INTERNATIONAL
AYURVEDIC MEDICAL
JOURNAL

IAMJ

International Ayurvedic Medical Journal, (*ISSN: 2320 5091)* (April, 2017) 5 (4)

PHARMACEUTICAL AND ANALYTICAL VALIDATION OF *YOGARAJ GUGGUL* TABLET – A POLYHERBAL *AYURVEDIC* FORMULATION

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ABSTRACT

Ayurvedic Pharma industry is rapidly expanding its demand in national as well as international market. Due to lack of pharmaceutical and analytical validation of *Ayurvedic* products, quality of *Ayurvedic* products differs from batch to batch. Pharmaceutical and analytical validation can be achieved, if the herbal products are evaluated and analyzed using both *Ayurvedic* as well as modern techniques of standardization; in process and after preparation of finished product. *Yogaraj Guggul* a poly herbal formulation is traditionally used for obesity, *Vata Vyadhi* (Osteoarthirtis), Neurological and Musculoskeletal disorders. Medicine prepared using traditional method may not have the desired quality and batch to batch consistency. Hence, there is need to validate the standard operating procedure as per scientific parameters. *Yogaraj Guggul* is traditionally used in pill form, in this study *Yogaraj Guggul* Tablets were prepared by using modern equipments and techniques also pharmacopoeial standards are set for this *Ayurvedic* formulation in tablet form. In this study the efforts were made to validate the manufacturing process of *Yogaraj Guggul* using different analytical techniques. All the three samples prepared by this method shows identical characteristics and analytical parameters does not show significant difference. Also the observations of analytical study show similarity to those parameters which are already set in API for this drug.

Keywords: *Ayurvedic* formulation, *Guggul*, Process validation, Tablet, *Yogaraj Guggul*.

INTRODUCTION

Standardization of herbal formulations is essential to assess quality of drugs. It is based on the concentration of their active principles, physical, chemical, Phyto-chemical, In-vitro, and In-vivo parameters. The quality assessment of herbal formulations is important

to justify their acceptability & safety. One of the major problems faced by the *Ayurveda* physicians is the unavailability of unique pharmaceutical and analytical validation for herbal medicines and their formulations. In India, department of AYUSH Government of India is now working on development of standard operating procedures for the manufacturing process of *Ayurvedic* preparation to avoid batch to batch variations. This can be achieved if the herbal products are evaluated and analyzed using both *Ayurvedic* as well as modern techniques of standardization during preparation and after preparation of finished product. There are different techniques to standardize raw drugs & finished products. This can be achieved; if herbal products are evaluated & analyzed using sophisticated modern techniques standardization such as UV visible, TLC, HPTLC, GCMS, Spectrofluorometric & other methods as Phyto-chemical constituents, Fingerprinting content, appearance, pH, Viscosity, Refractive index, Saponification value, Spread ability, Uniformity in weight, Disintegration time, Friability etc.

Yogaraj Guggul a poly-herbal formulation was mentioned in ancient text of *Ayurveda*. It is traditionally used for *Sthaulya* (obesity), *Vata Vyadhi* (Osteoarthirtis), Neurological and musculoskeletal disorders [1]. Preparation of *Yogaraj Guggul* is based on traditional methods mentioned in *Bhaishajya Ratnavali*. Due to Lack of pharmacopoeal standards for processing of *Yogaraj Guggul*, medicine prepared by using traditional method may not have the desired quality and batch to batch consistency. Traditionally *Yogaraj Guggul* is used as Pills, but there are various drawback of pill as a dosage form, like Pills are difficult to prepare in large scale, pills are prepared by handmade method so uniformity in size could not be achieved and chances of contamination due handling are more in pill form. In other way tablet dosage form is easy to prepare in industrial purpose, tablets can be prepared by automated machine, tablets are uniform size, due to less handling chances of contamination are minimum in this procedure. Hence, there is need to Validate the standard operating procedure for *Yogaraj Guggul* Tablets following scientific parameters including organoleptic characters, physical parameters, chemical analysis, etc. In this study guidelines prescribed in Good manufacturing Practices and Good Laboratory Practices for *Ayurvedic* medicines are strictly followed during preparation and on finished drug formulation.

Pharmaceutical study:

A *Yogaraj Guggul* a traditional *Ayurvedic* Poly herbal formulation was described in *Bhaishajya Ratnavali- Amavatadhikar* chapter, which consists of total 28 herbal ingredients. In this formulation all the constituents except *Guggul* are taken in 1 part of which the principal ingredient *Guggul,* is taken in sum of all other 27 ingredients. Three batches of 2 kg each were prepared using techniques mentioned in classical texts. The weights of each ingredient for 2 kg batch were derived in gram according to reference given in AFI [2] as below in table no.1.

