IJPSR (2023), Volume 14, Issue 7 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 21 October 2022; received in revised form, 03 June 2023; accepted 26 June 2023; published 01 July 2023

FORMULATION AND EVALUATION OF DRY POWDER SUSPENSION USING HERBAL SEED EXTRACT

Pratiksha G. Patil * and Varsha M. Jadhav

Department of Quality Assurance, Bharati Vidyapeeth's College of Pharmacy, Sector 8, C.B.D. Belapur, Navi Mumbai - 400614, Maharashtra, India.

Keywords:

Dry powder suspension, *Linum usitatissimum*, *Cucurbita pepo*, *Sesamum indicum*, *Helianthus annuus*, Herbal seeds extract

Correspondence to Author:
Pratiksha G. Patil

Research Scholar,
Department of Quality Assurance,
Bharati Vidyapeeth's College of Pharmacy, Sector 8, C.B.D. Belapur, Navi Mumbai - 400614, Maharashtra, India.

E-mail: pratikshapatil978@gmail.com

ABSTRACT: Introduction: Herbs, which have been used to cure numerous ailments since ancient times, are important in building the foundation of modern medications. They are relatively safe to use, easily available, and also affordable. The present study aimed to investigate dry powder suspension formulated with *Linum usitatissimum* seeds extract, *Cucurbita pepo* seeds extract, *Sesamum indicum* seeds extract and *Helianthus annuus* seeds extract. **Method and Material:** The Soxhlet apparatus prepared Plant extracts using ethanol as a solvent. Various batches were prepared using the dried seed extract of individual herbs and the excipients. Further evaluation studies were carried out for all the batches to finalize the optimized batch showing good flow properties and drug release profile. **Results:** The optimized formulations showed acceptable evaluation results, including pH, angle of repose, carr's index, sedimentation volume, redispersibility, viscosity, and drug release. **Conclusion:** The formulated dry powder suspension formulations showed good evaluation results and were within limits.

INTRODUCTION:

***Linum usitatissimum* (Flax seed):** Flaxseed **Fig. 1** is an annual herb member of the Linaceae family. The flax plant thrives in deep moist soils rich in sand, silt, and clay. The specie is native to the region extending from the eastern Mediterranean through Western Asia and the Middle East to India. The two basic varieties of flax seeds are brown and yellow or golden in colour [1]. It is cultivated on over 2.6 million hectares and the important linseed-growing countries are India, Canada, China, the United States, and Ethiopia [2, 3].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.14(7).3487-91

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.14(7).3487-91

The whole flaxseed is flat and oval with pointed tips, and contains a seed coat or true hull (also called testa), a thin endosperm, two embryos, and an embryo axis. The seed provides oil rich in omega-3, digestible proteins, and lignans [4].

FIG. 1: *LINUM USITATISSIMUM* (FLAX SEED)

***Cucurbita pepo* (Pumpkin):** The pumpkin belongs to the family Cucurbitaceae. It is an annual herb with a hairy stem and axillary tendrils, simple, alternate leaves, large yellow flowers, round fleshy

fruits, and oblong seeds **Fig. 2** [5, 6]. This plant is widely cultivated throughout India and in the most warm regions worldwide. This plant has been traditionally used in many countries such as India, China, Brazil, and America as an antidiabetic, antitumor, antihypertensive, anti-inflammatory, immuno-modulatory, and antibacterial agent [7, 8].

FIG. 2: *CUCURBITA PEPO* (PUMPKIN SEED)

***Helianthus annuus* (Sunflower):** The sunflower is an erect, coarse, tap-rooted annual plant with rough-hairy stems. The leaves are alternate, egg-shaped to triangular, and entire or toothed. The flower heads are wide. The sunflower is used as food and medicine worldwide. *Helianthus annuus* is cultivated for its seeds **Fig. 3**, which give the world's second most important source of edible oil. The seed oil, shoots, and herb tincture have many properties like anti-inflammatory, antioxidant, antitumor, antiasthmatic, antipyretic, astringent, anti-hypoglycemic, cathartic, diuretic, stimulant, vermifuge and antimicrobial [9].

