

Development of Quality Control and Standardization Parameters of Pathyadi Lepa

Khushboo Naik* and Nirmal Dongre

Institute of Pharmaceutical Sciences, SAGE University, Indore, (M.P.) – India

E.mail: naik.khushboo@gmail.com

Abstract

In traditional system of medicine approximately 80 % of the population depends on the indigenous system for relief. With such a huge section of an ever increasing population relying on herbal medicine, it is imperative that the plant products which have been in use for such a long time be scientifically supported for their efficacy. Pathyadi Lepa is an Ayurvedic preparation widely used for the treatment of skin diseases including inflammation caused by the same. The present paper deals with the investigation and development of quality control parameters for standardization of Pathyadi Lepa. Three laboratory batches (PL-I, PL-II & PL-III) of Pathyadi Lepa (PL) were prepared in laboratory as per procedure mentioned in Ayurvedic Pharmacopoeia and were evaluated for the testing of quality.

Keywords: Pathyadi Lepa, Standardization Parameters, Quality

Introduction

Focus on plant based research has been existing for many years in India and rest of the world. Large numbers of plants have been tested for pharmacological effect. Herbal preparations which have drawn wide spread acceptability as therapeutic agents include analgesics, anti-inflammatory, anti-diabetic, lipid lowering agent, hepatoprotective, anti-hypertensive and anti-microbial agents. In some cases, the crude extract of medicinal plants may be used as medicaments. On the other hand, the isolation and identification of the active principles and elucidation of the mechanism of action of a drug is of paramount importance. Hence, works in both mixture of traditional medicine and single active compounds are very important. Where the active molecule cannot be synthesised economically, the product must be obtained from the cultivation of plant material. The scientific study of traditional medicines, derivation of drugs through bioprospecting and systematic conservation of the concerned medicinal plants are thus of great importance. [1-3]

Pathyadi Lepa is an Ayurvedic medicine, in the form of lepa, used for external application to treat inflammation caused by skin diseases like psoriasis, leucoderma etc. It is also used to control Vata

and Kapha. The main ingredient is *Pathya* Chebulic Myrobalan fruit rind – *Terminalia chebula*. It is prepared according to the reference of Yogaratnakara Kushta Rogadhikara. So, far no any systematic study was carried out in evaluating the standardization parameters of Pathyadi Lepa, therefore, the present work was undertaken to reveal and develop the quality control parameters for standardization of preparation.

Material and Methods

Selection of poly herbal formulation

The selected polyherbal formulation i.e., Pathyadi Lepa is a well known formulation for the treatment of inflammation as mentioned in Ayurvedic pharmacopoeia. It comprises of some medicinally important plants, *Terminalia chebula* Retz. (fruits), *Pongamia pinnata* (L.) Pierre (seeds), *Brassica juncea* (L.) Czern (Seeds), *Curcuma longa* L. (rhizomes), *Psoralea cordifolia* L. (seeds), *Embelia ribes* Burm. f. (fruits), rock salt and cow urine. The Pathyadi Lepa was used from ancient in the treatment of inflammation as mentioned in folk lore, classical text and ayurvedic pharmacopoeia, therefore the present formulation was selected.

Collection and authentication of plant material

All the raw materials used in formulation were purchased from local market of Indore (M.P.) 452010, India and identified morphologically and compared with standard Pharmacopoeial Monograph. The sample of crude drug was also identified & authenticated by Dr. S.N. Dwivedi, Redt. Professor & Visiting Professor, APS University, Rewa (M.P.). Voucher Specimen no was allotted. J/Bot/PPPL-21.

Preparation of selected formulation

Medicines in the form of a paste used for external application are called lepas. The drugs are made into a fine powder. Before use on the body, it is mixed with some liquid or other medium indicated in each preparation and made into a soft paste. Water, Cow's urine, oil, and ghee are some of the media used for mixing.

