Kalka: Sneha: Drava Dravya* is 1/16: 1: 4.

1) Pattern of heating

Throughout the procedure the temperature of heating source was maintained so as to generate only bubble in the mixture.

2) **Observation of *sneha siddhi lakhsana*:** The heating was continued till observation of following:

- ✓ *Vartivata sneha kalka*
- ✓ *Sabdohino agni nikshipta*
- ✓ *Acchitava*

Above mention tests were observed sequentially, *Sabdohino agni nikshipta* test was observed to be positive in residual *kalka*.

3) **Filtration and Packaging:** After cooling, the mixture is filtered through four fold fine cotton cloth two times and packed into sterile jar. As the suitable condition is not available in the G.A.U. Pharmacy, the packing of eye drops was done at Indiana Ophthalmics, Surendra Nagar, under aseptic conditions. The procedure in brief is as given below-

- Filtration by 2.0 microns glass filter followed by 0.2 microns nylon filter.
- Filtered solution was filled in 5 ml sterile plastic bottles under Laminar Air Flow in aseptic conditions.
- Plugging and capping was also done in aseptic area.

PHYSICO-CHEMICAL PARAMETERS

Shunthyadi eye drops was prepared without altering the classical methods of *Grita paka* and by using authenticated raw material. The parameters used for the analysis has been mentioned below:

- Specific gravity
- Acid Value
- Refractive index
- Iodine Value
- Saponification value

❖ Specific Gravity

Definition: **Specific gravity** is the ratio of the density (mass of a unit volume) of a substance to the density (mass of the same unit volume) of a reference substance. Specific gravity of a liquid is the weight of a given volume of the liquid at a specific temperature compared with the weight of an equal volume of water at the same temperature, all weighing being taken in air. Density of a material is defined as its weight per unit volume.

Significance: A variety of substances with different specific gravities & densities are involved in preparation of final product. Hence it is necessary to know & thus standardise the specific gravity & density of the final product.

Method: A clean and dry 25 ml capacity Pycnometer was taken and its weight was noted. It was filled with the sample, cleaned properly from outside and the weight was taken at 40°C. Then it was cleaned, rinsed and filled with distilled water, dried from outside and the weight was noted at 40°C. The weight of sample and distilled water was calculated. Then the

Specific gravity was determined by dividing the weight of the sample by the weight of the water. Density is calculated by dividing weight of the sample by volume of the sample taken.

❖ Acid Value

Definition: Acid value is defined as the number of milligrams of potassium hydroxide required to neutralize the free fatty acid present in 1 gm. of the sample.

Method: Acid value is determined by taking about 10 gm accurately weighed sample in a 250 ml flask, dissolving it in a mixture of equal volume (50 ml) of Alcohol (95%) and solvent ether and titrating with N/10 potassium hydroxide using Alkali Blue-6B as indicator. (As some of the KBT samples possesses dark red colour, Alkali blue – 6 B was used as indicator). The appearance of pink colour from blue was the end point. Acid value was calculated with the following formulae:

Acid Value = No. of ml of N/10 Alkali used x 5.61 Weight of Sample in gram.

❖ Refractive Index

Definition: The refractive index of a substance is the ratio of the sine of the angle of incidence to the sine of the angle of refraction. In other words, it is the ratio of the velocity of the light in vacuum to the velocity in the substance or a chosen media.

Significance: The consistency of the media and solutes present in the media brings the difference in the refractive index. So, it is an important parameter for differentiating the oils.

Method: Refractive index of a substance varies with temperature. Hence, temperature is to be noted while determining R.I. The R.I. of different samples was measured by using Abbe's Refractometer at 40°C. The temperature was maintained at 40°C by circulating warm water.

❖ Iodine value

The iodine value is the weight of iodine absorbed by 100 parts by weight of the sample, when determined by the following method. Method: (Iodine monochloride method) (Wij's method) The sample, accurately weighed, was placed in a dry iodine flask of 250 ml of capacity, add 10 ml of carbon tetrachloride was added and dissolved. Then 10 ml of chloroform and 20 ml of iodine monochloride solution was added, insert the stopper, previously moistened with KI solution and allowed to stand in a dark place at a temperature of about 17°C for 30 minutes. Then 15 ml of KI solution and 100 ml of water were added, shaken well and titrated with N/10 sodium thiosulphate using starch mucilage as indicator. At the same time carried out the

operation in exactly the same manner, but without the sample and the number of ml N/10 sodium thiosulphate required was noted. From the reading the iodine value of the sample was calculated.