Table 1: Showing ingredients of *Yogaraj Guggul* and their weights for 2kg of sample.

Sr. No.	Sankrit Name	Latin Name	Parts Used	Weight of raw Material in gram
1	*Chitrak*	Plumbago zeylanica Linn	Root	37
2	*Pippalimula*	Piper lingum Linn.	Root	37
3	*Yavani*	Hyocyamus niger Linn.	Seed	37
4	*Krishna jirak*	Nigella sativa Linn.	Fruit	37
5	*Vidanga*	Embelia ribes Burm. F.	Fruit	37
6	*Ajamoda*	Apium graveolens Linn.	Fruit	37
7	*Jirak (Shweta Jirak)*	Cuminum cyminum Linn.	Fruit	37
8	*Devdaaru*	Cedrus deodar (Roxb.) loud.	Heart wood	37
9	*Chavya*	Piper chaba Hunter.	Stem	37
10	*Ela*	Elettaria cardamomum maton.	Seed	37
11	*Sandhav*	Rock salt	-	37
12	*Kushtha*	Sassurea lappa	Root	37
13	*Rasna*	Alpinia galangal Willd.	Root/ leaf	37
14	*Gokshur*	Pedalium murex Linn.	Fruit	37
15	*Dhanyak*	Coriandrum sativum Linn.	Fruit	37
16	*Haritaki*	Terminalia chebula Retz.	Fruit	37
17	*Bibhitaki*	Terminalia bellirica Roxb.	Fruit	37
18	*Amalaki*	Emblia officinalis Gaertn.	Fruit	37
19	*Musta*	Cyperus rotundus Linn.	Rhizome	37
20	*Shunth*	Zingiber officinale Rosc.	Rhizome	37
21	*Marich*	Piper nigrum Linn.	Fruit	37
22	*Pippali*	Piper longum Linn.	Fruit	37
23	*Twak*	Cinnamomum zeylanicum Breyn.	Stem bark	37
24	*Ushir*	Vetiveria zizanoides Linn.	Root	37
25	*Yavakshar*	Hordeum vulgare Linn.	Plant Ash	37
26	*Talishpatra*	Taxus baccata Linn.	Leaf	37
27	*Tejapatra*	Cinnamomum tamala	Leaf	37
28	*Shuddha Guggul*	Commiphora mukul Engl.	Exudates	1000
	Ghee (Sarpi)			37

All the raw materials were procured from local authentic market and were identified and approved by Quality control Laboratory of Unijules Life Sciences Limited, Kalmeshwar, Nagpur. The raw drugs have passed all quality control parameters mentioned in API. After confirmation all the samples were made free from adulteration and foreign matters. Raw materials were taken in appropriate weight as mentioned in above table no.1.

MATERIALS AND METHODS:

Yogaraj Guggul was prepared by following steps.

1) *Shodhan* of *Guggul*[3]: In addition to common purification and cleaning process of other plant ingredients as recommended, *Guggul*

may have additional physical impurities in it. Hence *Guggul Shodhan* was performed in decoction of *Triphala*. 360gm of *Triphala* was taken for purification of 1000gm of *Guggul*. All three ingredients of *Triphala* were taken in the ratio of 1:1:1 (Terminalia Chebula 120gm + Terminalis bellerica 120gm + Embelia officinalis 120gm). *Guggul* was melted in *Triphala* decoction and allowed to cool and keep for sedimentation. After sedimentation it was filtered through thin cotton cloth to remove physical impurities. The resultant decoction thus obtained was further heated to remove water content and to obtain *Guggul* in paste form. This semisolid paste of *Guggul* was dried in shed. The obtained well dried *Guggul* was used for the preparation of final product.

2) Pulverization of Raw Material: All the raw materials mentioned above in table no. 1 including Purified *Guggul* were taken in prescribed quantity and mixed together. These raw materials were pulverized in mass pulverizer to make it in powder form.

3) Mixing of Powder in Mass Mixer: Pulverized powder was again weighed to check processing loss and mixed uniformly in mass mixer.

4) Sifting of Powder: The obtained material was then sifted in mass sifter using mesh No. 80 to obtain fine powder of it.

