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Formulation and Evaluation of Herbal Gel Containing Ethanolic Extract of *Ipomoea Fistulosa*

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Abstract: ***The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing Ipomoea fistulosa stem extract. The gel formulation was designed using ethanol extract of Ipomoea fistulosa stem and evaluated using physiological measurements. The gel was formulated using accurately weighted amount of drug extract along with other additives, poured into the fixed amount of hydrated Carbopol-934 dispersion with constant stirring. The herbal gel formulations prepared were subjected to preliminary evaluation such as pH, Spreadability, Extrudability, Drug content uniformity, Viscosity and In vitro diffusion study. The pH of all the formulations was checked and found to be compatible with the normal pH range of the skin and so chances of skin irritation are least.***

Keywords: *Ipomoea fistulosa* extract, Carbapol-934, herbal Gel, ethanolic extract

1. Introduction

Topical gel preparations are intended for skin application or to certain mucosal surfaces for local action or percutaneous penetration of medicament.Gels are typically semi-solid formulations having a liquid phase that has been thickened with other components. The liquid phase allows free diffusion of molecules through the polymers scaffold and hence release should be equivalent to that from a simple solution [1] In different parts of India, the plant is known by different vernacular names /local names are English :Morning glory plant, Hindi: Behaya, Besharam, Oriya: Behayo [2].The milky juice of *Ipomoea fistulosa* is used for the treatment of Safed Dag[2].The juice is collected and applied externally on affected parts, having anti-inflammatory action[3]. It is used to decrease the teratogenic effect resulting from cyclophosphamide[4]. Aqueous extract of *Ipomoea fistulosa* shows neuromuscular blocking activity[3]

2. Material and method

The stem of the plant was collected from botanical garden; M.D.U campus in August 2011.The plant material was identified and authenticated by Dr. H.B Singh, Chief Scientist & Head of Raw Material Herbarium & Museum (RHMD), National Institute of Science Communication And Information Resources, New Delhi (Ref NISCAIR/RHMD/Consult/-20111-12/1861/161). A voucher specimen of the collected sample was deposited in the institutional herbarium for future reference.

3. Preparation of extracts

Fresh stems of plant were collected, split into small pieces and dried in shady away from direct sunlight. Dried stems were powdered using grinder and then stored in air tight container at room temperature to protect from moisture. The coarse powder of stem was extracted by continuous hot percolation using Soxhlet apparatus,8 hours/day for 6 days, until the extract is clear of any traces if present. Successive extraction is done with solvent of least polarity to most polar solvent water.

Petroleum ether < Toluene < Ethyl acetate < Ethanol < Water.Petroleum ether was used in initial step of extraction for defatting the plant materials. The successive extracts were filtered individually and concentrated at reduced temperature on a rotary evaporator. The yield was found to be around 0.8, 0.52, 0.34, 1.5, and 0.48 %(w/w) respectively. The potent ethanol extract (having antibacterial activity) was used for herbal gel formulation

4. Preparation of herbal gel

The required quantity of Carbopol-934 was slowly sprinkled into weighed amount of purified water with constant stirring to get the uniform dispersion and then kept overnight for hydration. The accurately weighted amounts of drug along with other additives were poured into the fixed amount of hydrated Carbopol-934 dispersion with constant stirring [5-6]. The composition of herbal gel prepared from ethanolic extract of *Ipomoea fistulosa* is tabulated in Table 1.

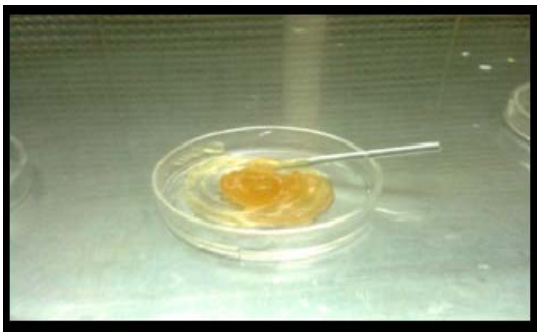

Figure 1: Petri plate with herbal gel formulation

Table 1: Composition of various gel formulations containing *Ipomoea fistulosa* extract

