Pharmaceutico-Analytical Standardization of *Yava Kshar*

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***Abstract*- This study presents a pharmaceutical-analytical investigation of *Yava Kshar (YK)*, a plant-based *Kshar* (alkali) preparation with the ability to mobilize and remove deformed body tissues. *Ksharana* is the property of this *dravya*, which is an alkaline substance derived from the ashes of medicinal plants. The study focuses on the validation of the standard operative procedure used in the preparation of *YK* by conducting three sequential procedures, including the preparation of ash, *Kshar jala* and evaporation of *Kshar jala*. The validation process involves scientific data collection and analysis at the level of each unit operation. The nomenclature, synonyms, properties, and therapeutic uses of *YK* in various diseases are also discussed. The study concludes that the process used in *Kshar kalpana* is validated by the results obtained from the three batches of *YK* prepared by the same method.**

***Keywords: Yava Kshar, Kshar Kalpana,* Therapeutic Indication, Standardization, Analytical validation**

Introduction:

Ayurved is the most sacred science of life with the holistic approach to maintain the physical and mental health of people as well as cure the disease from root level[1,2]. To achieve this target *Ayurvedic* scholars have prepared different *Kalpana's* to get quick therapeutic action with a small dose without producing any undesired effects if used properly. The process of making such formulations involved crude extraction, dependent upon the nature and solubility of active components from plants to achieve desired action.

Kshar Kalpana (white colored residue obtained after evaporation of filtrate of plant ash dissolved in water) is mainly prepared to get inorganic, alkali dominant material. *Kshar* is one, which possesses the *Ksarana* (corrosive) property[3]. It is the alkaline substance of the plants obtained by processing the ash (Whitish Gray colored formulation prepared through incomplete oxidation) of drugs. *Kshar* is significant among *Sastra* (sharp instruments)- *anusastra* (accessory instruments) since it is useful in case of surgical contraindications and to cure the disease[4]. According to the source of origin there are three types *Kshar- khanija* (mineral origin), *pranija* (animal origin), *vanaspatik* (herbal origin). On the basis of use, *paniya* (internal administration) and *pratisarniya* (external application); types are also mentioned in Samhitas[5]. These are further divided on the basis of potency – *Mridu* (Mild), *Madhyam* (Moderate), and *Tikshna* (High) *Kshar*[6]. *YK* is mentioned in *Kshar*dvya, *Kshar*triy, *Kshar*panchak and *Kshara*shtak[7]. The preparation of *Kshar* in this study used three sequential procedures i.e., 1) Preparation of Ash 2) Preparation of *Kshar Jala* (water soluble inorganic component of plant ash) 3) Evaporation of *Kshar Jala.* The concepts of standard operating procedures (SOPs) are written procedures for any process or system that is followed during the operation of any system or equipment. The purpose of this study is to make SOPs for the preparation of *Yava Kshar* and standardize it by testing it on pharmaceutical and physico-chemical parameters according to *Rasa Tarangini*.

Literary Review:

Yava Kshar, alkali preparation made with whole plant of Barley (*Hordeum vulgare Linn. Syn.). Jou* plant is grown in the plains as well as in hilly regions of Himalaya's up to an altitude of 14,000 ft. It is a common cereal crop under extensive agro-practices in country, especially plains. An annual, erect, stout, tufted herb, 3-4 ft. high; resembling wheat in habit[8].

Nomenclature –

Pakya[9,11,13]**,** *Kshar*[9,11]**,** *Yavakshar*[9,11]**,** *Yavshuk*[9,11,13], *Yavagraj*[9,11,12,13], *Yavlayas*[9], *Tikshnaras*[9], *Yavaj*[9,13], *Yavnalaj*[9,10,13], *Yavah*[10,13], *Shukpak*[10], *Shukaj*[10], *Yavya pak*[10], *Yavsuchak*[12], *Yavapatya*[12,13], *Yavashukaj*[13], *Yavya*[13]

Vernacular Name[14]**:**

Hindi- Javakhar, Bengali- Yav*Kshar*, Marathi- Jhalachethith, Gujrati- Kharo, Telegu- Manu vapu, Kannad- Marad uppu, English- Impure carbonate of potash, Latin- Potasii carbonas.