Iodine Value = $12.69 \times (b-a) \times 0.1 \text{ N}$ Wt. in g of the sample

where 'a' is titre value of sample and 'b' is titre value of blank.

❖ Saponification value

Definition: Saponification value is the number of mg of potassium hydroxide required to neutralize fatty acids resulting from the complete hydrolysis of 1 gm of the substance.

Method: Weighed accurately about 2g of the sample taken into a conical flask and added exactly 25 ml of the alcoholic potassium hydroxide solution. A reflux condenser was attached and heated the flask in boiling water for one hour, shaking frequently. It was titrated, while hot, using Alkali blue-6B as indicator. A blank was also performed.

Saponification value = $(b - a) \times 0.02805 \times 1000$ Wt. in g of the sample

where 'a' is titre value of sample and 'b' is titre value of blank

RESULTS OF PHYSICO-CHEMICAL PARAMETERS

Sr. No.	Parameters	Results
1	Loss on drying	0.004 %
2	Specific gravity	0.9134
3	Refractive Index	1.4730
4	Acid value	2.0053
5	Iodine value	11.98
6	Saponification value	234.068

❖ HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY (HPTLC) (Plate-2)

Stationary Phase – Silica Gel GF 254

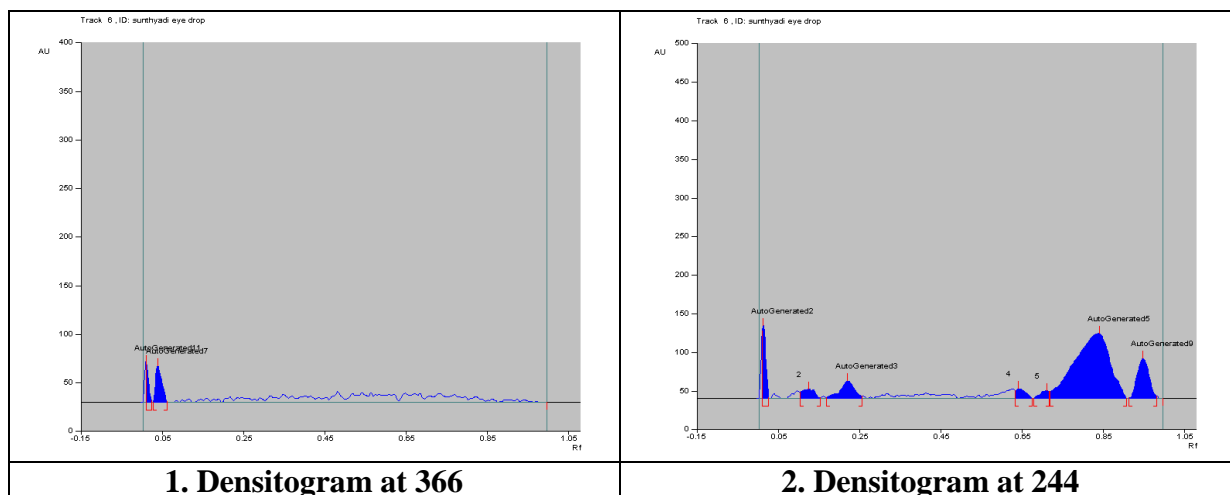
Mobile Phase – Toluene: Ethyl Acetate : Acetic Acid (7 : 2 : 1) V/V

Detection – Short UV (254 nm), Short UV(366 nm)

R_f values obtained by HPTLC

Sample	Visualize under short UV (254 nm)		Visualize under short UV (366 nm)	
	No. of spots	R _f value	No. of spots	R _f value
Shunthyadi eye drops	07	0.01, 0.11, 0.17, 0.64, 0.68, 0.72, 0.92	2	0.01, 0.03

Plate 1: Preparation of *Shunthyadi* eye drops**Powdered drugs made into bolus****Prepared Kalka mixed with the Ghee****After adding water heating on low flame****Continuous heat being given till *Snehasiddhi lakshana*****Final product- *Shunthyadi Ghrita*****Packaged eye drops**

Plate 2: HPTLC plate of *Shunthyadi* eye drops**CONCLUSION**

Physico-chemical profile of *Shunthyadi* eye drops is an essential parameter for quality assurance; in present work the obtained results were found within prescribed limits. For the first time, pharmaceutical and analytical profile of *Shunthyadi* eye drops was established. On the basis of observations and experimental results, this study may be used as reference standard in the further quality control researches.

REFRANCES

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