Ingredients	F11	F12	F21	F22	F31	F32
Carbopol-934	1.0g	1.0g	0.75g	0.75g	0.5g	0.5g
Polyethylene	10g	10g	10g	10g	10g	10g
Triethanol Amine	1.5g	1.5g	1.5g	1.5g	1.5g	1.5g
Sodium Sulphite	0.1g	0.1g	0.1g	0.1g	0.1g	0.1g
Plant extract	1%	2%	1%	2%	1%	2%
Water up to(ml)	100	100	100	100	100	100

5. Evaluation of Herbal Gel

All the prepared gel formulations were subjected for preliminary evaluation as follows:

5.1 pH

The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours .The measurement of pH of each formulation was carried out in triplicate and the average values are represented in Table 2. The pH of dispersions was measured using pH meter [7]

Table 2: pH values of gel formulations of *Ipomoea fistulosa*

S. no.	Formulation	Ph
1	F11	7.1
2	F12	7.0
3	F21	6.9
4	F22	6.75
5	F31	6.7
6	F32	6.8

5.2 Viscosity and Rheological studies

Viscosities of gels were determined using Brookfield viscometer. Gels were tested for their rheological characteristics at 250C using Brookfield viscometer (DV-III programmable Rheometer). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30seconds between 2 successive speeds and then in a descending orders[8].

Table 3: Viscosity of gel formulations of *Ipomoea fistulosa*

S.no.	Formulation	Viscosity (cps)	%drug content
1	F11	1882	61.66
2	F12	1898	62.4
3	F21	1662	82.4
4	F22	1670	82.6
5	F31	1520	92.1
6	F32	1540	92.8

5.3 Spreadability

Spreadability is a term expressed to denote the extent of area to which the gel readily spreads on application to skin or affected part.

Spreadability is calculated by using the formula: S=ml/t Where, m = weight tide to upper slide l = length moved on the glass slide t = time taken to separate the slides completely from each other[9-12] Spreadability of different formulations were recorded as below:

Table 4: Spreadability of formulations at the time of preparation:

Formulation	T1	T2	T3	Mean Time	Spreadability
F11	6.8	6.5	6.8	6.7	24.70
F12	6.7	6.7	6.9	6.8	24.41
F21	5.5	5.7	5.6	5.6	29.60
F22	5.9	5.5	5.7	5.7	29.12
F31	5.0	5.0	5.0	5.0	33.20
F32	5.3	5.2	5.1	5.2	31.92

5.4 Drug content uniformity

About 1 gm of gel was accurately weighed and transferred to 100ml volumetric flask to which about 70ml of methanol was added. After mixing, the volume was made up to 100ml with methanol. The content was filtered using filter paper. A quantity of 1ml was pipette out from the filtrate and suitably diluted with methanol. Then the extract was estimated spectrophotometrically by using Shimadzu UV/VIS spectrophotometer-1700 at respective λ max[13].

Table 5: Drug content study of prepared topical gel formulation

S.no.	Formulation	%drug content
1	F11	61.66
2	F12	62.4
3	F21	82.4
4	F22	82.6
5	F31	92.1
6	F32	92.8

5.5 Extrudability

Extrudability is the force required to exude material out of tube ;determining the consistency of preparation
The extrudability was calculated using the following formula :Extrudability = Applied weight to extrude gel from tube (in gm) / Area (in cm2) [14]

Table 7: Extrudability study of prepared topical gel formulation

Formulation	Net wt of formulation in tube(g)	Wt of gel extruded(g)	Extrudability amount (%)	Grade
F11	2	1.58	79	++
F12	2	1.53	76.5	++
F21	2	1.67	83.5	++++
F22	2	1.65	82.5	++++
F31	2	1.78	88.5	++++
F32	2	1.77	89.0	++++

