ISSN 2581-6217

World Journal of Pharmaceutical Science & Technology

Journal homepage: www.wjpst.com

Review Article

PHARMACEUTICAL STANDARDIZATION AND INFORMATION ON *BAL RASAYANA* SYRUP – A NEXT GENERATION SYRUP

Dr. Sumod Khedekar[1]

1. B.A.M.S., M.D., PhD. Scholar, HOD, Assistant Professor, Department of *Kaumarbhritya*, GAM&RC, Shiroda, Goa, India.

Address for correspondence:

Dr. Sumod Khedekar, B.A.M.S., M.D., PhD. Scholar, HOD, Assistant Professor, Department of *Kaumarbhritya*, GAM&RC, Shiroda, Goa, India.
E-mail- vaidya.sumod@gmail.com

Received: 15-9-2022, Revised: 29-9-2022, Accepted: 10-10-2022

ABSTRACT

Many medicinal formulations and combinations have been mentioned in Ayurvedic literature to compete with the different diseases of children. These formulations have some drawbacks, including a big dose, an unpleasant flavour, a short shelf life, and portability issues, especially when dealing with children. Formulations must be modified without losing their effectiveness to improve practicality, palatability, minimum dose, ease of administration, enhanced bioavailability, and shelf life. The goal of the current study was to pharmaceutically standardize and to learn various pharmacological actions of *Bal Rasayana* Syrup, a next generation Syrup used as an immunomodulator and effective in various diseases of children such as Respiratory problems, GIT problems, worm infestation, and in various infections. It comprises authentic Ayurveda Herbs indicated in classical texts of Ayurveda. This medication is prescribed in powder form in the original text, but when administered to children, it becomes unpalatable, so it is modified into syrup form and given the name *Bal Rasayana* Syrup. At the Abhinav Healthcare Products Pvt. Ltd, Nehroli, Wada, Maharashtra, *Bal Rasayana* Syrup underwent pharmaceutical preparation and analytical study. The formulation was initially tested for organoleptic parameters such as odour, taste, and colour. Followed by Physico-chemical analysis and microbial standards testing. The syrup is having brown colour, a distinctive odour, and a sweet taste with Strawberry flavour. Analytical standards for *Bal Rasayana* Syrup

such as specific gravity, and pH, were 1.241 g/mL, and 6.15 respectively. After the screening for Safety and toxicity, Syrup was found to comply with respect to standards.

Keywords: *Bal Rasayana* Syrup, Ayurveda, Pharmaceutical Standardization, Children, Pediatrics.

INTRODUCTION

Ayurveda always considers Medicine as a very important tool for the management of human health. *Aushadhi* [1] is used to maintain good health as well as to cure disease. *Bhaishajya Kalpana* which is a pharmaceutical branch of Ayurveda deals with a wide range of the preparation of different medicines. The five basic *Kalpana* [2] are known as primary formulations & all other *Kalpana* like *Churna*, *Vati*, etc, were derived from these basic formulations & these are known as secondary formulations. These medicinal formulations are advised to potentiate the properties of drugs. It aids a physician to utilize the medicine in various forms and styles to fight the disease and thus helps in easy administration. While dealing with the pediatric population these are of prime importance. To meet the need of the present time and for more acceptance, different modalities have to be used to modify the formulations without changing their efficacy and original qualities. It is difficult to administer powder with a bitter and pungent taste to children. Such formulations need to be modified into suitable forms without changing their basis of ingredients and mode of action.

One such formulation is *Bal Rasayana* Syrup which comprises various medicines indicated in Classical texts of Ayurveda. The herbs which are used in *Bal Rasayana* Syrup are prescribed in powder form in the original text with reference to various pediatric ailments, but when administered to children, it becomes unpalatable, so it is modified into Syrup form and given the name *Bal Rasayana* Syrup. This is used as an immunomodulator and is effective in various diseases of children such as Respiratory problems, GIT problems, worm infestation, and in various infections with promising results.

The goal of the current study was to pharmaceutically standardize *Bal Rasayana* Syrup and to study its efficacy, toxicity and other parameters. Standardization of formulation is the need of the hour to generate evidence for existing literature and for reproducibility. Standardization of *Bal Rasayana* Syrup was carried out in three batches and parameters for quality assurance were studied.

MATERIALS AND METHODS

Raw materials were procured by Exert team of Abhinav Healthcare Products Pvt. Ltd, Nehroli, Wada, Maharashtra. Taxonomists carried out the identification and authentication. *Bal Rasayana* Syrup was pharmaceutically prepared as per the standard guidelines. According to API guidelines, [3] the analytical lab examined organoleptic characteristics, physicochemical analysis, microbial contamination, and Toxicity studies.

