



STANDARD MANUFACTURING PROCEDURE OF ASHWAKANCHUKI RASA

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Abstract: Rasashastra is a branch of Ayurveda which deals with the processing of minerals, metals and poisonous herbs having their therapeutic importance. During the medieval period so many Rasa Acharya extensively worked and developed a number of processing method for a single or compound drug. They all are standard manufacturing procedure (S.M.P.) which ensure the quality, safety, efficacy and reproducibility of the product. Ayurvedic physician were producing medicines by themselves according to their need. Now a days, due to commercialization of Ayurvedic medicine and ignorance of classical method quality of the drug has deteriorated. At present, the demand of Ayurvedic drugs in the global market is so much increasing day by day. Hence, it is the need of time to develop S.M.P. of Ayurvedic product on modern parameter for global acceptability. This paper aims at providing S.M.P. for the manufacturing of Ashwakanchuki Rasa. It is a Kharaleeya Rasa preparation having herbo-mineral ingredients. All the prepared batches of Ashwakanchuki Rasa is evaluated on modern parameter shows the positive evidence in safety and efficacy.

Keywords: Ashwakanchuki Rasa, Bhavana, Shodhana, Kharaleeya, herbo-mineral.

Introduction: Herbo-mineral compound are at great demand globally for primary health care due to their higher safety margin and their cost effectiveness. Quality control of herbo-mineral compound generates a lot of problem. So, first and foremost task is the selection of the right kind of metals, minerals and herbs which is therapeutically efficacious compound. Herbo-mineral are being manufactured on a large scale where manufacture face many problem such as low quality materials, lack of authentication of raw materials, non-availability of standards, lack of standardisation methodology of compound drug or formulation and lack of quality control parameter. Various processing techniques are involved in order to make them suitable for human body and use of their in treating various diseases. Eg. different Shodhana media like Lime powder (Sudha), (Nistusha) Lahsuna, saindhava Lavana, Godugdha, Goghrita, Kushmanda swarasa, Gomutra, bhringaraja Swarasa are used for purification of Parada, Gandhaka,

Tankana, Hartala, Vatsnabha, Jaypala for Ashwakanchuki Rasa preparation. Ashwakanchuki Rasa described in Rasayogasagara^[1] for the treatment of various diseases. Now a days there is need to standardise pharmaceutical method, so that we can obtain Ashwakanchuki Rasa of same quality in every batch. In this paper, attempts are made to develop S.M.P. of Ashwakanchuki Rasa.

Aims and Objectives

- To develop standard manufacturing process of Ashwakanchuki Rasa.
- To develop analytical profile of formulation of Ashwakanchuki Rasa
- Heavy metal analysis of both compound AKR-001 & AKR-002
- To access microbial overload of Ashwakanchuki Rasa

Materials and Methods

Collection of Raw Materials: All the raw material were collected from Sundar Ayurveda teaching pharmacy, J. S. Ayurveda College,

Nadiad after authentication. Metals, minerals and poisonous herbs were processed through *Shodhana* and trituration with some herbs to prepare *Ashwakanchuki Rasa*. Table -1 gives information of materials required for *Shodhana* process.

Table -1 : Shodhanaof ingredients of Ashwakanchuki Rasa

Shodhana Dravya	Shodhana media / dravya	Principle	Reference	Wt. Before Shodhana (gm)	Wt. After Shodhana (gm)	Wt. loss (gm)
<i>Parada</i> ^[2]	<i>Sudha, lahsuna, saindhava lavana</i>	<i>Mardana</i>	R.T. 5/27-29	500	455	45
<i>Gandhaka</i> ^[3]	<i>Godugdha, Goghrita</i>	<i>Dhalana</i>	R.T.8/7-12	500	332	168
<i>Tankana</i> ^[4]	-	<i>Nirjalikarana</i>	R.T. 13/77-78	500	260	240
<i>Hartala</i> ^[5]	<i>Kushmanda Swarasa, Triphala Kashaya</i>	<i>Swedana</i>	R.T. 11/19	400	335	65
<i>Vatsnabha</i> ^[6]	<i>Gomutra</i>	<i>Atapasshoshana</i>	R.T. 24/19	600	350	250
<i>Jaypala</i> ^[7]	<i>Godugdha</i>	<i>Swedana</i>	R.T. 24/313-314	3000	750	2250

Note : Kajjali, Triphala churna, Trikatu churna and (Bhavna Dravya) Bhringraja swarasa prepared as per reference.