5.6 *In vitro* diffusion study

Cellophane membrane obtained from Hi-media laboratories Pvt Ltd. was used for this study. In modified Franz diffusion cell, 2gm of gel was placed in donor compartment of cell. The entire surface of membrane was in contact with the receptor compartment containing 60ml of phosphate buffer

pH 6.8. The receptor compartment was continuously stirred (100rpm) using a magnetic stirrer with temperature maintained at normal body temperature ie. 37±10C. The study was carried out for 8hr with the interval of 0.5, 1, 2, 3, 4, 5, & 6 hrs. The surface area available for diffusion was calculated and was found to be 3.14cm^2. The sample was withdrawn at predetermined time interval and same volume was replaced with fresh phosphate buffer. The absorbance of withdrawn sample was measured after suitable dilution at respective λ max to estimate drug concentration. The experiment was carried out in triplicate and average values are reported in Table and Figure below respectively [15,16,17].

Table 6: *In-vitro* drug diffusion study of prepared topical gel formulation

In vitro Drug Diffusion Study Time (hrs.)	*F11*	*F12*	*F21*	*F22*	*F31*	*F32*
0	0	0	0	0	0	0
0.5	10.7	9.04	12.6	10.8	13.7	14.04
1	21	14.47	23.8	13.7	25.5	27.85
2	25.2	25.82	31.3	23.5	34.4	36.57
4	29.8	34.32	41.1	31.9	46.9	48.71
6	35.7	40.19	49.7	43	56.2	57.2

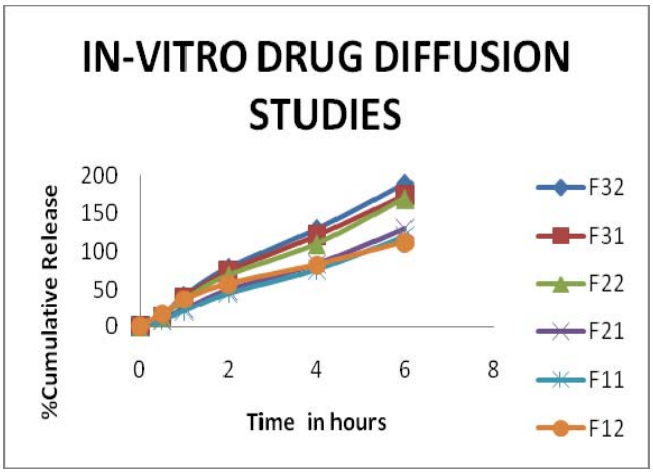

Figure 2: Graphical representation of drug diffusion studies of *Ipomoea fistulosa*

5.7 Drug Polymer Compatibility Studies

The interaction studies were carried out to ascertain any kind of chemical interaction of drug with the excipients used in the preparation of gel formulations. Fourier-transform infrared (DRS) spectra were obtained by using an FTIR-Affinity-1 spectrophotometer (DRS-8000) SHIMADZU, Japan. The dried pure drug sample was grounded and then mixed thoroughly with potassium bromide. The KBr powder was used as blank for background correction in FT-IR (DRS) studies. Forty five scans were obtained at a resolution of 4 cm-1, from 4000 to 300 cm-1.