Chemical Constituents[15]:
It consists mainly Potassium chloride, Potassium sulphate and Potassium Bicarbonate. It is a mixture of Potassium salts. Apart from this, Sodium, Iron and other elements are also intact in it.

Properties and Action:
Rasa (Taste): *Katu* (pungent)
Guna (Physical Property): *Laghu* (lightness), *Snigdh* (sliminess/unctuousness), *Sukshma* (minuteness/penetrating)
Virya (Potency): *Usna* (hotness)
Vipaka (Drug Metabolism): *Katu* (pungent)
Doshkarma (Pharmacological Action): *KaphaVata Nashak* (deplation of *kapha* and *vata dosha*)

***Rogaghnta* (Pharmacological Indications)**:
Hridya (cardio tonic)[16,17,18,19,21], *Pandu* (anaemia)[16,18,19] *Grahani* (derangement of agni situated in grahani)[16,18,19], *Pliha* (spleenic disorders)[16,17,18,19,21], *Gal Graha/ Kanth Roga* (choking sensation in throat/disorders of throat)[16,17,18,19,21], *Kasa* (Cough)[16], *Arsh* (haemorrhoids)[16,18,19], *Aanah* (barborygmus with distention)[16,17,18,19,21], *Gulm* (palpable glandular enlagment in abdomen/abdominal lump)[17,18,19,21], *Opsargic Prameh* (diabetes due to disease)[17,21], *Amlapitta* (hyperacidity)[17,21], *Mutrakricch* (dysuria)[17,20,21], *Phalakosh Nivaran* (cure the scrotal swelling)[17,21], *Swed Pravartak* (excessive sweating)[17,21], *Aadhman* (abdominal distension)[17], *Udar roga* (ascites)[17,20,21], *Agnideepak* (stimulate digestive power)[18,19], *Aamdosh* (vitiated Aam)[18], *Shwas* (breathlessness/difficult breathing)[18,19], *Shoola* (colicky pain in the abdomen)[18,19,20], *Ashmri* (urolithiasis)[20], *Vish dosh* (poisoning disorder)[20], *Mutral* (increase micturition) [21]

Dosage-
Mahoshadh Nighantu – 1-3 *Masha*[22] (1-3 gm.)
Rasa Tarangini – 3-10 *Ratti*[23] (375mg.-1250mg.)

***Aamyik Prayog* (Therapeutic Usages)-**

Table no.1: *Aamyik prayog* (therapeutic usages) of *Yava Kshar*[24]

S.No.	Therapeutic Indication	*Prayog* (Therapeutic usages)
1.	*Makkal Shoola* (post-partum pain)	*YK* with lukewarm water or ghee
2.	*Agnivardhak* (stimulate digestive fire) & *Pachak* (digestive)	*YK* with *Trikatu* powder + *Jeerak* (powder of *Cuminum cyminum Linn.*)
3.	*Gulm* (abdominal lump) & *Pliha Roga* (splenic disorders)	YK with *Rohitak churna* (powder of *Tecomella undulata G.Don*) or *Sarpunkha churna* (powder of *Tephrosia purpurea Linn.*)
4.	*Basti Shoola* (Colicky pain in the urinary bladder)	YK with *Marich* (*Piper nigrum Linn.*) + *Shunthi churna* (powder of *Zingiber officinale Rosc.*) + *Ushna jala* (luke warm water)
5.	*Daha-Shoth yukt Mutrakricch* (dysuria with burning and swelling)	YK with *Ela beej churna* (powder of seeds of *Ellettaria cardamomum Linn.*) + *Khand* (muscovado)
6.	*Malavrodhjanya Mutrakricch* (dysuria with constipation)	YK with *Gokshur kwath* (decoction of *Tribulus terrestris Linn.*)
7.	*Tridoshjanya Udar shola* (pain in abdomen due to *tridosha*)	YK with *Shankh Bhasma* + *Trikatu churna*+ *Sendhav lavan* (rock salt) + *Ushna jala* (lukewarm water)
8.	*Bahumutra* (polyuria)	YK with *Vasa swaras* (juice of *Adhatoda vasika Nees.*)
9.	*Parshva shola* (flank pain), *Hridya shola* (pain in heart), *Basti shola*	YK with *Sahijana kwath* (decoction of *Moringa oleifera Gaerth.*) + *Madhu* (honey)