Preparation of Ashwakanchuki Rasa According to Rasayogasagar

Table-2 : Ingredients

Sr No.	Classical name	Botanical name/ English name	Parts used	Quantity (gm)
1	<i>Kajjali</i>	-	-	50
2	<i>Shuddha Hartala</i>	Orpiment	-	25
3	<i>Shuddha Tankana</i>	Borax	-	25
4	<i>Shuddha Vatsnabha</i>	<i>Aconitum ferox</i> Wall.	Root	25
5	<i>Shuddha Jaypala</i>	<i>Croton tiglium</i> Linn.	Seed	25
6	<i>Haritaki churna</i>	<i>Terminalia chebula</i> Retz.	Fruit	25
7	<i>Bibhitaki churna</i>	<i>Terminalia bellirica</i> Roxb.	Fruit	25
8	<i>Amaliki churna</i>	<i>Emblica officinale</i> Gaertn.	Fruit	25
9	<i>Sunthi churna</i>	<i>Zingiber officinale</i> Rosc	Rhizome	25
10	<i>Pippali churna</i>	<i>Piper longum</i> Linn.	Fruit	25
11	<i>Maricha churna</i>	<i>Piper nigrum</i> Linn.	Fruit	25
12	<i>Bhringraja swarasa</i>	<i>Eclipta alba</i> Hassk	Plant	20.420 L

Procedure

- All the above mentioned materials/ ingredients were taken in specified amounts separately and mixed well in a steel plate.
- This mixture was taken in *khalvayantra* and triturated till it forms homogenous fine powder.
- Now, *Bhringraja Swarasa* is extracted.
- The mixture powder was subjected to *Bhavana* with *Bhringraja Swarasa* as required and then triturated well carefully.
- This *Bhavana* process was repeated 21 times and triturated.
- After completion of *Bhavana* process when the mixture become like *Kalka*, the binding

Associated Drugs and their Procurement: *Kushmanda* were procured from local market, *Nadiad*. *Godugdha* and *Gomutra* were collected from cow shed.

agent (*Acacia Arabica*) was added and prepared granules from granule machine and tablets of 125 mg. was prepared in automatic Tablet making machine.

- Prepared tablet kept in air tight glass jar.

Precaution

- Trituration should be done after each *Bhavana* process.
- Fresh *Bhringraja Swarasa* was used during each *Bhavana*.
- Binding agent completely mixed and then granules should be prepared.
- After granulation process tablet must be prepared of 125 mg.
- Tablet must be kept in air tight glass jar.

Table 3 :- Showing description of Bhavana process

No of Bhavana	Date of starting	Date of completion	Wt. of Bhringraja (gm)	Volume of Bhringraja Swarasa (ml)	Time taken(in days)	Wt. after bhavana
1	2-5-16	3-5-16	900	300	2	313
50 gm sample has taken for analysis						
2	3-5-16	5-5-16	950	300	2	269
3	5-5-16	7-5-16	930	300	2	275

4	7-5-16	9-5-16	930	300	2	289
5	9-5-16	11-5-16	933	300	2	305
6	11-5-19	13-5-16	950	310	2	319
7	13-5-16	16-5-16	950	320	3	332
50 gm sample has taken for analysis						
8	16-5-16	18-5-16	945	320	3	300
9	18-5-16	20-5-16	950	320	2	314
10	20-5-16	23-5-16	950	320	3	330
11	23-5-16	25-5-16	950	325	2	343
12	25-5-16	27-5-16	950	325	2	359
13	27-5-16	30-5-16	950	330	4	372
14	30-5-16	2-6-16	1000	370	3	383
15	2-6-16	4-6-16	1000	370	2	395
16	4-6-16	6-6-16	1000	370	2	401
17	6-6-16	9-6-16	980	380	3	412
18	9-6-16	13-6-16	1000	400	5	422
19	13-6-16	16-6-16	990	400	3	430
20	16-6-16	20-6-16	1012	420	4	439
21	20-6-16	25-6-16	1200	450	5	449
Total			20420	7230	58	449

