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Development and Evaluation of Triphala Formulations

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The objective of the present study was to develop formulations of *Triphala*. Tablet formulations were developed using wet granulation and direct compression techniques. With a view to reduce the total dosage size and to incorporate more amounts of actives, it was decided to develop formulations containing alcoholic extract of *Triphala*. Addition of different diluents like, di-calcium phosphate, lactose, microcrystalline cellulose and co-crystallized lactose-microcrystalline cellulose were studied for improving the flowability and compressibility. Binders such as starch paste and alcoholic polyvinyl pyrrolidone were used for optimization of the formulation. Dried starch powder was used as a disintegrating agent. Pre and post formulation parameters were studied for all the batches. Co-crystallized lactose-microcrystalline cellulose and alcoholic polyvinyl pyrrolidone proved to be the best diluent and binder, respectively. The results showed that direct compression method is a better alternative technique than wet granulation since it minimizes the processing steps involved in the tabletting. Tablets of *Triphala* powder showed high friability compared to tablets of *Triphala* extract. In the dissolution study also *Triphala* extract tablets exhibited better performance, 95% of total tannins were released. This study suggests that *Triphala* extract tablets are superior to *triphala* powder tablets due to higher actives, ease of formulation, elegance and dissolution performance.

Last decade has witnessed a sudden increase in the awareness of herbal formulations. However, data about *in vitro* dissolution, content uniformity, in-process quality control parameters, final evaluation of dosage form and pharmacokinetics parameters that are available for allopathic formulations is not available for majority of the herbal products. Hence, we developed *Triphala* tablets with a view to standardize various formulation parameters by employing different forms of ingredients. *Triphala* powder (TP) is a popular Ayurvedic formulation consisting of powders of three fruits, *amla* (*Embelica officinalis*, Family: Euphorbiaceae), *harade* (*Terminalia chebula*, Family: Combretaceae) and *baheda* (*Terminalia belierica*, Family: Combretaceae) in equal proportions. It is widely prescribed as an anthelmentic and purgative[1]. *Triphala* formulation is traditionally prescribed in the form of *churna*, a powder of dried fruits of all the three ingredients. Ayurvedic Formulary of India[1] specifies the dose of *Triphala churna* to be 5-10 g per day. If concentrated extracts of the ingredients are employed, the dose can be reduced. Dispensing and consumption of powder formulation is inconvenient to the patients. Hence, in the present investigation, an attempt was made to prepare formulations of TP and *Triphala* extract (TE) to improve patient compliance and acceptability.

Recently, Lalla *et al*[2] reported physicochemical, phytochemical and certain preformulation studies on *Triphala churna*, but no systematic studies on alternate dosage forms or dissolution parameters are available in the literature. Hence, we made an attempt to carry out a systematic study to develop and evaluate tablets of TP and TE. Formulation studies were also carried out for tablets of TE using wet granulation and direct compression techniques. The

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TABLE 1: EFFECT OF DILUENT ON DERIVED PROPERTIES OF *TRIPHALA* POWDER GRANULES

Batch No	D1	D2	D3	D4
Diluents Parameters	**Lactose**	**MCC**	**Lactose-MCC**	**DCP**
Bulk Density (g/ml)	0.47	0.47	0.47	0.49
Tapped Density (g/ml)	0.57	0.58	0.58	0.69
Carr's Index	28.32	18.08	18.62	28.67
Hausners' Ratio	0.97	1.45	1.22	1.40
Angle of Repose (^{0})	35.78	36.28	31.62	33.23

Ratio of *Triphala* Powder (TP) to diluent is 1:0.5. MCC is Microcrystalline Cellulose and DCP is Di-calcium Phosphate.

preformulation and dissolution data of tablets of TP and TE are discussed in this paper.

MATERIALS AND METHODS

Powders of *amla, harade* and *baheda* were purchased from an established local supplier, L. V. Gandhi and Sons, Ahmedabad and passed through 60 mesh. Other materials used in the study such as lactose, di-calcium phosphate (DCP), microcrystalline cellulose (MCC), co-crystallized lactose-MCC, magnesium stearate, talc, starch and polyvinyl pyrrolidone (PVP) of pharmaceutical grade were purchased from Saraiya Chemicals, Ahmedabad. Double distilled water was used throughout the study. Rectified spirit was used for preparation of extracts. All chemicals used for analysis were of analytical grade.