10.	*Jalayukta Urastoya* (hydrothorax)	YK with *Punarnava swaras* (juice of *Boerhavia diffusa Linn.*)
11.	*Sujak* (gonorrhea)	YK with *Sariva kwath* (decoction of *Hemidesmus indicus*)
12.	*Mutravrodh* (retention of urine) & *Basti shola*	YK with *Tila Kshar* + *Nimbu swaras* (juice of *Citrus limon Linn.*)
13.	*Mutraghat* (urinary retention) & *Shukra-ashmari* (urolithiasis due to *sukra*)	YK with *Petha swaras* (juice of *Benincasa hispida Thunb. Cogn.*) + *Guda* (jaggery)
14.	*Ashmari* (urolithiasis) & *Basti shola*	YK with *Varun* (*Crataeva nurvula*), *Gokshur* and *Pashanbhed kwath* (decoction of *Bergenia ligulate(wall.)*)
15.	*Gulm*, *Shoola*, *Hridya roga* (heart disease), *Kasa*, *Shwas*	YK with *Dashmoola kwath* + *Sendhav lavan* (rock salt)

Pharmaceutical study:

Material and Method

Collection of *Yava panchanga:*

Fresh *Panchang of Yava* (whole plant of *Hordeum vulgare Linn.*) procured from surrounding of DSRRAU campus and authenticated by Quality control lab, DSRRAU, Jodhpur.

Preparation of *Yava Kshar*

For validation of *YK* three pharmaceutical batches were prepared. The batches were labelled as YKN_1, YKN_2 and, YKN_3. Whole process was divided into three phases; these are the preparation of *Kshar* Ash, the preparation of *Kshar Jala*, and the evaporation of *Kshar Jala*.

Preparation of *Kshar* Ash

For the preparation of *Kshar* Ash, matured whole plant of *Yava* (*Hordeum vulgare Linn.*)[25] was collected and carefully dried. The dried plants were burned in a cement tank, and after self-cooling, the resulting ash was collected[26]. The ash obtained had specific characteristics such as a whitish grey color, characteristic salty taste, and a powder-like consistency. The weight of dry *Yava panchanga* and the percentage of ash obtained were recorded for each batch, along with the time required for burning and self-cooling. [Image-1 and Image-2]

Table No.:3 Observations and results obtained during the preparation of *YK* ash

Parameters	YKN_1	YKN_2	YKN_3	Average
Weight of Dry *Yava panchanga*	12 kg.	12 kg.	12 kg.	12 kg.
Weight of ash obtained	1.960 kg.	1.650 kg.	1.700 kg.	1.770 kg.
% Of ash obtained (w/w)	16.33 %	13.75 %	14.16 %	14.74%
Time to burn	9 hr.	8.20 hr.	8 hr.	8.4 hr.
Self-cooling & White-grey Ash	15 hr.	14 hr.	14 hr.	14.33 r.

Preparation of *Kshara Jala*:

The next step involved the preparation of *Kshar Jala*. The ash obtained from the previous step was mixed with demineralized water in a specific ratio (1 Part Ash and 8 Part water) [26] and thoroughly rubbed to ensure proper mixing. After allowing it to settle overnight, the clean supernatant liquid was decanted Seven times through two-three folded cotton cloth[27].

