



Evaluation of Clinical Efficacy and Tolerance of Khasceeze –SF Cough Syrup

S Satam^{1*}, R Jain², J Dagaonkar², C Chotalia², A Suthar², R Joshi³

¹5, Ganga Bhavan, Caves Road, Jogeshwari (E), Mumbai, Maharashtra, India

²Piramal Life Sciences Ltd., 1, Nirlon Complex, Off. Western Express Highway, Goregaon (East), Mumbai 400 063, Maharashtra, India

³Om Clinical Research Private Limited, 14, Shiv Shanti, Juhu Versova Link Road, Andheri(west), Mumbai 400053, India

ABSTRACT

Fifty patients of either sex aged 15 - 65 years entered the study to test the efficacy and tolerability of a herbal preparation known as Khasceeze-SF Cough Syrup. They were studied for cough and related symptoms such as sore throat, sneezing, breathlessness and fever. Substantial improvement, i.e., excellent to good response, in relief of cough and other symptoms was noted over 84% out of 50 patients and fair response in 11.64%. Only 4.10% patients showed poor relief in symptoms hence suggested Khasceeze-SF Cough Syrup facilitated a healing touch to the diseased bronchial tree and helps alleviate the cough of any aetiology. No drowsiness, irritability, or dryness in mouth was seen with Khasceeze-SF Cough Syrup.

Keywords: Khasceeze-SF, cough, cold, sore throat and clinical study.

INTRODUCTION

Cough as symptom is often nagging and entails a faster relief from problems that make the life miserable, be it just the sound effect or, a feeling of 'something stuck in throat' caused by the thickened mucus. Cough is sometimes due to environmental pollution, sometimes as a result of self-inflicted injuries as is seen in smokers. Cough could be of different types - productive, dry, spasmodic etc. The ingredients of the routinely used cough syrups mostly contain those ingredients, which cause drowsiness, irritability, or dryness in mouth. This affects an individual's day-to-day functioning. In brief, the requirements differ from person to person yet, faster symptomatic relief and trouble-free nature of the product remains supreme. 'Khasceeze-SF' Cough Syrup (a product of Piramal Life Sciences Ltd, which is Department of Science and Technology, Govt. of India recognized institute focused on pharmaceutical and clinical research and development) contains time-tested herbal ingredients, which cover a broader spectrum of symptoms of cough, while hitting the causative factors too. Besides this, it also enhances the immunity of the respiratory tract thus avoid the frequent respiratory tract infections, and can be used by individuals from all age groups.

The principal ingredients used in Khasceeze-SF' and their

main pharmacological actions reported in the literature are: (a) Vasaka (*Adhatoda vasica*), the most important among all herbs is known for its value in liquefying and expelling out the respiratory mucus (muco-lytic and muco-kinetic action) from the bronchial tree due to the presence of two strong phyto-actives, viz. vasicine and vasicinone, ^[1] (b) Similarly, Basil (*Ocimum sanctum*) is also a proven anti-allergic which is similar to disodium chromoglycate. It is also an adaptogen and anti-microbial which boosts the host defense mechanism, ^[2-3] (c) From centuries; Liquorice (*Glycyrrhiza glabra*) is used as a home remedial measure for treating hoarseness of voice and bad throat as a demulcent. It is also used in throat infections, ^[4-5] (d) Beleric Myrobalan (*Terminalia belerica*) is rich in polyphenolic compounds that could help facilitate the healing of damaged mucosa fast, ^[6] (e) Experimentally, Spiked Ginger Lily (*Hedychium spicatum*) has not only shown potent anti-inflammatory and anti-spasmodic activity in the spasms induced by histamine and 5-hydroxytryptamine, but has also proved its eosinopaenic value, and both these activities are very important in treating chronic allergies, ^[7] (f) The bark and root of Bharangi (*Clerodendron serratum*), a perennial tree found in India has also proved to be a powerful anti-histaminic in animal models. Reputed traditional literature considers it very good for controlling dry coughs, ^[8-9] (g) Long pepper (*Piper longum*), which is claimed to be of great value in any respiratory trouble in age old text books of Ayurveda has also proved its worth as a bronchodilator, muco-lytic, expectorant

*Corresponding author: Dr. Shubhangi Satam, BSES MG Hospital, S. V. Road, Opp . Rly. Station, Andheri (West), Mumbai, Maharashtra, India; Tel.: +91-98202 20413; E-mail: s_stm@rediffmail.com

and, of late, as a bioavailability enhancer for therapeutically active drug molecules.^[10]

Based on the above inputs, we can put forth that the combination is meant to give a healing touch to the diseased bronchial tree and help alleviate the cough of any aetiology.

MATERIAL AND METHODS

Fifty patients of both sex aged 15 - 65 years (28 male and 22 female) with cough and related symptoms participated in clinical study (Table 1). A predesigned Case Record Form was utilized to record the details while thorough head and neck examination was carried out to rule out other diseases. Patients suffering from cardiac asthma, severe conditions of respiratory disorder and general metabolic disorders were excluded from the study. Khasceezee SF was given 2 teaspoonfuls (10 ml) 3 times a daily for 7 days. Clinical symptoms were assessed initially and on the 7th day for the efficacy and tolerability of syrup. Concomitant medication with other preparations was not allowed during the study period and no local therapies were given. The signs and symptoms evaluated were cough, cold, sore throat, sneezing, breathlessness and fever. The intensity of the symptoms and signs were graded on a 4 point scale, i.e. absent-0, mild-1, moderate-2 and severe-3 (Table 2). At the end of the treatment both patient and the physician evaluated the efficacy of treatment on the following scale – excellent, good, fair (moderate) and nil (poor).