Amla, harade and *baheda* powders were mixed in equal proportion to form TP. Each of 100 g powder was extracted separately in 95% alcohol by cold maceration method. The maceration was continued for 4 d and filtered, filtrate concentrated on a water bath at 50±0.5° till a gummy mass was obtained. *Triphala* extract (TE) was prepared by mixing semi solid extracts of *amla, harade* and *baheda* in equal proportions. Total tannins in individual powders, extracts, TP and TE were estimated by redox titration with potassium permanganate and calculated as tannic acid[3].

Formulations of *Triphala* powder:

Triphala powder was blended with diluents like, lactose, DCP, MCC, Co-crystallized lactose-MCC in the ratio of 1:0.5. Granules were prepared using PVP (3%, 5%, 7%) in isopropyl alcohol or starch paste (5%, 7%, 10%). Dried starch powder (3%, 5%, 7%) was added as a disintegrating agent (Table 1 and 2). Granules were lubricated with 1% magnesium stearate and 2% talc. Granules were compressed using a Dhiman make single stroke multipunch tablet press with oblong punches. The tablets had an average weight of 800 mg. The average crushing strength was 5.0 kgf and friability was 1.5%. The composition of the formulations is shown in Table 3.

In order to minimize the processing steps an attempt was made to prepare *Triphala* tablets by direct compression technique. *Triphala* powder was blended with directly compressible diluents like MCC, DCP:MCC and co-crystallized lactose-MCC as shown in Table 4. Dried starch powder (5% and 7%) was added as a disintegrating agent. The final powder blend was lubricated with 1% magnesium stearate and 2% talc and compressed as described earlier.

Formulations of *Triphala* extract:

Tablets of TE were prepared by wet granulation method. Since the extract is semi-solid, less amount of binder would be necessary to prepare tablets. Diluent was selected on the basis of results of TP studies. PVP (2%)/starch paste (5%) and dried starch powder were added as a binder and disintegrating agent, respectively (Table 5). The same diluents that were utilized for the directly compressible TP formulation were used for developing directly compressible TE formulation (Table 6).

Evaluation of *Triphala* tablets:

The tablets of TP and TE extract prepared by wet granulation and direct compression were evaluated for preformulation and postformulation parameters. Angle of Repose, Carr's Index, Hausners' Ratio, crushing strength, friability and disintegration time was measured as per standard methods[4,5]. The results are shown in Tables 1 to 6.

In-vitro dissolution study of *Triphala* tablets:

Best formulations of TP and TE were subjected to *in vitro* dissolution study in USPXXIV dissolution apparatus

TABLE 2: EFFECT OF BINDERS ON DERIVED PROPERTIES OF GRANULES/ TABLET PROPERTIES OF *TRIPHALA* POWDER

Batches / Parameters	W1	W2	W3	W4	W5	W6
PVP (%w/w)	3	5	7	-	-	-
Starch Paste (%w/w)	-	-	-	5	7	10
Carr's Index	18. 6	23.5	28.3	18.1	28.3	29.0
Hausners' Ratio	1.36	1.22	0.97	1.45	1.22	0.83
Angle of Repose (^{0})	32.6	31.6	34.1	29.5	30.0	30.3
Friability (%)	2.1	1.9	1.4	**	2.81	1.98
Crushing strength (Kgf)	2.82	5.52	5.64	**	2.34	4.2
Disintegration time (min)	22	23	23	21	20	18

**indicates high % friability and poor hardness. Each tablet contains 600mg *Triphala* powder (TP) and co-crystallized lactose-MCC as a diluent. MCC is Microcrystalline Cellulose and PVP is Polyvinyl Pyrrolidone.

Type II at 37±0.5° and at 100 rpm using distilled water as a dissolution medium. Total tannins released were analysed using a previously reported standard method[3]. Content uniformity was also studied for the formulations (Table 7).

RESULTS AND DISCUSSION:

The phytochemical investigation of TP indicated that tannins are the major constituents present in the fruits of *amla, harade* and *baheda* and hence we studied tannins as a means for qualitative analysis. Each raw material was analysed individually for its total tannin content. The tannin content of powders was found to be 29.5 %w/w, 32.5 %w/w, 25.8 %w/w and 30.1 w/w% in *amla, harade, baheda* and TP, respectively. Extractive values were found to be 29.6% w/w, 29.3% w/w and 18.7% w/w for *amla, harade* and *baheda*, respectively. Each extract when individually analysed for total tannins, showed 75.1 %w/w, 73.1 %w/w, 86.2 %w/w and 78.2 % w/w in *amla, harade baheda* and TE, respectively.