The resulting *Kshar Jala* was a yellowish-brown liquid with a characteristic odor and salty taste. The weight of ash taken, volume of water used, filtration cycle, and the amount of *Kshar Jala* obtained were measured for each batch. [Image-3 and Image-4]

Table No.:4 Observations and results obtained during preparation of *YK jala*

Parameters	Batches			
	YKN_1	YKN_2	YKN_3	Average
Weight of ash taken	1960 gm.	1650 gm.	1700 gm.	1770 gm.
Volume of water taken	15680 ml.	13200 ml.	13600 ml.	14160 ml.
Conc. of Ash (w/v)	12.5%	12.5%	12.5 %	12.5 %
Filtration Cycle	7	7	7	7
Kshar Jala obtained	13956 ml.	12113 ml.	12407 ml.	12825 ml.

(After filtration)				
Kshar Jala loss (During filtration)	1724 ml.	1087 ml.	1193 ml.	1334 ml.
Time required for preparation of *Kshar Jala*	7 days	7 days	7 days	7 Days

Evaporation of *Kshar Jala:*

Finally, the *Kshar Jala* was subjected to evaporation. The liquid was heated in stainless steel vessel over a *Chullika yantra* (earthen stove) until all the water had evaporated. The resulting light brown *Kshar* was obtained[28]. Then powdered and stored in an airtight glass container. The evaporation process involved specific observations and precautions to ensure the quality of the final product. [Image-5 and Image-6]

Table No.:6 Observation of temperature during evaporation of *YK jala*

Time	Temperature °C				Observations
	YKN_1	**YKN_2**	**YKN_3**	**Average**	
Initial	38°C	38°C	38°C	38°C	Yellowish brown color liquid with characteristic smell and salty taste
0-30 min.	74°C	73°C	70°c	71.6°C	Aggregation and Vapor started
30-1 hr.	100°C	100°C	100°C	100°C	Creaking sound, Aggregation and Vapor increased
1-1.30 hr.	100°C	100°C	100°C	100°C	Slowly boiling started from central part
1.30 - 2 hr.	100°C	100°C	100°C	100°C	Vigorous boiling, *Kshar* started adherence to wall of the vessel
2 - 2.30 hr.	93°C	96°C	92°C	92.6°C	Vigorous boiling started sticking to wall of vessel. Color changes from yellow-brown to brown
2.30 - 3 hr.	75°C	77°C	73°C	75°C	Brownish semisolid mass
3 hr. – till Complete	57°C	59°C	58°C	58°C	Light Brown *Kshar* was obtained

Table No.:7 Observations and results obtained during evaporation of *YK jala*

Parameters	Batches			
	YKN_1	**YKN_2**	**YKN_3**	**Average**
Kshar Jala taken for evaporation	13956 ml.	12113 ml.	12407 ml.	12825 ml.
Time required for evaporation of *Kshar Jala*	3.42 hr.	3.35 hr.	3.55 hr.	3.44 hr.
Kshar obtained	353.1gm.	301.6 gm.	328.5 gm.	327.7 gm.
Kshar obtained (w/v)	0.0253 gm/ml	0.0248 gm/ml	0.0264 gm/ml	0.0255 gm/ml
% Of *Kshar* obtained (w/v)	2.53 %	2.48 %	2.64 %	2.55 %

Analytical Study-

Analysis was done at S.R. Labs, Jaipur (an Ayush approved (Ayush DTL/03) and ISO 9001:2015 certified laboratory). Sample quantity of drug was 25 gm. In this phase of study, physio-chemical analysis of *YK* was evaluated in different parameters.

Physio-chemical Evaluation:

Preliminary physicochemical parameters like pH, loss on drying at 110°C, ash value, acid insoluble ash value, Potassium content, Sodium content were carried out.

Table No.:9 Average results of physio-chemical analysis of *YK*

Physio-Chemical Parameters	Results
pH	9.69
Loss of Drying	5.73 %v/w
Total Ash	89.27 %w/w
Acid Insoluble Ash	8.80 %w/w
Potassium content (K)	36121.3 mg/100gm
Sodium content (Na)	8021.2 mg/100gm

Results and Discussion:

Kshar is one, which possesses the *Ksarana* and *Kshalana* (Killing) property[3]; explained the word, *Ksharana* "as one which mobilizes and removes the deformed flesh, skin etc. and also removes the vitiated Doshas from their location. It is the alkaline substance of the plants obtained by processing the water-soluble ashes of drugs[29]. *Kshar* has been told to be having the topmost place among all surgical and para-surgical measures in *Ayurveda*, due to its efficacy even in surgical measures though being considered as para-surgical one (*Chhedya* (excision), *Bhedya* (incision), & *Lekhya Karanat* (scraping))[4].

