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Formulation and Evaluation of Triphala Orodispersible Tablet

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Abstract

Triphala is a mixture of three fruits that is amla (*Emblica aofficinalis*), baheda (*Terminalia belerica*), harada (*Terminalia chebula*) widely used in ayurvedic system of medicine as blood purifier, rejuvenator, antioxidant and also as laxative. This is given in churna preparation. Hence, an attempt was made to develop orodispersible formulation of triphala using superdisintegrants in different concentrations for dose accuracy, increase in bioavailability and to avoid bitterness. Three main ingredients were thus subjected for extraction, standardized using ascorbic acid and gallic acid by thin-layer chromatography. A method was then developed to formulate these extracts into dispersible tablets by direct compression method and evaluated for post compression parameters. Formulation DX_7 was best among all formulation batches with respect to its disintegration parameters.

Key-Words: Triphala, ascorbic acid, gallic acid, orodispersible tablet

Introduction

In the last few decades, there has been an exponential growth in the field of ayurvedic medicine.[1] Ayurvedic formulations effect or help to rectify the three doshas in the body, and restore homeostatic balance that builds up in the body's digestive system and spread to the tissues.[2] Triphala is a traditional ayurvedic herbal formulation, consisting equal parts of three medicinal plants namely *Terminalia chebula*, *Terminalia belerica* and *Embellica officinalis*. Triphala has been reported to possess antioxidant activity, improves mental and physical power and also assist in weight loss. A nutritive and cleansing property of triphala makes it special. Triphala gently stimulates the cleansing of accumulated toxins from all tissues of the body, reduces cholesterol and high blood pressure, and improves circulation. Triphala also claimed to have various biological activities like heart protective, cardio tonic, improves digestion, liver function and hepatoprotective. It is mild, nonhabit forming and rejuvenative.[3] *Triphala* contains quercetin, rutin ,gallic acid, ellagic acid, ascorbic acid known for its effect.[4] In this study gallic acid is used as marker constituent for *Terminalia chebula* and *Terminalia belerica*, and ascorbic acid is used as marker for *Embellica officinalis*.[5]

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The most used and popular dosage form of triphala is churna (herbal powdered form) which meet several disadvantages such as low shelf life, deliquescence or hygroscopic nature, difficulty to swallow and misunderstanding of the correct dose, etc.[6-7] In recent days churna is formulated into tablets in order to fix the dose easily.[8] Since, tablets are the most widely preferred solid dosage forms of medication that ensure rapid onset of action, increased bioavailability and good stability, [9-10] it was thought worthwhile to develop tablets of this formulation. Although an effort has already been made in past in this direction. The present study was planned to carry out to prepare the extracts of three ingredients, standardize through marker analysis, develop method for dispersible tablet formulation and evaluated by keeping the natural goodness of this ayurvedic formulation intact. Dispersible tablet is"a solid dosage form containing medicinal substance, which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue" The basic approach in the development in ODT is the judicial use of super disintegrants in the respective formulation composition. Few illustrations include such as cross carmellose sodium, cross povidone, sodium starch glycolate, poly vinyl pyrollidone (PVP) etc.[11] Recently this formulation is popular as Novel drug delivery system because they are easy to administer and lead to better patient compliance.

Material and Methods

Materials

Amla fruits, baheda fruits and harada fruits were procured from Yucca enterprises, Mumbai. Other chemicals were procured from Research Lab, Mumbai. The plant materials were properly authenticated before proceeding to the next step.

Extraction

Three ingredients that is amla, harada and baheda each of 100 gm. powders were separately extracted by soxhlet extraction using ethanol water (50:50) as solvent. Extracts were filtered and concentrated using rotary evaporator. Extractive values for three were calculated as %w/w.

Standardization

For standardization, the prepared extracts were subjected for marker analysis. Qualitative estimation of gallic acid in *Terminalia chebula* and *Terminalia belerica* (solvent system Toluene: Ethyl acetate: glacial acetic acid: formic acid) (20:45:20:05) and ascorbic acid in *Embellica officinalis* (solvent system ethanol: glacial acetic acid: toluene (5.5:1:1.5), was performed using thin layer chromatography using silica gel G as stationary phase.