Three laboratory batches (PL-I, PL-II & PL-III) of Pathyadi Lepa (PL) were prepared in laboratory as per procedure mentioned in Ayurvedic Pharmacopoeia. [4-5]

Table 1: Composition of Pathyadi Lepa

S/No.	Botanical Name	Local Name	Part Used	Parts
1.	<i>Terminalia chebula</i>	Harad	Fruits	1

2.	<i>Pongamia pinnata</i>	Karanj	Seeds	1
3.	<i>Brassica juncea</i>	Sarso	Seeds	1
4.	<i>Curcuma longa</i>	Haldi	Rhizomes	1
5.	<i>Psoralea cordifolia</i>	Bakuchi	Seeds	1
6.	Rock salt	Sedha namak	-	1
7.	<i>Embelia ribes</i>	Vidanga	Fruits	1
8.	Cow urine	Gomutra	-	qs

Development of Quality Control Parameters [6-10]

Development of sensory profile (Morphological studies)

The studies of sensory characters provides the simplest and quickest means to establish identity, purity and, possibly, quality of crude drugs. If a sample is found to be significantly different, in terms of color, consistency, odor or taste, from the specifications, it is considered as not fulfilling the requirements. The entire laboratory batch of PL and one marketed formulation (MF-PL) of each and every raw ingredient of all the formulation were subjected to sensory examination.

Development of physical characteristics

The entire laboratory batches of PL, marketed formulations and raw ingredient of the formulation were evaluated for their physical properties in form of tap density, bulk density, angle of repose, Hausner's ratio and Carr's index by using standard method.

Physico-chemical studies

Various physicochemical parameters were evaluated as per standard procedure mentioned by WHO. In this study LOD, FOM, Ash Values, Extractive values were determined.

Results and Discussion

The present research work carries results of "Development of Quality Control and Standardization Parameters of Pathyadi Lepa". It indicates the quality control parameters of Pathyadi Lepa, an Ayurvedic formulation widely used for the treatment of inflammation mainly caused due to skin infections. In the present research work morphological study, physicochemical parameters and phytochemical screening were carried out and reported.

Three laboratory batches (PL-I, PL-II & PL-III) of Pathyadi Lepa (PL) were prepared in laboratory as per procedure mentioned in Ayurvedic Pharmacopoeia using standard procedure and were named as PL-I, PL-II & PL-III. One marketed formulations named MF-PL was purchased from local

pharmacy store of Indore. These samples were stored at optimized conditions of temperature, light and moisture. All the raw materials *Terminalia chebula* Retz. (fruits), *Pongamia pinnata* (L.) Pierre (seeds), *Brassica juncea* (L.) Czern (Seeds), *Curcuma longa* L. (rhizomes), *Psoralea cordifolia* L. (seeds), *Embelia ribes* Burm. f. (fruits), rock salt and cow urine, each laboratory batch (PL-I, PL-II & PL-III) and marketed formulation (MF-PL) were subjected to sensory examination (table 1), physical properties viz., ap density, bulk density, angle of repose, hausner ratio and carr's index (table 3) were determined. Various standardization parameters were evaluated for all the raw materials, each laboratory batch (PL-I, PL-II & PL-III) and marketed formulation (MF-PL). LOD, FOM, SI, FI, Ash Values, Extractive values were evaluated and found within the limit (table 3). Extractive values are determined in various solvents with a view to study the distribution of various constituents of PL and its raw material.

Table 1: Sensory characters of raw materials and formulation

S. No.	Drug	Color	Odor	Taste
1.	<i>Terminalia chebula</i>	Light Brown	Pungent	Sour
2.	<i>Pongamia pinnata</i>	Brown	Characteristics	Bitter
3.	<i>Brassica juncea</i>	Yellow	Characteristics	Pungent
4.	<i>Curcuma longa</i>	Yellow	<i>Camphoraceous</i>	Bitter
5.	<i>Psoralea cordifolia</i>	Brownish black	Odorless	Bitter
6.	<i>Embelia ribes</i>	Dull red	Aromatic	Astringent
7.	Rock Salt	Colorless	Odorless	Salty
8.	Cow Urine	Yellow	Peculiar	Nutty
9.	PL- I	Brown	Characteristics	Bitter
10.	PL-II	Brown	Characteristics	Bitter
11.	PL-III	Brown	Characteristics	Bitter
12.	MF-PL	Brown	Characteristics	Bitter