References of YK are found at many texts of *Ayurveda*. Detailed explanation regarding *Kshar* has been texted in *Sushruta Samhita*[30], but in *Rasa Tarangini*, there is systematic description of preparation and therapeutic uses of YK[31]. YK, alkali prepared with whole plant of Barley (*Hordeum vulgare*). When the crop is ripe and ready to be harvested, before cutting the crop including the fruit, it is used to make YK[32].

Whole plant of *Jou*/Barley dried in sun light and should be made into small pieces for better drying[29], burnt to open place for whitish-grey color ash due to maximum oxidation[32]. It should be burnt by keeping it in a non-reactive vessel[29, 32] in an open place so that it can burn properly (maximum oxidation) and can be collected easily. Whole plant of *Yava* burn should be added little by little into the fire for proper burning[29,32]. *Panchang* of *Yava* burn slowly when it was burn, Therefore, the time taken for the whole plant to burn and cool down to obtain whitish-grey ash was more. Maximum temperature during burning was 310ºC. Average 14.74% (1770 gm.) whitish-grey ash was obtained in average twenty-three hours from twelve-kilogram whole plant of *Jou*. Because the organic part of in the plant material gets destroyed by burning, only the inorganic part and residue black carbons remains.

The ratio of water in ash is different according to *Acharyas* (Four-time[33], six time[34]) but, according to *Ras Tarangini* for the preparation of *Kshar Jala* eight times[26] of water needs to be added to obtained better solubility. Water is a chemically stable compound that can be used to dissolve a wide variety of compounds[35]. De-mineralized water was used to avoid any interference[29]. Ash should be rubbed well with water for proper mixing[29,32] left overnight[32] or at least 3 hours[29] for better absorption of alkaloids. *Kshar* is considering as a water-soluble ash[29], but all water-soluble content cannot be obtained within a single wash or filter; some of them may remain as residue[29]. So Different methods of filtering water have been told in the scriptures that it should be filtered 21 times[36] with multi-folded cotton cloth or decant 7 times[27] but ultimate aim is to make the carbon free clear liquid or *Ksharjala*. Average 12825 ml. *Ksharjala* was obtained from whitish-grey ash and loss observed was 1334 ml, it may be due to the soaking of water in ash material which cannot be separated. The color of *Kshar Jala* is yellowish brown and the taste is salty with a Characteristic odor.

After getting a clear liquid, it is heated moderate followed by *mild flame*[27]. After the 2/3 parts of water evaporation on the fire, it changes its color to brown and starts stick to the vessel. At this time, it is cooked (*Pakva*) on low flame so that the *Kshar* does not burn and sticks less on the vessel. When the water content in the *Kshar* is reduced and it becomes semi-solid, it is taken out in another vessel or tray and dried in the sun light until it becomes solid powder form. Average 2.55% YK was obtained from the whole plant material. The color of YK was light brown. Color of *Kshar* depends on the nature of vessels and medium of *agni*. When wood and coal are used instead of LPF gas as fuel and iron vessel is used instead of steel-ness steel as the vessel, the color of *Kshar* is relatively dark.

The results of the study showed the quantity of *YK* ash and *Kshar Jala* obtained for each batch, as well as the percentage of ash and *Kshar* obtained. The time taken for the preparation and evaporation of *Kshar*a *jala* was also recorded.

This pharmaceutical study highlights the importance of following standardized procedures and validation protocols to ensure the production of high-quality herbal medicines. By subjecting Indian Medicinal herbs to rigorous scientific testing and establishing modern standards, the Indian pharmaceutical industry can enhance the quality of its products and meet the demands of the global market.

Term Quality Control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical product. Analytical tests were performed on *YK* to assess the formulations against the standard parameters.

