Preparation of *Nigella Sativa* Seeds Tablets and Its Evaluations in PPR Infected Goats

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ABSTRACT

The extractability percentage of the ethanolic extract of *Nigella sativa* was 21.70 %. The herbal tablet was then used to treat naturally infected goats with PPR.The immunomodulatory tablet prepared from ethanolic seed extract of *Nigella sativa* has reduced the recovery period in goats in PPR infection. The direct compression process was used to prepare the *Nigella sativa* herbal tablet. The compressed formulation was evaluated based on several criteria, including friability, hardness, thickness, weight fluctuation, and appearance The tablet feeding shows improvement in PPR infected goats. Hence, this therapy can be used as supportive/immunomodulatory therapy along with conventional therapy.

INTRODUCTION

A larger number of medicinal plants and their purified constituents have been shown to have beneficial therapeutic potentials, such as seeds of *Nigella sativa*, a dicotyledon of the Ranunculaceae family, which have been employed for thousands of years as a spice and food preservative. The oil and seed constituents, particularly thymoquinone (TQ), have shown potential medicinal properties in traditional medicine. In recent years, the importance of various immunomodulatory therapies has become well known, unlike conventional antibiotics used to kill particular bacteria, and such treatments exert their protective effects by acting on the host immune system.The current study aimed to create an herbal formulation with *Nigella sativa* ethanolic extract. The *in-vitro* results were used to determine the formulation's dose. The direct compression process was used to prepare the *Nigella sativa* herbal tablet. The compressed formulation was evaluated based on several criteria, including friability, hardness, thickness, weight fluctuation, and appearance.

The seed powder of *Nigella sativa* was prepared and subjected to the cold extraction method with the most suitable solvent, ethanol (99%). The extractability percentage of ethanolic extract of *Nigella sativa*, its colour and consistency.

MATERIAL & METHOD

Step 1: Defatting seeds extract of *Nigella sativa*

In a Soxhlet apparatus/extractor, 250 gm of the extracted oily powder mass was defatted for 50 cycles using 250 mL of hexane.

Step 2: Drying of defatted powder extract

After extraction, the powder mass was collected and dried in a hot air oven at 50^{0} ˚C for one hour.

Step 3: Formulation of tablets:

Item No.	Name of Ingredient	Use of Ingredient	Qty (% w/w)	Qty taken (mg)
1	*Nigella sativa* Powder	**Active**	--	1000 mg

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2	Prosolv (Silicified MCC)	Directly compressible diluent	30	300 mg
3	Magnesium stearate	Lubricant	2	20 mg
4	Talc	Glidant	1	10 mg
5	Prosolv	Weight adjustment	--	20 mg
	Total weight of a tablet			**1350 mg**

Step 4: Tablet compression

All the materials were then sifted through a sieve No. 45 and taken for the compression. The weight of the tablet was set at 1350 mg. Tablets were prepared using a 10-station automatic punching machine (Karnavati make) with a 20 mm punch set.

Step 5: Evaluation of prepared tablets

The prepared tablets were evaluated for hardness, friability, weight variation, and disintegration test as per the IP (Indian Pharmacopoeia) protocol

RESULT AND DISCUSSION

All of the assessment parameters of the prepared tablets were studied as follows. Pre-compression tests on herbal tablets revealed that their thickness, hardness, weight fluctuation, and friability were carried out. The herbal tablet was then used to treat naturally infected goats with PPR. In the present study, an investigation of the immunomodulatory activity of ethanolic seed extract of seeds of *Nigella sativa* was carried out, which can act as enhancers in PPR-affected goats.various paramets studied as follows.