(Figure. 1 - Method of preparation, packing and labelling, Final product)

Preparation of *Bal Rasayana* Syrup:

To the manufacturing vessel add *Musta, Pippali, Ativisha, Guduchi, Vasa, Kutaja, Patol, Kutaki, Sariva, Patha, Yashtimadhu, Vidanga, Aamlaki, Bibhitaki, Haritaki* etc. After adding all these materials add water for decoction preparation. Then heat the liquid for some time to prepare *Kadha*. After cooling filter *Kadha* with #200 Nylon cloth. Once the extract addition is completed add sodium methyl paraben and sodium propyl paraben with continuous mixing. Continue heating till the temperature attains 800^0C. Then start adding the sugar slowly with continuous mixing and maintains temperature between 75-800^0C. After complete addition maintain the temp at 850^0C. for 30 min ensuring the complete dissolution of sugar. Add with mixing the strawberry flavour at a temp 450^0 and mix for 30 min with continuous cooling. At room temp. make up the volume by adding DM water. Mix for 15 min with 10 min recirculation and start filtration with a filter press and transfer to the storage vessel. Similarly, three batches were prepared.

Table 1: Ingredients of *Bal Rasayana* Syrup [Each 10 ml contains extracts obtained from]

Sr.No.	Drug Name	Botanical Name	Dosage
1	*Musta*	*Cyperus rotundus*	100mg
2	*Pippali*	*Piper longum*	100mg
3	*Ativisha*	*Aconitum heterophyllum*	100mg
4	*Guduchi*	*Tinospora cordifolia*	100mg

5	*Vasa*	*Adhatoda vasica*	100mg
6	*Kutaja*	*Holarrhena antidysenterica*	100mg
7	*Patol*	*Trichosanthes dioica*	100mg
8	*Kutaki*	*Picrorhiza kurroa*	100mg
9	*Sariva*	*Hemidesmus indicus*	100mg
10	*Patha*	*Cissampelos pareira*	100mg
11	*Yastimadhu*	*Glycyrrhiza glabra*	100mg
12	*Vidanga*	*Embelia ribes*	100mg
13	*Aamlaki*	*Emblica officinalis*	100mg
14	*Bibhitaki*	*Terminalia bellirica*	100mg
15	*Haritaki*	*Terminalia chebula*	100mg

Analytical Study

Analysis of samples was conducted as per the API standards in the analytical lab of Abhinav Healthcare Products Pvt. Ltd, Nehroli, Wada, Maharashtra, to establish the basic standards for *Bal Rasayana* Syrup**.** The formulation was first tested for organoleptic parameters such as odour and colour (Table 2). Physicochemical analysis (Table 3) includes Specific gravity and pH. Microbial specifications were tested to validate its safety for internal as well as external use. *Enterio bacteriaceae*, Total fungus count, *E. coli*, *Salmonella*, *Staphylococus aureus* and *Psudomonas aueruginosa* were performed as par CCRAS parameters (Table 4). Safety and toxicity were also studied for establishing compliance with respect to standards. (Table 5).

OBSERVATION AND RESULTS

Table 2: Average result of Organoleptic parameters of *Bal Rasayana* Syrup.

Sr.No.	Test	Specification	Observations	Result/ Inference
1	Description	brownish- viscous liquid	Brownish coloured viscous liquid	Complies
2	Taste	Bitter and slightly sweet	Sweet and Bitter	Acceptable
3	Colour	Brownish	Brownish	Complies
4	Odour	Characteristic	Characteristic	Complies

Table 3: Average results of Physico-chemical parameters of *Bal Rasayana* Syrup.

Sr.No.	Test	Specification	Observations	Result/ Inference
1	pH	6-7	6.15	Complies
2	Specific Gravity at Room Temp.	1.20-1.25 g/mL	1.241 g/mL	Complies

Table 4: Average results of Microbiological specification of *Bal Rasayana* Syrup.

Sr. No.	Specific Tests or types of Tests performed	Specification, standard (method) or technique used	Test Results/ Unit	Result/ Inference
I	Total Microbial Count	IS 5402 :2012 (RA 2018)	6.27 x 10 cfu/ml	Acceptable
2	Yeast & mould	IS 5403: 1999 (RA 2018)	<l cfu/ml	Acceptable
3	E. Coli	IS 5887 (Part-I): 1976 (RA 2018)	Absent/ml	Acceptable
4	Salmonella	IS 5887 (Part-3): 1999(RA 2018)	Absent/25ml	Acceptable

Table 5: Results of Heavy Metal specification of *Bal Rasayana* Syrup.

Sr. No.	Specific Tests or types of Tests performed	Specification, standard (method) or technique used	Unit	Requirements (PPM)	LOQ	Results
1	Heavy Metals					
i	Arsenic	IS 1699:1995	ppm	0.06	0.03	Not Detected
ii	Cadmium	AOAC 20th Edition 2016, 999.11	ppm	0.05	0.02	Not Detected
iii	Lead		ppm	15	0.1	Not Detected
iv	Mercury	IS 1699: 1995	ppm		0.11	Not Detected
Note: Not Detected — Less Than LOQ						

Table 5: Results of Pesticides specification of *Bal Rasayana* Syrup.