Organoleptic characters of YK were observed that the *Kshar* was fine powder in appearance with characteristic odor and salty in taste. The color of YK was Light brown.

The pH value of a sample expresses the degree of acidity or alkalinity of a sample solution[37]. pH of YK is 9.69. High alkaline nature of *Kshar* or drug indicates the site of absorption and action of the drug[38].

Loss of drying is a specific analytical technique removing not only water but all other volatile impurities from a sample[39]. Moisture content in YK is 5.73% w/w.

Ash Value is useful in determining authenticity and purity of sample and also these values are important qualitative standards[40]. Total Ash value of YK is 89.27% w/w while Acid Insoluble Ash[41] value of YK is 8.80%. Total Ash is important and indicates to some extent the amount of care taken in the preparation of the drug[38].

In YK the quantity of Potassium Content is 36121.3 mg/100gm while the quantity of Sodium Content is 8021.2 mg/100gm[42].

YK is the compound of Potassium and Sodium Salts. In our study the *Kshar* was rich in Potassium & Sodium content.

Due to its *laghu* and *sukshma guna*, it's use as an emergency medicine in practice. This *Kshar* have great potential to treat the many diseases.

Conclusion-

To validate the standard operative procedure three batches of YK were prepared by the process mentioned in *Rasa trangini* (Preparation of Ash, Preparation of *Kshar Jala*, Evaporation of *Kshar Jala*) and all the possible Pysico-chemical studies were done as mentioned in API. The average yield of *YK* from the whole plant was 2.55%. Pharmaceutic-analytical observations results from this study are helpful for further work and use as a reference. It can be a fore step for Standard Operative Procedure for the preparation of the YK on large scale.

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Conflicts of interest-

There are no conflicts of interest.

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Image 5: Evaporation of Kshar Jala

Image 4: Brown k

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CERTIFICATE OF ANALYSIS

Report No.- TR-R-0129/0721		Sample ID-SRN-R-210702-02	
Name of manufacturer from whom sample is received	Dr. Jay Prakash Gupta PG Department of RS & BK, Dr. Sarvapalli Radhakrishnan Rajasthan Ayurved University, Jodhapur-342304, Rajasthan		
Reference no. or letter from the manufacturer	TRF-R-210702 Dated-03/07/2021		
Name of ASU drug or Raw material	Yavakshar		
Sample Quantity	01 X 25 g	Mfg. License No.-	NS
Batch No.	NS	Batch Size	NS
Date of Mfg.	NS	Date of sample receipt	03/07/2021
Date of Exp.	NS	Date of sample tested	08/07/2021

Description:-

Appearance	Fine powder	Color	Brown
Odour	Characteristic	Taste	-

S. No.	Test Parameters	Test method	Unit	Results	Limit
A.	**Physiochemical Analysis**				
1.	pH (2%w/v Aq. Solution)	API Part I, Vol.-VI, 2009	-	9.69	NS
2.	Loss on Drying	API Part I, Vol.-VI, 2009	%w/w	5.73	NS
3.	Total Ash	API Part I, Vol.-VI, 2009	%w/w	89.27	NS
4.	Acid insoluble Ash	API Part I, Vol.-VI, 2009	%w/w	8.80	NS
5.	Potassium content (K)	IS : 9497	mg/100g	36121.3	NS
6.	Sodium content (Na)	IS : 9497	mg/100g	8021.2	NS

API- Ayurvedic Pharmacopoeia of India, NS-Not Specified

Date: 08/07/2021
Place: Jaipur, Raj.

SR LABS Authorised Signatory

PERSON IN CHARGE TESTING

(Page 1 of 1)

Note: Party asked for above test only.
4. The result listed refer only to the sample (as provided by the party) and tested for applicable parameter, on the date of analysis, endorsement of products is neither inferred nor implied.
5. The certificate of analysis is not to be reproduced –wholly or in part and cannot be used as an evidence in the court of law and should not be used in any advertising media without our special permission in writing.
6. The jurisdiction for any legal case shall be limited to competent courts at Jaipur only.

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