FIG. 3: *HELIANTHUS ANNUUS* (SUNFLOWER SEED)

***Sesamum indicum* (Sesame):** Sesame belonging to the family Pedaliaceae, is a herbaceous annual plant. Sesame seed **Fig. 4** contains 50-60% of oil which is rich in polyunsaturated fatty acids and natural antioxidants, sesamin, sesamolin, and tocopherol homologues. Sesamin and sesamolin are lignans and they have cholesterol-lowering effects and prevent high blood pressure [10]. Sesame seed is high in protein, dietary fiber, phosphorous, iron, calcium, magnesium, copper, zinc, and vitamin B1 [11].

FIG. 4: *SESAMUM INDICUM* (SESAME SEED)

MATERIAL AND METHODS:

Plant Material: The *Linum usitatissimum* seeds, *Cucurbita pepo* seeds, *Sesamum indicum* seeds, and *Helianthus annuus* seeds were purchased from Bhau Korde Super Shop, Panvel, Navi Mumbai 410206. All herbs were authenticated by Alarsin House A/32, Street No. 3 M.I.D.C. Andheri (East), Mumbai, India 400093. Report No. of authenticated herbs is ALA/RMA/1214.

Preparation of Extracts: The seeds were washed with distilled water, sun-dried, and then ground to powder. The individual drug weighing 50 g each of *Linum usitatissimum*, *Cucurbita pepo*, *Sesamum indicum*, and *Helianthus annuus* were extracted with ethanol by hot continuous percolation method in Soxhlet apparatus. The ethanolic extracts were filtered, evaporated, and dried in an electric water bath.

Development of Formulation: Ingredients used for the formulation of reconstitution of dry suspension powder are given in **Tables 1, 2, 3, 4.** The formulation was prepared using the dried ethanolic extracts of *Linum usitatissimum*, *Cucurbita pepo*, *Sesamum indicum*, and *Helianthus annuus* seeds.

Procedure:

1. All the ingredients were sifted through sieve #60.
2. Sucrose was milled and sifted through #80.
3. Dried extract of drugs was triturated with lactose and starch using a mortal and pestle.

4. Above blend was geometrically mixed with all ingredients in step 1.

5. The powder was blended thoroughly.

6. The powder blend was sifted and passed through sieve #100 in the final step.

Weighed and dispensed in amber-coloured bottles.

TABLE 1: PRELIMINARY FORMULATION DEVELOPMENT USING FLAX SEED EXTRACT

	Batches (in grams)					
Ingredients	**A1**	**A2**	**A3**	**A4**	**A5**	**A6**
Flax seed extract	1.0	1.0	1.0	1.0	1.0	1.0
Lactose	0.98	0.98	0.98	0.98	0.98	0.98
Acacia	0.20	-	0.10	0.10	-	-
Tragacanth	-	0.20	0.10	0.10	-	-
Povidone	-	-	-	-	0.20	0.20
Sodium lauryl sulphate	-	0.08	-	0.08	-	0.08
Starch	0.80	0.80	0.80	0.80	0.80	0.80
Sucrose	0.80	0.80	0.80	0.80	0.80	0.80
Aerosil	0.04	0.04	0.04	0.04	0.04	0.04
Sodium benzoate	0.02	0.02	0.02	0.02	0.02	0.02
Sodium citrate	0.08	0.08	0.08	0.08	0.08	0.08
Ascorbic acid	0.004	0.004	0.004	0.004	0.004	0.004