Sr. no	Test Parameter	Specification Standard or Technique used	Unit	LOQ	Results
A	Pesticides				
1	Cis — chlordane	TTI/A-44	mg/l	0.02	Not Detected
2	Trans Chlordane			0.02	Not Detected
3	Chlorothalonil			0.02	Not Detected
4	Dicofol			0.02	Not Detected
5	Alpha - Endosulphan			0.02	Not Detected
6	Beta — Endosulphan			0.02	Not Detected
7	Endosulphan Sulfate			0.02	Not Detected
8	Endrin			0.02	Not Detected
9	Hexaconazole			0.02	Not Detected
10	Heptachlor			0.02	Not Detected
11	Heptachlor Epoxide			0.02	Not Detected

DISCUSSION:

Different pharmaceutical preparations are scientifically designed by ancient Ayurvedic experts. Advancement of Ayurvedic pharmaceutical science and new technology may explore new horizons for finding newer formulations. The present formulation is used in the form of Syrup. Ingredient Powder is a fine powder obtained after thoroughly pounding a dry drug and filtering it through a clean cloth. Herbal powders preserve their potency for up to 6 months if kept in airtight containers. Moreover, there is a possibility of deterioration of powder if the powder is exposed to moisture conditions. The contents of this combination are Bitter and pungent, and it is very difficult to administer to the children as they are not palatable. Hence to overcome these difficulties, these herbs' *Churna* was modified into a Syrup formulation along with strawberry flavour without changing its original form. The syrup was prepared with advanced technology and machine as it helps in maintaining uniformity which is needed for fixing the dose for administration. This syrup can be preserved for two to three years if kept in an airtight container, thus it is having the advantages of long shelf life, portability, fixed dosage forms and global acceptance. The syrup was prepared in three batches to generate standard manufacturing procedures and to check its reproducibility and pharmaceutical variability. In the prepared batches, the moisture content is much less i.e., this formulation has more stability. The physical parameter such as pH was determined to determine the basic nature of the sample as the action of enzymes is affected by pH and pH is an important factor in taste and safety. Each medicine has an optimum pH value, and if the pH value is too high or too low, it likely indicates the medicine won't taste right or that safety has been compromised. The observed pH of *Bal Rasayan* Syrup is 6.15 and it can be interpreted that the dissolution and absorption rate of *Bal Rasayan* Syrup is most favourable at this pH level. results of Microbiological specification of *Bal Rasayana* Syrup for parameters such as Total microbial count, Yeast & mould, *E. Coli, Salmonella* found to be in permissible limit of standards. It was also screened for Toxicity study and heavy metal screening, the result of the same compliance with the standards.

The main contents of the Syrup are *Rasapachak Churna*, [4] *Balchaturbhadra Churna* [5] and *Triphala Churna* [6]. *Rasapachak Churna* is very much effective in *Rasavaha* and *Annavaha Stotas Vyadhi*. *Balchaturbhadra Churna* is a proven medication for various disorders of children such as Cough, Cold, Fever, Vomiting and Diarrhoea. *Triphala Churna* is a potent combination which is helpful in Deworming, as a laxative, *Rasayana* and Immunity Booster. Combine action of these formulations are

- Immunity booster
- Appetizer
- Helps in Deworming
- Useful in Allergic conditions & Respiratory problems.
- Useful in common infections such as Repeated Cough & Cold, Diarrhoea, Vomiting etc.

Ingredients of Syrup are already proven with research work with Mucolytic, Antitussive [7] Antiallergic [8], *Rasayana* – rejuvenating effect [9], Bioavailability enhancer, Immunomodulator [10], Anti-helminthic activity [11] [12], Antioxidant [13,14], Antibacterial [15,16,17], Anti-inflammatory [18,19], Antiviral [20,21], Nootropic effect [22], Anti-asthmatic activity [23], Antidiarrheal [24], Antipyretic [25], Antispasmodic [26].

Bal-Rasayana Syrup is a unique combination fortified with Ayurveda drugs with proven efficacy and safety. This syrup is useful in common problems of children such as low immunity, loss of appetite, constipation, frequent infections, unable to gain weight, worm infestation, skin disorders, allergic conditions like asthma, etc. It can be given as a general tonic for children to keep them Healthy.

CONCLUSION:

Analytical standards for *Bal-Rasayana* Syrup were found to be in the permissible limit of their standards. After screening for Toxicity studies and heavy metal, the result of the same compliance to the standards. *Bal-Rasayana* Syrup is a unique combination fortified with Ayurveda drugs with proven efficacy and safety. This syrup is useful in common problems of children such as low immunity, loss of appetite, constipation, frequent infections, unable to gain weight, worm infestation, skin disorders, allergic conditions like asthma, etc. It can be given as a general tonic for children to keep them Healthy. Due to its broad-spectrum activity in various ailments of children, it is termed as Next generation syrup.

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