Formulation development and evaluation

Because Triphala is a mixture of three fruits equally mixed thus, it was decided to mix the extracts on the basis of their percentage extractive yield (w/w).The ratio of different concentrations of superdisintegrants were used to obtain best result. Tablet was prepared by direct compression method. After compression, the triphala dispersible tablets were evaluated for hardness, friability, weight variation test, disintegration test. The hardness of tablets was determined using Monsanto Hardness tester and the friability of tablets was determined using Roche friabilator (Lab India Limited, India). The disintegration test was carried out using the disintegration test apparatus, and their mean disintegration time was calculated.

Results and Discussion

The extractive values of amla, baheda and harada was obtained as 8.32 and 5.88 and 6.37 (%w/w) respectively. During marker analysis by TLC, the Rf values reported were 0.66 and 0.51 which matches with Rf of standard gallic and ascorbic acid respectively.

Based on the extractive values 80 mg of triphala extracts were decided to incorporate in to the tablet of the total weight of 250 mg. For this purpose, three extracts that is, 34.5 mg of amla, 21.5mg of baheda and 24.0 mg of harada were mixed to get 80 mg and formulated into tablet by direct compression method. Nine batch of formulation from DX1 to DX9 were prepared by varying the concentration superdisintegrants to get the best suitable product. [Table1]

The post compression parameters such as hardness, friability, weight variation, content uniformity and dispersion time were evaluated as shown in [Table 2]. The weight variation of all the tablets was found to be within the pharmacopoeial limits.

Hardness of all the batches of tablets was near 3.9-4.2 kg/cm^2. Friability of the tablets was found less than 1% w/w for all the batches. The uniformity of the contents was under the prescribed pharmacopoeial limits. The dispersion time of batch DX_7 was less dispersible time than other formulated batches thus considered best.

It was thus observed that the developed composition of preparing dispersible tablets of triphala passes all required parameters, should be considered as a successful effort. The total weight of the tablet that is, 250 mg will carry 80 mg of active ingredients disintegrate at a comparatively faster rate. The dose variation will be negligible. It will give advantage over traditional churna to enhance therapeutic activity.

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Table 1: Composition of dispersible tablet of Triphala

Ingredients	DX_1	DX_2	DX_3	DX_4	DX_5	DX_6	DX_7	DX_8	DX_9
Triphala extract	80	80	80	80	80	80	80	80	80
Starch	5	5	5	5	5	5	5	5	5
CCS	10	-	5	20	-	10	40	-	20
SSG	-	10	5	-	20	10	-	40	20
Anhydrous Lactose	64	64	64	64	64	64	64	64	64
Mannitol	70	70	70	60	60	60	40	40	40
Aspartame	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Magnesium stearate	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5
Talc	5	5	5	5	5	5	5	5	5
Peppermint flavour	2	2	2	2	2	2	2	2	2

Average weight of tablet was 250 mg. All quantities are expressed in milligram.SSG: Sodium starch glycolate, CCS: Cross carmellose sodium.

Table 2: Post compression evaluation of dispersible tablet of Triphala

Formulated batch	Weight Variation(%)(n=10)	Hardness kg/cm^2	Friability (%)	Dispersion time (n=6)	Content uniformity % (n=3)
DX_1	249±8.1632	3.92	0.14	5.30min	97.84±0.46
DX_2	248±7.1026	4.10	0.32	8.29 min	97.92±0.31
DX_3	250±8.8641	4.00	0.38	7.40 min	98.56±0.60
DX_4	248±8.3219	4.13	0.25	2.18 min	97.89±0.48
DX_5	251±7.3832	3.99	0.18	6.45 min	98.19±0.54
DX_6	249±7.8846	3.86	0.39	5.16 min	97.80±0.21
DX_7	249±7.9324	3.92	0.12	1.10 min	98.38±0.58
DX_8	249±8.6541	4.18	0.26	3.12min	97.52±0.67
DX_9	249±7.3513	3.95	0.40	2.15 min	97.12±0.49

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