Since, tannins constitute major chemical entities in *Triphala* and also since Lalla *et al.*[2] evaluated *Triphala* with respect to tannins, we thought it logical to evaluate our formulation with respect to tannin content. Tannin content can be taken as a reliable and reproducible parameter for assay and dissolution studies of the formulation.

The results shown in Table 1 revealed that co-crystallized lactose-MCC gives the lowest Carr's Index (18.6) and angle of repose (31.6°). Thus, it can be concluded that co-crystallized lactose-MCC gave better compressibility and flow properties as compared to other diluents. Starch paste did not give satisfactory results (Table 2 and 3). Tablets had a very high friability (3.8–1.95%) and low crushing strength (2.3-4.2 kgf). Polyvinyl pyrrolidone at 5% and 7% showed better tablet characteristics, friability (1.7%) and crushing strength (5.52 kgf). In order to decrease the disintegration time, dried starch powder was added to the formulations. Formulation WP3 containing 7% disintegrating agent showed disintegration time of 13 min.

TABLE 3: FORMULATION OF *TRIPHALA* POWDER BY WET GRANULATION TECHNIQUE

Batches / Parameters	WP1	WP2	WP3
Lactose-MCC (mg)	220	230	240
PVP (%w/w)	5	5	5
Dried starch Powder (%w/w)	3	5	7
Crushing strength (Kgf)	4.8	5.3	5.5
Friability (%)	2.2	2.0	2.1
Disintegration Time (min)	20	18	13

Each tablet contains 600mg *Triphala* powder (TP). MCC is Microcrystalline Cellulose and PVP is Polyvinyl Pyrrolidone.

TABLE 4: EFFECT OF DILUENTS ON FORMULATION PARAMETERS OF TRIPHALA POWDER TABLETS BY DIRECT COMPRESSION TECHNIQUE

Batch no.	Diluents	Dried starch powder (%w/w)	Properties of powder/blend			Tablet Properties		
			Carr's Index	Hausners' ratio	Angle of Repose	Crushing strength (Kgf)	DT (min)	% Friability
T P			28.8	1.40	25.1			
DP1	DCP:MCC (1:0.25)	5	31.2	1.46	26.0	5.2	16	2.3
DP2		7	30.4	1.43	36.6	5.2	13	2.2
DP3	Lactose-MCC	5	21.0	1.32	35.6	5.1	13	1.8
DP4		7	21.7	1.27	33.3	5.1	10	1.6
DP5	MCC	5	34.0	1.59	40.2	6.8	2	1.4
DP6		7	34.8	1.54	39.3	6.8	2	1.4

Each tablet contains 600mg *Triphala* powder (TP). MCC is Microcrystalline Cellulose, DCP is Di-calcium Phosphate and DT is Disintegration time.

In direct compression experiments, TP showed poor compressibility (Carr's Index: 28.8) and flowability (angle of Repose: 25.1°). Directly compressible diluents like DCP:MCC, co-crystallized lactose-MCC, were used to improve the flow property and compressibility of TP. Results shown in Table 5 revealed that flow property and compressibility of TP improved with co-crystallized lactose-MCC. Batches DP5 and DP6 showed very low disintegration time (2 min) but the tablet required 45% MCC, which from industrial point of view, is expensive. DP3 and DP4 also showed good tablet properties and would be commercially viable.

Triphala extract (TE) showed more tannin content (78.2 w/w %) compared to TP (30.3 w/w %). As the total tannin percentage in extract is increased, fewer tablets would be needed to fulfill the dosage requirement. The manufacturing problems associated with the use of powder like high friability and low compressibility could also be resolved by use of extract.

Tablets of TE were prepared by wet granulation method. From the results shown in the Table 6, all the batches showed good crushing strength at low concentration of binders. In TE formulations percent friability was found to be very less compared to TP formulations. The average crushing strength and friability of all the formulations were 5.4 kgf and 0.9%, respectively. Batch WE6 with less disintegration time (10 min) was selected for *in vitro* dissolution study.