Table 4 : showing result of Ashwakanchuki Rasa prepared in three different batches

Sr no.	Results	Batch 1	Batch 2	Batch 3
1	Date of starting	2-5-16	1-7-16	1-9-16
2	Date of completion	26-6-16	28-8-16	26-10-16
3	Wt of drug taken	300 gm	300 gm	300 gm
4	Wt. of drug after Bhavna	449 gm	432 gm	441 gm
5	Wt of Bhiringraja panchang taken	20.420 kg	20.407 kg	20.327 kg
6	Volume of BhiringrajaSwarasa used	7.23 L	6.70 L	7.20 L
7	Wt of tablet formed	430 gm	403 gm	418 gm

In this era, there is a shifting of expectations in the society from efficacy to safety. Hence it is necessary to identify the nature of compound which we prescribe to our patients. For knowing whether it contains any harmful substances or not, analytical study of Ayurvedic especially of metallic and mineral preparations is mandatory.

Table-5: Classical analytical evaluation methods for powder form of Ashwakanchuki Rasa

Sr No.	Parameters	Kajjali	Before Bhavna	After Bhavna
1	Rekhapurnatva	+++	++	++++
2	Varitara	++++	+++	++++
3	Slakshnatva	++++	++	++++
4	Nischandratva	++++	++++	++++

Table-6: Result of Physical analysis of Ashwakanchuki Rasa tablet

Parameters	AKR – 001	AKR - 002
Shape	Round & Flat	Round & Flat
Hardness	1.5 kg/cm ²	1.5 kg/cm ²
Average weight	122 mg	122 mg
Disintegration time	22 min	23 min

Table-7 : Modern parameters

Parameters	Batch – 1 After Bhavna			Batch – 2 After Bhavna			Batch – 3 After Bhavna		
	1 st	7 th	21 st	1 st	7 th	21 st	1 st	7 th	21 st
pH ^[8]	6.79	6.45	6.23	7.76	6.83	6.58	6.19	6.12	6.09
Loss on drying(% w/w) ^[9]	13.1	9.8	7.6	12.2	10.4	8.2	12.7	10.1	7.7
Ash value(% w/w) ^[10]	84	67.5	26.5	81	31	22.5	83	60.2	20.4
Acid insoluble ash(% w/w) ^[11]	2.0	1.9	1.5	5.5	3.1	2.3	4.8	2.6	1.7
Water soluble extract(% w/w) ^[12]	31.2	10	9.8	30.5	11.7	10.6	31.5	9.9	9.8
Alcohol soluble extract(% w/w) ^[13]	12.1	10.2	8.7	16.8	8.0	8.3	9.6	9.6	4.8

HPTLC profile of AKR 001 & AKR 002 tablet

Preparation of Reference Solution: Piperine and Gallic Acid: Reference standard – Piperine (S1): Exact 10.00 mg of Standard Piperine (Purity 99%) was taken in 10mL volumetric flask and volume was made up to 10mL with

Methanol. Take the solution for HPTLC Profiling.

Reference Standard: Gallic Acid (S2): Exact 10.00 mg of Standard Gallic Acid (Purity 99%) was taken in 10mL volumetric flask and volume was made up to 10mL with Methanol. Take the solution for TLC/HPTLC Profiling

Preparation of Test Solution: Extract 2.0 gm of Test material with 20 mL of Methanol & reflux it on water bath at 90-100 °C for 20 min. Filter and evaporate up to 5mL in porcelain dish. Fill in 10mL volumetric flask and volume made up to 10mL with Methanol. Take the solution for HPTLC profiling.