5) Addition of Excipients: Starch and M.C.C were added in above mixture for proper binding of tablets. In batch of 2 kg starch 240gm and M.C.C. 160gm were added. The mixture was uniformly mixed in suitable Stainless steel vessel. It was then subjected to drying in electric air dryer at temperature not more than 60^0C.

6) Granulation in Multi Miller: Above material was passed through Multi miller through sieve no. 2 for proper granulation and further procedure of material.

7) Tabletting: Uniform tablets, each 500 mg were prepared using automated tablet pressing machine. About total 4000 to 4100 tablets were obtained from each sample batch A, B and C. Tablets were packed in air tight bottle and stored in cool dry place. All hygienic conditions were maintained during preparation of *Yogaraj Guggul* Tablet. Above detailed procedure was adopted for preparation of three different (sample A, sample B, sample C) batches of *Yogaraj Guggul* Tablets.

OBSERVATION AND RESULTS:

Classical parameters: The tablets of three samples of *Yogaraj Guggul* were examined using classical parameters like *Shabda* (Sound), *Sparsh* (Touch), *Rupa* (Appearance), *Rasa* (Taste), *Gandha* (Odour).

Table 2: Showing Classical parameters for *Yogaraj Guggul table*

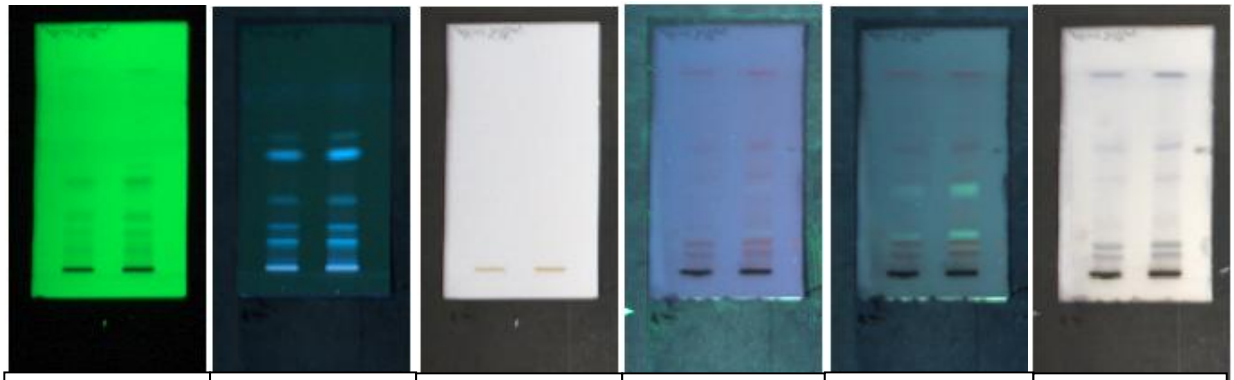
Sr. No	Test Name	Sample A	Sample B	Sample C
1	*Shabda* (Sound)	Nil	Nil	Nil
2	*Sparsh* (Touch)	Soft in touch	Soft in touch	Soft in touch
3	*Rupa* (Appearance)	Blackish brown	Brown	Blackish brown
4	*Rasa* (Taste)	Bitter	Bitter	Bitter
5	*Gandha* (Odour)	Pleasant ghee mixed smell	Pleasant ghee mixed smell	Pleasant ghee mixed smell

Physico-chemical analysis: For quality assurance of the formulation all three samples of finished products were checked using relevant modern parameters viz. Color, Uniformity in weight, Diameter, Thickness, Hardness, Friability, Disintegration time and HPTLC analysis. Obtained results are tabulated below in table no.3.

Table 3: Showing comparative physico-chemical values of all three samples.

Sr	Test Name	Sample A	Sample B	Sample C	Mean SD ±
1	Color	Blackish Brown	Brown	Blackish Brown	-
2	Average Weight	0.4981g	0.5026g	0.5008g	0.0022
3	Uniformity in weight	Not > 5%	Not > 5%	Not > 5%	Complies
4	Diameter	10.11mm	10.19mm	10.20mm	0.049
5	Thickness	4.48mm	4.96mm	4.70mm	0.240
6	Hardness	2.000kg/cm^2	2.000kg/cm^2	1.6666kg/cm^2	0.192
7	Friability	0.25 %w/w	0.15 %w/w	0.18 %w/w	0.051
8	Disintegration time	55min	56 min	58min	1.527
9	pH	3.71	3.73	3.68	0.025
10	HPTLC Spots Obs	12	10	11	Complies
	Spots	0.04, 0.07, 0.10, 0.17, 0.24, 0.29, 0.41, 0.47, 0.51, 0.58, 0.67, 0.71	0.01, 0.10, 0.17, 025, 0.41, 0.47, 0.52, 0.57, 0.68, 0.80	0.04, 0.07, 0.10, 0.17, 0.24, 0.29, 0.41, 0.47, 0.57, 0.68, 0.80	Complies