TABLE 5: FORMULATIONS OF *TRIPHALA* EXTRACT BY WET GRANULATION TECHNIQUE

Ingredients	WE1	WE2	WE3	WE4	WE5	WE6
PVP (%w/w)	2	2	2	-	-	-
Starch Paste (%w/w)	-	-	-	5	5	5
Dried Starch powder (%w/w)	5	7	10	5	7	10
Crushing strength (Kgf)	5.2	5.3	5.2	5.3	5.6	5.6
Disintegration Time (min)	16	14	11	16	13	10
Friability (%)	0.87	0.92	0.91	0.91	0.93	0.93

Each tablet contains 300mg *Triphala* extract (TE) and co-crystallized lactose-MCC as a diluent. Each tablet weighs 600mg. MCC is Microcrystalline Cellulose and PVP is Polyvinyl Pyrrolidone.

TABLE 6: EFFECT OF DILUENTS ON FORMULATION PARAMETERS OF *TRIPHALA* EXTRACT TABLETS BY DIRECT COMPRESSION TECHNIQUE

Batch no.	Diluents	Dried starch powder (%w/w)	Properties of powder/blend			Tablet Properties		
			Carr's Index	Hausners' ratio	Angle of Repose	Crushing strength (Kgf)	DT (min)	% Friability
DE1	DCP:MCC (1:0.25)	7	26.5	1.31	38.6	6.1	16	0.7
DE2		10	27.1	1.28	37.3	5.8	14	0.7
DE3	Lactose-MCC	7	20.7	1.19	35.2	7.2	14	0.5
DE4		10	21.0	1.20	34.8	6.8	12	0.5
DE5	MCC	7	36.4	1.53	40.1	6.4	2	0.3
DE6		10	35.0	1.49	40.2	6.2	1.5	0.3

Each tablet contains 300mg *Triphala* extract (TE) and co-crystallized lactose-MCC as a diluent. Each tablet weighs 600mg. MCC is Microcrystalline Cellulose, DCP is Di-calcium Phosphate and DT is Disintegration time.

TABLE 7: CONTENT AND PERCENT RELEASE OF TOTAL TANNINS FROM THE OPTIMIZED BATCHES OF *TRIPHALA* POWDER AND *TRIPHALA* EXTRACT

Batch no	Content (%w/w) of total tannins *		Percent tannins released from tablet * Practical
	Theoretical	Practical	
WP3	29.3±0.92	30.1±1.3	79.6±0.81
DP4	29.3±0.92	29.5±0.40	85.3±0.68
WE6	78.2±0.29	76.8±2.10	95.8±2.12
DE4	78.2±0.29	78.8±1.1	97.8±2.27

* Mean±SEM of three values. Total tannins are calculated as tannic acid.

Similar results were also obtained with directly compressible TE tablets. Batches DE5 and DE6 containing MCC as directly compressible diluent gave good results for disintegration time and friability. Batch DE4 containing lactose-MCC also gave better compressibility and flow properties. Less amount of relatively cheaper diluents are employed in batch DE4. Hence, it is considered an ideal formulation. Tablets of TP show less percentage release of tannins compared to TE tablets (Table 7). Hence, from the overall study it is revealed that TE definitely has better advantage with regard to formulation feasibility, elegance and dissolution. Previous studies have not dwelt upon crucial preformulation and post formulation aspects of *Triphala*. Our studies give sufficient and reliable inputs for formulating *Triphala*. In conclusion, co-crystallised lactose-MCC and alcoholic PVP proved to be best diluent and binder, respectively. Tablets of *Triphala* powder showed high friability compared to tablets of *Triphala* extract. Direct compression technique was found to be more feasible than wet granulation. In the dissolution study also TE tablets exhibited better performance. The proposed formulation has certain distinct advantages such as concentrated actives, compact tablet form, ease of handling and administration. Our study further brings out current needs to generate similar data on other important Ayurvedic formulations.

REFERENCES:

1. The Ayurvedic Formulary of India, Part I, 1st Edn., The Controller of Publications, Delhi, 1978, 85.
2. Lalla, J.K., Hamarapurkar, P.D. and Mammania, H.M., **Indian Drugs**, 2001, 38, 87.
3. Official Methods of Analysis ands the Association of Official Analytical Chemists (AOAC), 1970, 513.

4. Aulton, M.E. In; Pharmaceutics: The Science of Dosage Form Design, 1st Edn., Churchill Livingston, Medical Publications Division, Toronto, 1992, 568.

5. Lachman, L and Liberman, H.A. In; The Theory and Pra Industrial Pharmacy, 2nd Edn., Varghese Publishing Mumbai, 1991, 299.