Table 2: Physical characteristics of raw materials and formulation

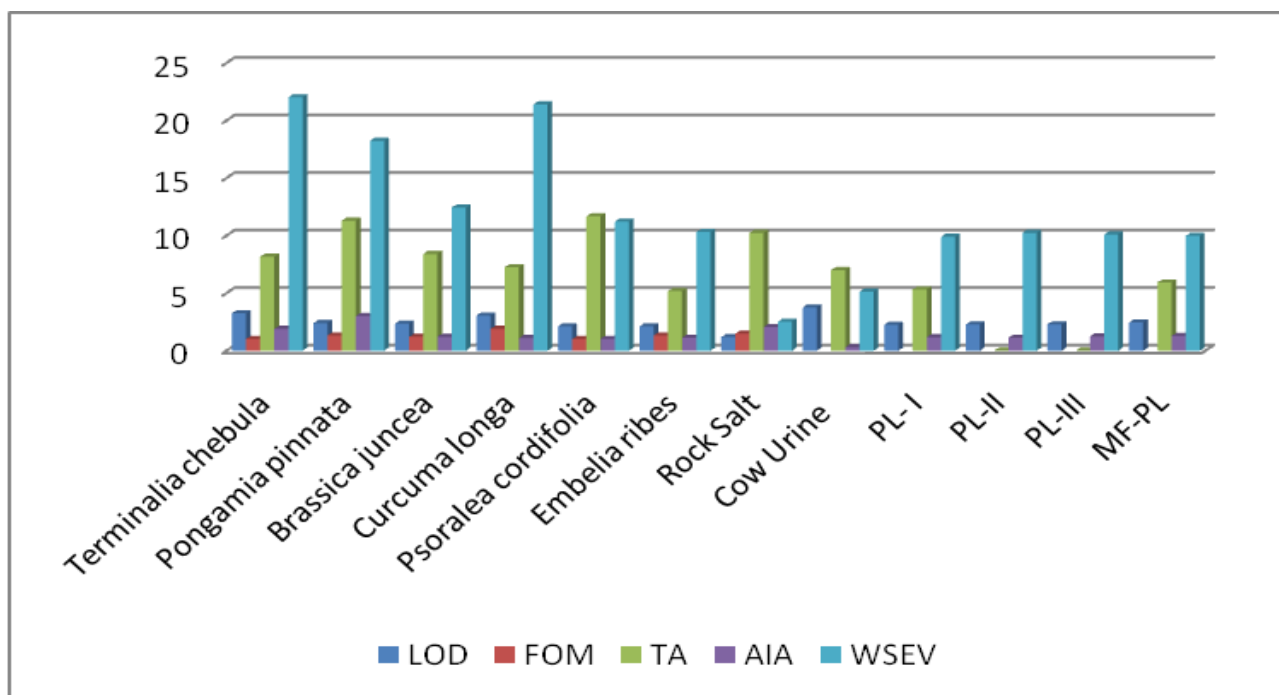
S. No.	Drug	Tap density	Bulk density	Angle of repose	Hausner ratio	Carr's index
1.	<i>Terminalia chebula</i>	0.581	0.623	20.98	0.893	10.12
2.	<i>Pongamia pinnata</i>	0.579	0.632	24.27	0.894	11.19

3.	<i>Brassica juncea</i>	0.569	0.630	23.12	0.896	11.18
4.	<i>Curcuma longa</i>	0.588	0.619	23.42	0.878	11.04
5.	<i>Psoralea cordifolia</i>	0.583	0.628	22.92	0.894	10.94
6.	<i>Embelia ribes</i>	0.587	0.639	24.12	0.898	11.38
7.	Rock Salt	0.583	0.629	23.90	0.882	11.86
8.	Cow Urine	-	-	-	-	-
9.	PL- I	0.578	0.644	23.59	0.889	11.46
10.	PL-II	0.583	0.649	23.62	0.898	11.32
11.	PL-III	0.587	0.667	24.01	0.891	11.62
12.	MF-PL	0.591	0.669	23.91	0.899	11.92