All three samples batches of this formulation were underwent for HPTLC study and Spots were observed. Extract 5 g of formulation powder by using Petroleum Benzene & Ethyl acetate in 3:1 ratio was used to carry out the thin-layer chromatography. 10 µl layers were applied on HPTLC plate and the plate was developed to a distance of 8 cm using Petroleum Benzene & Ethyl acetate in 3:1 ratio as mobile phase. After development the plate was allowed to dry in air and examine under ultraviolet light (254 nm, 360nm) and also in visible light. It shows major spots as given in above table no.3



Under 254nm UV light Batch A	Under 366nm UV light Batch A	Under white light Batch A	Under 254nm UV light Batch B	Under 366nm UV light Batch B	Under white light Batch A

DISCUSSION

Dosage form is an important way of administration of drug. Amongst all available dosage forms Tablet is most suitable and widely accepted amongst all dosage forms. Tablets have more advantage over other dosage forms like as it can deliver exact quantity to the patient, easy to transport, easy for packaging, easy to administer etc. Pharmaceutical and Analytical validation of *Yogaraj Guggul* Tablet has become possible by strictly following every step in proper way and by modern physico-chemical analysis of finished product. It was also inferred that appropriate processing sequence was strictly followed and changes were noted after each step from pulverization of raw material to packaging of finished product. Weight was notes after each pharmaceutical process to note processing loss. Average 5-8% weight loss was observed in pharmaceutical process. Finished product was examined both on classical as well as Modern Physico-chemical parameters to check batch to batch variations and consistency.

In all three sample batches the quality control parameters for this drug does not show significant difference in their values. The analytical parameters for *Yogaraj Guggul* Tablet which is prepared by the above said method may be set as per following table No.4.

Table 4: Showing set parameters for Yogaraj Guggul tablet.

Sr. No	Test Name	Set Parameters
1	Color	Blackish Brown to gray
2	Average Weight	0.495gm to 0.525gm
3	Uniformity in weight	Not > 5%
4	Diameter	10mm to 11mmm
5	Thickness	4.50mm to 5.30mm
6	Hardness	1.5000kg/cm^2 to 2.000kg/cm^2
7	Friability	Not > 1%
8	Disintegration time	Not > 60min
9	pH	3.68 to 4.00

As a part of standardization process and to check batch to batch consistency fingerprinting of HPTLC were obtained for three consecutive batches. The occurrence of same no. of spots and fingerprinting structure on TLC plates confirms the consistency of finished product. Such a stipulation for obtaining TLC including number of spots and corresponding Rf values gives the guidelines for preparation of *Yogaraj Guggul* Tablet. Hence all the three samples of *Yogaraj Guggul* were within the compliance show no significance difference in their fingerprinting structures. Also above observations shows similarity to those parameters which are already set in API. The formulation does not show any significant difference in their physicochemical analysis on studying all the three batches and are identical.

CONCLUSION

The manufacturing process of *Yogaraj Guggul* Tablet- an *Ayurvedic* formulation has been validated by using modern scientific physico-chemical parameters and *Ayurvedic* parameters which are mentioned in relevant

text. Thus the methods is validated and can be used to lay down pharmacopoeial standards for the preparation of *Yogaraj Guggul* Tablet by which we get an optimal efficacy of the finished product. Hence we can say that the pharmaceutical and Analytical parameters for Yogaraj guggul Tablet are validated by above said method is standard one and will not show batch to batch variation and has optimum efficacy.

Acknowledgement:

Author is thankful to Dr. Sarang Deshapande and Mr. Tarun Pable for providing us all raw materials and their valuable guidence. Author is also thankful to Mr.Gadkari, Head of Quality control laboratory of Unijules Life sciences Pvt. Ltd For his help in Physico-chemical analysis of the drug. Author will also like to express gratitude to Dr.Raman Belge for their valuable guidance and continuous support during this entire work.

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Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: Sule Hareshwar Et Al: Pharmaceutical And Analytical Validation Of Yogaraj Guggul Tablet – A Polyherbal Ayurvedic Formulation. International Ayurvedic Medical Journal {online} 2017 {cited April, 2017} Available from: http://www.iamj.in/posts/images/upload/1044_1050.p