TABLE 2: PRELIMINARY FORMULATION DEVELOPMENT USING PUMPKIN SEED EXTRACT

Ingredients	**B1**	**B2**	**B3**	**B4**	**B5**	**B6**
Pumpkin seed extract	1.80	1.80	1.80	1.80	1.80	1.80
Lactose	1.65	1.65	1.65	1.65	1.65	1.65
Acacia	0.35	-	0.175	0.175	-	-
Tragacanth	-	0.35	0.175	0.175	-	-
Povidone	-	-	-	-	0.35	0.35
Sodium lauryl sulphate	-	0.14	-	0.14	-	0.14
Starch	1.40	1.40	1.40	1.40	1.40	1.40
Sucrose	1.40	1.40	1.40	1.40	1.40	1.40
Aerosil	0.07	0.07	0.07	0.07	0.07	0.07
Sodium benzoate	0.035	0.035	0.035	0.035	0.035	0.035
Sodium citrate	0.14	0.14	0.14	0.14	0.14	0.14
Ascorbic acid	0.007	0.007	0.007	0.007	0.007	0.007

TABLE 3: PRELIMINARY FORMULATION DEVELOPMENT USING SUNFLOWER SEED EXTRACT

Ingredients	**C1**	**C2**	**C3**	**C4**	**C5**	**C6**
Sunflower seed extract	1.50	1.50	1.50	1.50	1.50	1.50
Lactose	0.97	0.97	0.97	0.97	0.97	0.97
Acacia	0.25	-	0.125	0.125	-	-
Tragacanth	-	0.25	0.125	0.125	-	-
Povidone	-	-	-	-	0.25	0.25
Sodium lauryl sulphate	-	0.10	-	0.10	-	0.10
Starch	1.0	1.0	1.0	1.0	1.0	1.0
Sucrose	1.0	1.0	1.0	1.0	1.0	1.0
Aerosil	0.05	0.05	0.05	0.05	0.05	0.05
Sodium benzoate	0.025	0.025	0.025	0.025	0.025	0.025
Sodium citrate	0.10	0.10	0.10	0.10	0.10	0.10
Ascorbic acid	0.005	0.005	0.005	0.005	0.005	0.005

TABLE 4: PRELIMINARY FORMULATION DEVELOPMENT USING SESAME SEED EXTRACT

Ingredients	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**
Sesame seed extract	1.60	1.60	1.60	1.60	1.60	1.60
Lactose	1.36	1.36	1.36	1.36	1.36	1.36
Acacia	0.30	-	0.15	0.15	-	-
Tragacanth	-	0.30	0.15	0.15	-	-
Povidone	-	-	-	-	0.30	0.30
Sodium lauryl sulphate	-	0.12	-	0.12	-	0.12
Starch	1.20	1.20	1.20	1.20	1.20	1.20

Sucrose	1.20	1.20	1.20	1.20	1.20	1.20
Aerosil	0.06	0.06	0.06	0.06	0.06	0.06
Sodium benzoate	0.03	0.03	0.03	0.03	0.03	0.03
Sodium citrate	0.12	0.12	0.12	0.12	0.12	0.12
Ascorbic acid	0.006	0.006	0.006	0.006	0.006	0.006

Evaluation of Reconstitution of Dry Suspension Powder: All twenty-four batches (A1- D6) of dry suspension powder formulation reconstitution were evaluated. The optimized batch was selected using a no. of parameters like carr's index, angle of repose, pH determination, viscosity, redispersibility, sedimentation volume, *in-vitro* drug release, and drug content.

Flow Properties: Flow properties such as angle of repose and compressibility index were determined.

pH Measurement: The formulation's pH was measured using a digital pH meter (MK-VI, Syntronics) by dipping the glass electrode completely into the formulation. The pH meter was standardized using pH 4.0 and 7.0 buffer prior to use.

Viscosity: A viscosity study was carried out using a Brookfield Synchro-electric Viscometer (Model LVT).

Redispersibility: Each batch of the reconstituted suspension was shaken vigorously to form a uniform dispersion and 50 mL was transferred to a measuring cylinder. The suspensions were left to stand for fourteen days to form sediment. It was determined by gently inverting the suspensions and the number of inversions required to disperse the particles to form a uniform suspension was recorded.