Table – 8 : Chromatographic conditions

Application mode	CAMAG Linomat 5 - Applicator
Filtering system	Whatman filter paper No. 41
Stationary Phase	MERCK - HPTLC Silica gel 60 F254 on Aluminum sheets
Application (Y axis) Start Position	10 mm
Development (Y axis) End Position	80 mm from plate phase
Band width	6 mm
Sample Application Volume	5µL and 10µL
Development Mode	CAMAG TLC Twin Trough Chamber
Chamber Saturation Time	30 minutes
Mobile Phase (MP)	Toluene: Ethyl acetate: Methanol: Formic Acid (6:6:1.8:0.25)
Visualization	@254nm, @366nm, @ Visible (after spray of Anisaldehyde Sulphuric acid reagent)
Derivatization mode	CAMAG – Dip tank for about 1 minute
Drying Mode, Temp. & Time	TLC Plate Heater Preheated at 100± 5 °C for 3 minutes

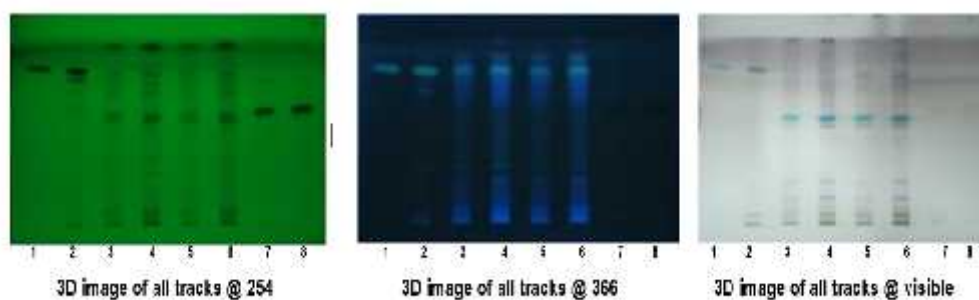
Quantification of Piperine & Gallic acid was carried out at 254 nm.

Table– 9 : Quantification of Piperine

	Piperine		AKR 001 Tablet		AKR 002 Tablet	
	Spot 1	Spot 2	Spot 3	Spot 4	Spot 5	Spot 6
Inj. Vol	5 µL	10 µL	5 µL	10 µL	5 µL	10 µL
Area @ 254nm	15572.8	18920.3	3924.1	7063.4	5296.5	6975.3
Max Rf	0.79	0.79	0.78	0.79	0.79	0.78
Result(%)	---	---	0.14%	0.20%	0.18%	0.19%
Mean result(%)	---	---	0.17%	0.185%	0.185%	0.19%

Table – 10 : Quantification of Gallic Acid

	Gallic Acid		AKR 001 Tablet		AKR 002 Tablet	
	Spot 7	Spot 8	Spot 3	Spot 4	Spot 5	Spot 6
Inj. Vol	5 µL	10 µL	5 µL	10 µL	5 µL	10 µL
Area @ 254nm	19371.8	25982.3	8418.4	15621.6	9066.5	15257.6
Max Rf	0.52	0.52	0.52	0.52	0.52	0.52
Result(%)	---	---	0.21%	0.29%	0.22%	0.28%
Mean result(%)	---	---	0.25%	0.25%	0.25%	0.28%