Table 1: Clinical Diagnosis of Cough and Related Symptoms

| Clinical Diagnosis | No. of Complaints |
|--------------------|-------------------|
| Cough | 50 |
| Cold | 30 |
| Sore Throat | 45 |
| Sneezing | 32 |
| Breathlessness | 11 |
| Fever | 32 |

Table 2: Clinical Diagnosis before Treatment

| Clinical Diagnosis | 0 | 1 | 2 | 3 |
|--------------------|----|---|----|----|
| Cough | 0 | 0 | 6 | 44 |
| Cold | 20 | 0 | 3 | 27 |
| Sore Throat | 5 | 1 | 6 | 38 |
| Sneezing | 18 | 0 | 10 | 22 |
| Breathlessness | 35 | 4 | 4 | 7 |
| Fever | 18 | 0 | 4 | 28 |

0: Absent; 1: Mild; 2: Moderate; 3: Severe

Table 3: Patients Response to Khasceezee SF

| Clinical diagnosis | Excellent | Good | Fair | Poor |
|---------------------|-----------|------|--------|-------|
| Cough | 12 | 32 | 5 | 1 |
| Cold | 4 | 23 | 3 | 0 |
| Sore Throat | 4 | 36 | 3 | 2 |
| Sneezing | 5 | 22 | 5 | 0 |
| Breathlessness | 0 | 7 | 2 | 2 |
| Fever | 4 | 25 | 3 | 0 |
| Over all relief (%) | 84.26% | | 11.64% | 4.10% |

RESULTS AND DISCUSSION

Out of the fifty patients who completed the trial, all of them had cough, thirty had cold, forty five had sore throat, thirty two had sneezing, eleven had breathlessness and thirty two had fever. The majority of patients were in the 3rd to 6th decades. The overall percentage of improvement on the grading of excellent (complete relief of symptoms of cough and associated problems) to good (substantial relief of cough and undisturbed night sleep) response, in relief of cough and

other symptoms was noted 84.26% out of 50 patients and fair (partial relief of cough, not reaching the criteria of good response) response in 11.64%. Only 4.10% patients showed poor (no relief or deterioration of cough bouts) relief in symptoms (Table 3). There was no untoward incident in any of the patients.

All patients accepted the remedy well. Indeed, treatment with Khasceez SF Syrup leads to better clinical improvement in terms of both rapidity of action and improvement of the symptoms at the end of therapy. Khasceezee SF Syrup was well tolerated and no adverse effects were observed in any of the patients.

Cough and related symptoms are an annoying and exhausting symptom in a wide variety of respiratory disorders. Many of the presently available antitussive drugs have either a central depressing action or irritability and drying action on the respiratory. In the present study, Khasceezee SF Syrup has been found to be free from such effects. It was helpful in providing significant relief from the distressing symptoms of cough and associated problems cold, sore throat, sneezing, breathlessness and fever. It also facilitated easy expectoration of sputum while soothing the respiratory passages. No adverse effects were reported by the patients. Thus, Khasceezee SF Syrup can be considered a useful and safe substantial relief of cough and associated symptoms.

REFERENCES

- Dhuley JN. Antitussive effect of *Adhatoda vasica* extract on mechanical or chemical stimulation-induced coughing in animals. *J. Ethnopharmacol.* 1999; 67:361-365.
- Agarwal P, Nagesh L, Murlikrishnan. Evaluation of the antimicrobial activity of various concentrations of Tulsi (*Ocimum sanctum*) extract against *Streptococcus mutans*: an in vitro study. *Ind. J. Dent. Res.* 2010; 21:357-359.
- Goel A, Kumar S, Singh DK, Bhatia AK. Wound healing potential of *Ocimum sanctum* Linn. with induction of tumor necrosis factor- α . *Ind. J. Exp. Biol.* 2010; 48:402-406.
- Houssen ME, Ragab A, Mesbah A, El-Samanoudy AZ, Othman G, Moustafa AF, Badria FA. Natural anti-inflammatory products and leukotriene inhibitors as complementary therapy for bronchial asthma. *Clin. Biochem.* 2010; 43:887-890.
- Gao X, Wang W, Wei S, Li W. Review of pharmacological effects of *Glycyrrhiza* radix and its bioactive compounds. *Zhongguo Zhong Yao Za Zhi.* 2009; 34:2695-2700.
- Potential of tannins: A review. Bele AA, Jadhav VM, Kadam VJ. *Asian J. Plant Sci.* 2010; 9(4): 209-214
- Tandon SK, Chandra S, Gupta S, Lal J. Analgesic and anti-inflammatory effects of *Hedychium spicatum*. *Ind. J. Pharma. Sci.* 1997; 59:148-150.
- Narayanan N, Thirugnanasambantham P, Viswanathan S, Vijayasekaran V, Sukumar E. Antinociceptive, anti-inflammatory and antipyretic effects of ethanol extract of *Clerodendron serratum* roots in experimental animals. *J. Ethnopharmacol.* 1999; 65:237-41.
- Gupta SS, Bhagwat AW, Modh PR. Effect of *Clerodendron serratum* saponin on the mast cells of rat mesentery. *Ind. J. Med. Sci.* 1971; 25:29-31.
- Ojha N. Management of respiratory allergic disorders (rads) in children: some clinical and experimental evidences from ayurveda. *J. Herbal. Med. Toxicol.* 2011; 5: 103-109.