Dimensions of tablets: Dimensional analysis of tablets includes thickness and diameter

Table 1. Tablet dimension parameters

Sr. No.	**Parameters studied**	**NSET (*Nigella Sativa* Extract Tablet)**
1.	Thickness (mm)	4
2.	Diameter (mm)	20

Weight variation test: The weight variation was studied on 20 tablets of *Nigella sativa* formulation, which were selected randomly to determine their average weight. Not more than 2 of the individual weights may deviate from the average weight by more than the % deviation, and none should deviate by more than twice that percentage. The USP and IP limit for weight variation is as follows:

Table 2. United State Pharmacopoeia and Indian Pharmacopoeia limit of Tablet

USP Limit		**IP limit**	
Average weight of tablet(mg)	**Maximum variation**	**Average weight of tablet(mg)**	**Maximum variation**
130 or less	±10.0%	80 or less	±10.0%
130 to 324	±7.5%	80 to 300	±7.5%
More than 324	±5.0%	More than 300	±5.0%

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Observations:

Table 3. Tablet evaluation and weight variation test

Sr. No.	Particular	NSET
1.	Total wt. of 20 tablets (mg)	27202
2.	Average	1360.1
3.	% Deviation	±5%
4.	Lower limit of tablet weight (mg)	1292
5.	Upper limit of tablet weight (Mg)	1428

Inference: No tablet deviates more than the upper and lower limits, so the tablet batch passed the weight variation test.

Hardness: Table 4. Hardness test of Tablet

Batch Code	Specification as per IP	NSET (kg/cm2)
Tablet 1	4 Kg/cm2	4.1
Tablet 2		3.9
Tablet 3		4.2
Average Hardness		4.06

Inference: The hardness values of both batches are within the specification limit, and hence, the tablet batch passed the hardness test.

Friability: Friability is another measurement of tablet strength, as tablet hardness is not an absolute indicator of strength. The Roche friabilator was used as laboratory equipment to determine friability. It has a plastic chamber that revolves at 25 rpm; the tablet drops a distance of 6 inches with each revolution, and was operated for 100 revolutions. Conventional tablet granules lose weight of 0.5 to 1.0 %.

Table 5. Friability test of Tablet

Sr. No.	Particular	Specification	NSET
1.	Initial weight (gm)	Weight loss < 1%	13500
2.	Final weight (gm)		13250
3.	% Wt. loss		0.98%

Inference: The weight loss was less than 1%; hence, the tablet batch passed the Friability test.

Disintegration time

Breaking a tablet into smaller particles or granules is known as disintegration, and the time taken to break the tablet into a suitable medium is called the disintegration time. It is determined by USP Disintegration test

apparatus. It consists of 6 glass tubes, each 3 inches long, open at the top, and has 10 mesh screens at the bottom end of the basket rack. One tablet is placed in each tube and placed in a one lit. of water, simulated gastric fluid, or simulated intestinal fluid at 37ºC ± 2ºC, it moves up and down through a distance of 5-6 cm at 28-32cm. The uncoated tablet has a disintegration time of as low as 5 minutes. The majority of tablets have a DT of 30 minutes. DT of an enteric-coated tablet is one hour in simulated gastric fluid and 2 hours in simulated intestinal fluid.

Table 6. Test for Evaluation of Disintegration Time of Tablet

Sr. No.	Batch Code	Specification as per IP	Disintegration Time (Min)
1.	NSET 1	NMT 30 min	17
2.	NSET 2		15
3.	NSET 3		14
	Average Time (min)		15

Inference: Disintegration time was found to be on the slightly higher side, but satisfactory

Karnavati made Tablet Punching Machine

Tablet of *Nigella sativa*

All of the assessment parameters of the prepared tablets were within an acceptable range. Pre-compression tests on herbal tablets revealed that their thickness, hardness, weight fluctuation, and friability were all within an acceptable range. The herbal tablet was then used to treat naturally infected goats with Peste des Petits Ruminants. In the present study, an investigation of the immunomodulatory activity of ethanolic seed extract of seeds of *Nigella sativa* was carried out, which would create an opportunity to produce a safe, economical and readily available source that could prove an alternative to synthetic or chemical-based immunity enhancers in PPR-affected goats.The tablet of *Nigella sativa* @ 50 mg /kg body weight (1000mg/20kg body weight) for 15 days showed significant improvement in PPR-infected goats.

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