Table 3: Standardization Parameters of raw material and formulation

Drug	% LOD	%FOM	Total ash % w/w	Acid insoluble ash % w/w	Extractive Value (Aqueous)% w/w
<i>Terminalia chebula</i>	3.25±0.25	1.02±0.02	8.16±1.18	1.89±0.02	22.02±0.11
<i>Pongamia pinnata</i>	2.43±0.11	1.32±0.01	11.30±0.92	3.02±0.29	18.24±0.02
<i>Brassica juncea</i>	2.35±0.32	1.21±0.05	8.40±0.81	1.20±0.91	12.43±0.18
<i>Curcuma longa</i>	3.05±0.18	1.89±0.02	7.25±0.28	1.10±0.68	21.39±0.29
<i>Psoralea cordifolia</i>	2.12±0.28	1.01±0.01	11.68±0.39	1.02±0.43	11.21±0.03
<i>Embelia ribes</i>	2.12±0.08	1.32±0.03	5.18±0.48	1.12±0.47	10.32±0.38
Rock Salt	1.18±0.24	1.48±0.08	10.23±0.81	2.05±0.93	2.52±0.03
Cow Urine	3.75±0.18	NIL	7.0±0.24	0.30±0.61	5.13±0.18
PL- I	2.25±0.45	NIL	5.32±0.19	1.16±0.42	9.89±0.054
PL-II	2.28±0.23	NIL	5.96±0.09	1.11±0.31	10.24±0.89
PL-III	2.28±0.43	NIL	5.14±0.20	1.23±0.09	10.09±0.52
MF-PL	2.45±0.12	NIL	5.92±0.18	1.28±0.01	9.98±0.47

Values are expressed in Mean±SEM, n=6



Graph 1: Physicochemical Parameters of Raw Material and Formulation

Conclusion

Development of quality parameters of the medicinal plants is of prime importance in order to reveal safety aspects. In traditional system of medicine herbal healers treat diseases using the plants which have immense medicinal potentiality. But due to lack of standardization parameters correct identification of the plant is lacking, therefore development of QC parameters is of great interest. The present work was undertaken to reveal the standardization parameters of Pathyadi Lepa. Results of flow property indicate that all have good flow property and the data so obtained were in limit when compared with Pharmacopoeia. Various standardization parameters accessed for laboratory batches (PL-I, PL-II & PL-III) of Pathyadi Lepa (PL) and MF-PL were found within the limit.

References

1. Ambasta, S. P. (1992). *The useful plants of India*, Publications & Information Directorate, CSIR, New Delhi, 251.
2. Dwivedi Sumeet, Dwivedi Abhishek and Dwivedi S. N. (2008). Folklore uses of some plants by the tribals of Madhya Pradesh with special reference to their conservation, *Ethno. Leaflets*, 12:763-771.
3. Dwivedi, S.N. (2009). Status and utilization of medicinal plants in Shahdol district, Madhya Pradesh, India, Part 1. *NutraCos* (Milano-Italy), 8 : 28-31.
4. Divakar M.C. (2002). *Plant drug evaluation-A laboratory guide*, CD remedies, 2 Edition, 84-92.

5. The Ayurvedic Pharmacopoeia of India (2001), Part-I, Vol-I, The Controller Publication, Govt. of India, Ministry of Health & Family Welfare.
6. Harborne J.B. (1984). *Phytochemical Methods*”, Chapman and Hall, London, I Edition, 138.
7. Mukherjee P.K. (2008). Marker analysis of polyherbal formulation, Triphala – A well known Indian traditional medicine. *Indian Journal of Traditional Knowledge*, 7(3): 379-383.
8. Kokate C.K. (1997). *Practical Pharmacognosy*, Vallabh Prakashan, Delhi, 4 Edition, 107-111.
9. Harborne J.B. (1984). *Phytochemical Methods*”, Chapman and Hall, London, I Edition, 138.
10. WHO (1998). *Standardization of herbs and herbal products*. Geneva