Sedimentation Volume: Each batch of the reconstituted suspension was shaken vigorously to form a uniform dispersion and 50 mL was transferred to a measuring cylinder and the volume (Hu) occupied by the suspensions were recorded. The measuring cylinders were left to stand on a vibration-free stand and the volume (Ho) occupied by the solid in the measuring cylinder below the supernatant was recorded. The sedimentation volume was determined using the equation;

$$F = Hu/Ho$$

Where F is the sedimentation volume, Hu is the final volume of sediment and Ho is the original volume of the suspension [12].

***In-vitro* Drug Release:** An *in-vitro* drug release study was performed using a USP type II dissolution apparatus. For the *in-vitro* drug release study Simulated Salivary Fluid pH 6.8, water, and 0.1 N HCl buffer were used as dissolution media. The volume of the dissolution medium was 900 mL and it was maintained at a temperature of (37 ± 0.5 °C) and stirred at 50 rpm. 10 mL samples were collected at 5, 10, 15, 20, 25 and 30 minutes intervals. The withdrawal samples were replaced by an equal amount of dissolution medium to maintain constant volume during the study. UV Spectrophotometry analyzed samples for determination of Beta-sitosterol content using calibration curve equation data [13].

Drug Content: The drug content of the formulation was determined by dissolving 50 mg of formulation in 5 ml of methanol in a volumetric flask. The mixture was centrifuged for 15 min and the supernatant was collected. The supernatant was used and HPTLC analysis was done. The drug content was calculated from the linear regression equation obtained from the calibration curve.

RESULTS AND DISCUSSION: Evaluation results of optimized batches are given in **Table 5**, **Fig. 5** and all the parameters are within acceptable limits.

TABLE 5: EVALUATION OF BATCHES

Parameters	A6	B6	C6	D6
Angle of repose	30.65°	29.45°	28.439°	32.12°
Carr's index	13.55%	7.684%	12.489%	10.54%
pH	6.76	6.54	6.75	6.63
Viscosity (cps)	356	369	348	359
Redispersibility	9	11	8	10

Sedimentation	0.85	0.87	0.83	0.89
Drug content	96.73%	95.48%	96.45%	94.93%

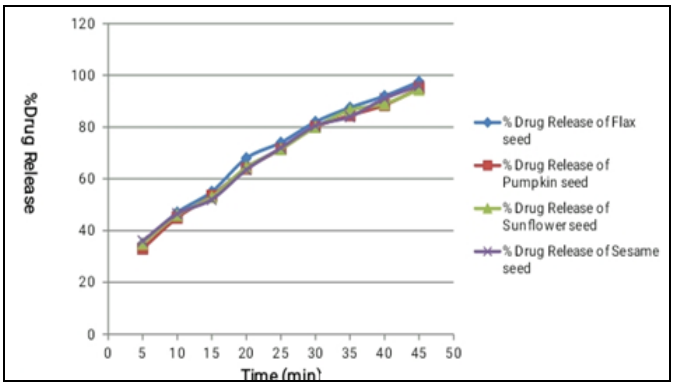

FIG. 5: *IN-VITRO* DRUG RELEASE

CONCLUSION: In the present work, an attempt has been made to formulate and evaluate herbal drugs and incorporate them in dry powder suspension formulations. The prepared formulations showed satisfactory rheological characteristics, release behaviour, appearance, and pH.

ACKNOWLEDGEMENTS: The authors are thankful to Bharati Vidyapeeth's College of Pharmacy for their constant support and encouragement during the research work and to Alarsin Pharmaceuticals, Mumbai for the authentication of plant material.

CONFLICTS OF INTEREST: The authors declare no conflict of interest.

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How to cite this article:
Patil PG and Jadhav VM: Formulation and evaluation of dry powder suspension using herbal seeds extract. Int J Pharm Sci & Res 2023; 14(7): 3487-91. doi: 10.13040/IJPSR.0975-8232.14(7).3487-91.