HPTLC Chromatogram at three different wavelengths

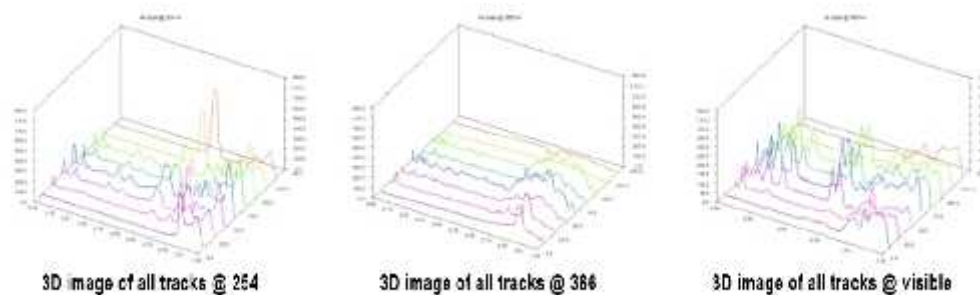


Table – 11 : Heavy metal analysis

Sr No.	Parameters	Permissible limit	Result	Test Method Reference
AKR 001 Tablet				
1	Lead (Pb)	10 ppm	0.364 ppm	API, Part- II, Vol. III
2	Cadmium(Cd)	0.3 ppm	72.365 ppm	
3	Arsenic (As)	3 ppm	12540 ppm	
4	Mercury (Hg)	1 ppm	41062 ppm	
AKR 002 Tablet				
1	Lead (Pb)	10 ppm	0.432 ppm	API, Part- II, Vol. III
2	Cadmium(Cd)	0.3 ppm	89.617 ppm	
3	Arsenic (As)	3 ppm	15394 ppm	
4	Mercury (Hg)	1 ppm	47861 ppm	

Data of heavy metal analysis of AKR-001 & AKR-002 reveal that tablets contain very high level of Mercury, Arsenic and Cadmium as that of permissible limit of API. This is probably due to cross contamination because of simultaneously ongoing formulation containing these elements

as a major ingredient. Both sample had shown very high level of Mercury, Arsenic and Cadmium than permissible limit of API as well as which may be due to use of running water and steel drum for wet grinding.

Table – 12: Microbial overload of Ashwakanchuki Rasa

Sr No.	Parameters	Permissible limit	Result	Test Method Reference
AKR 001 Tablet				
1	Total Plate Count	10 ⁵ cfu/g	326 cfu/g	API, Part-1, Vol.VI
2	Total Yeast & Mould Count	10 ³ cfu/g	Absent	
3	Escherichia coli	Absent	Absent	
4	Salmonella sp.	Absent	Absent	
5	Staphylococcus aureus	Absent	Absent	
6	Pseudomonas aeruginosa	Absent	Absent	
AKR 002 Tablet				
1	Total Plate Count	10 ⁵ cfu/g	397 cfu/g	API, Part-1, Vol.VI
2	Total Yeast & Mould Count	10 ³ cfu/g	Absent	
3	Escherichia coli	Absent	Absent	
4	Salmonella sp.	Absent	Absent	
5	Staphylococcus aureus	Absent	Absent	
6	Pseudomonas aeruginosa	Absent	Absent	

Observation & Results

Ashwakanchuki Rasa is a *Kharaleeya Rasayana* and very potent drug for the treatment of *Tamaka Shwasa* (Bronchial Asthama). In *Rasatantrasara* and *Siddhaprayoga sangraha*, therapeutic usage of *Ashwakanchuki Rasa* is elaborated with different *Anupana*. The potency of *Ashwakanchuki Rasa* will be increases due to repeated *Bhavna* of *Bhringraja Swarasa*. The manufacturing process of different batches and analytical profile of *Ashwakanchuki Rasa* shows the efficacy and safety of particular drug compound. In microbial evaluation there is no unwanted yeast and particular bacilli Eg. *Escherichia coli*, *Salmonella Sp.*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* not seen in both samples of *Ashwakanchuki Rasa*(AKR -001

& AKR-002).It shows that, both samples are very safe and efficacious in therapy.

Note

- AKR- 001 is *Ashwakanchuki Rasa* prepared with *Bhringraja Swarasa Bhavna*
- AKR-002 is *Ashwakanchuki Rasa* prepared with additional *bhavna* of *Ardraka Swarasa*.

Conclusion

- *Ashwakanchuki Rasa* is a herbo-mineral compound widely used in *Tamaka Shwasa* (Bronchial Asthama).
- Very potent *Kharaleeya Rasayana* prepared in three batches in regard to S.M.P. purpose.
- All the prepared batches of *Ashwakanchuki Rasa* is evaluated on modern parameter shows the positive evidence in safety and efficacy.

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