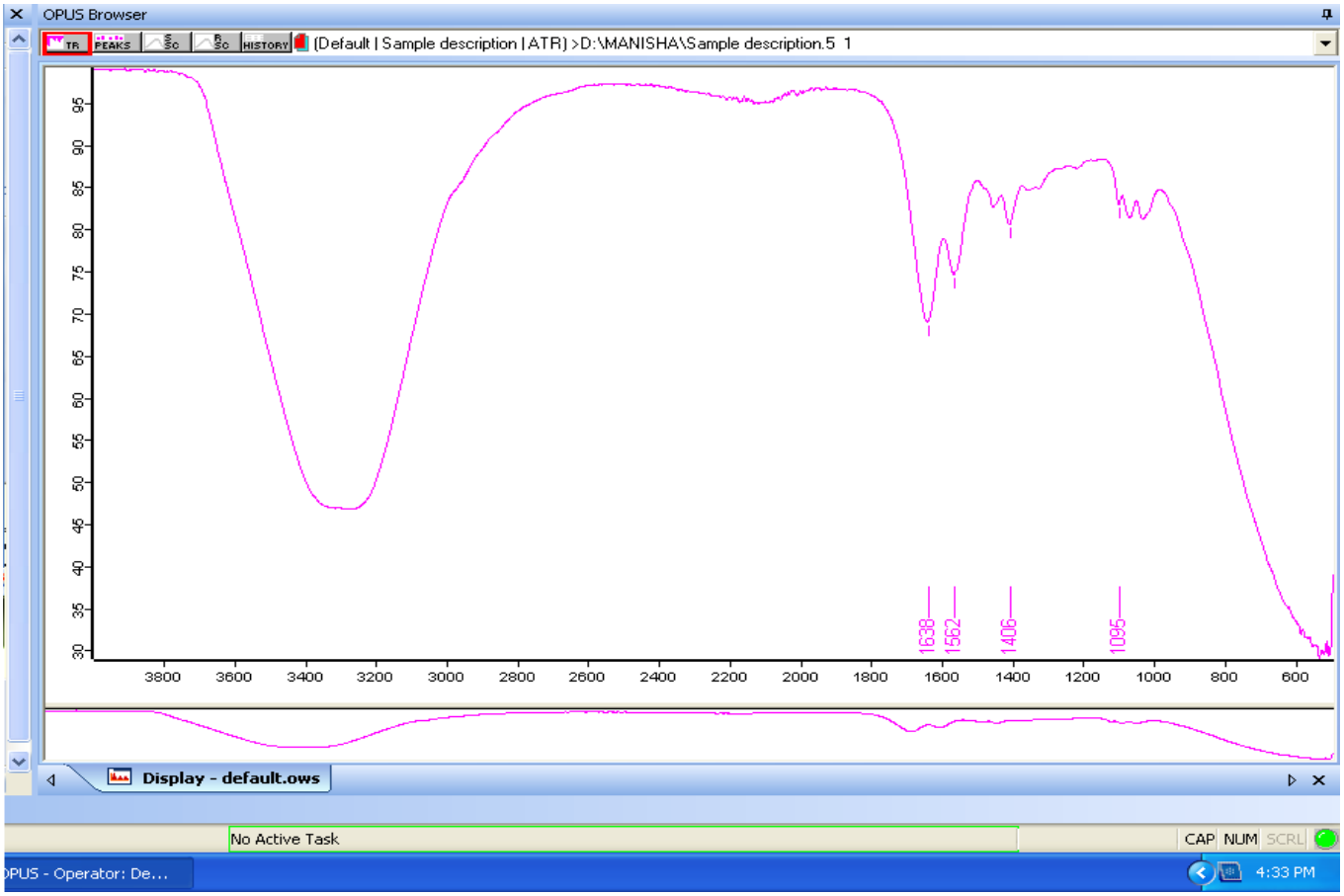

Figure 3: FTIR of carbopol

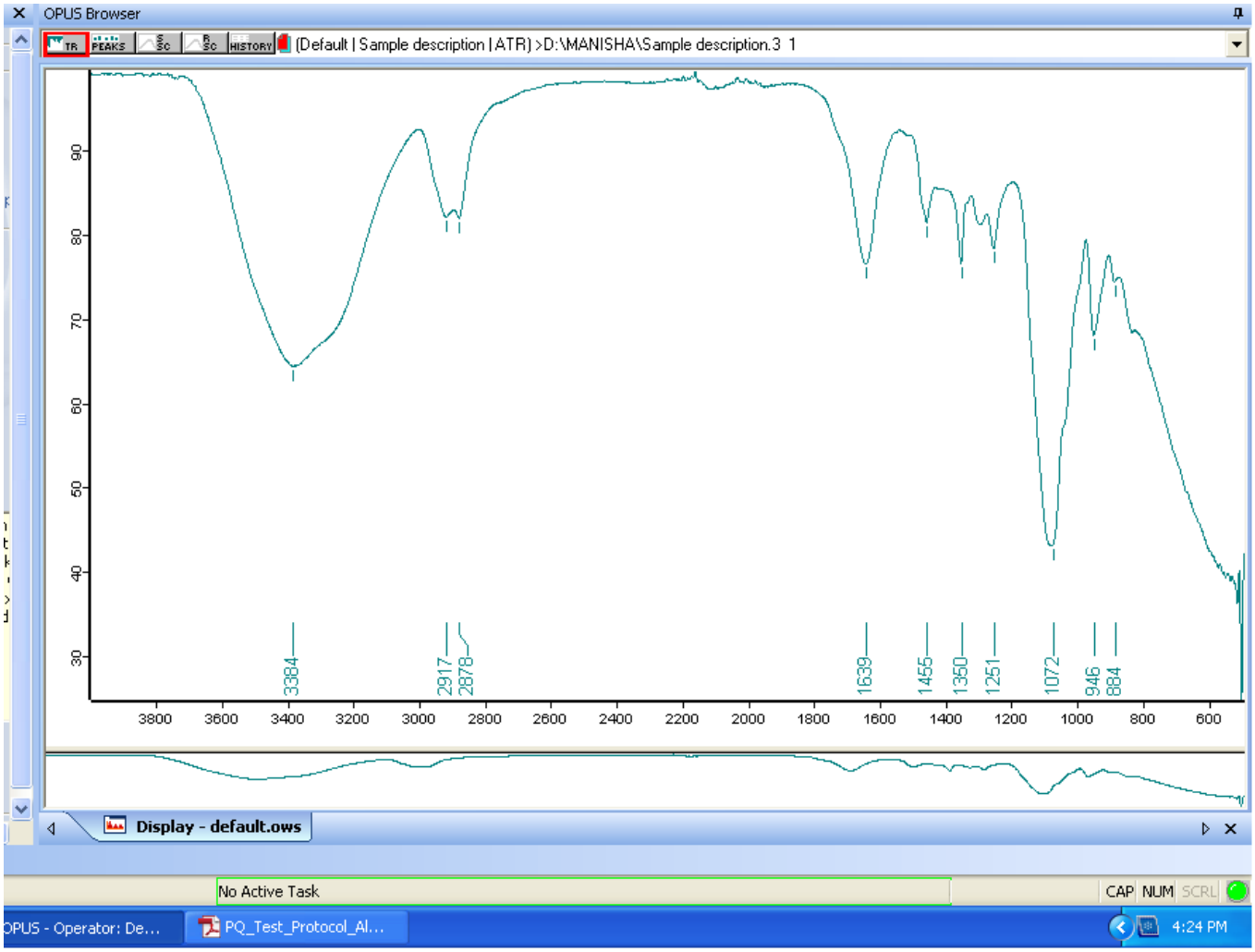

Figure 4: FTIR of extract of *Ipomoea fistulosa*

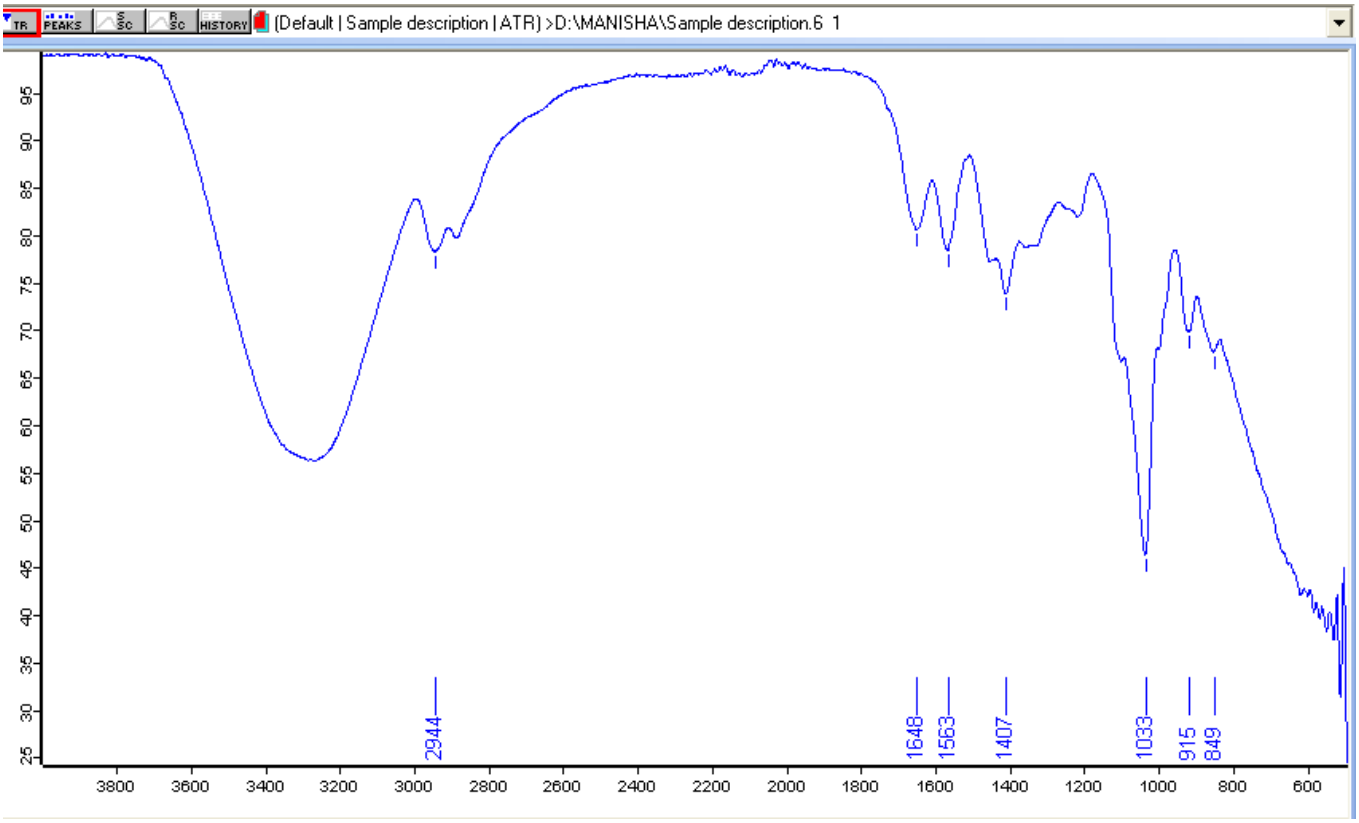

Figure 5: FTIR of *Ipomoea fistulosa* extract + carbopol

6. Conclusion

This research work was carried out to develop a new topical herbal gel formulation for topical application. The prepared herbal gel was further evaluated for pH, Viscosity and extrudability, Spreadability, Drug content uniformity, , In vitro diffusion study, and Drug Polymer Compatibility Studies. The optimized formulation F32 complies with all the parameters. However, *In vivo* models are required for further studies to evaluate the potential of the herbal gel formulation and then it can be useful for the clinical application.

7. Results and Discussion

The various physicochemical properties of the prepared gel formulations are shown above. From the results it is clearly evident that all the gel formulations showed good gelling property and homogeneity. The pH of all the formulations was in the range compatible with normal pH range of the skin. The drug content released was also above average. The rheological behaviors of the gel formulations were studied with Brookfield viscometer. The results indicated the viscosity of gel formulations was consistent neither too thick nor too thin. A comparative study of viscosity and Spreadability showed that with increase in viscosity of the formulation, the Spreadability decreased and vice versa. The FT-IR spectra of gel formulations did not show the presence of any additional peaks for new functional groups. The major peaks of the drug remained unchanged in the mixture were observed in FT-IR spectra. Thus overall the gel formulation F32 has all the desirable properties that must be present in an ideal gel formulation.

8. Future Prospects

This plant has anti-inflammatory activity and extract of stem of his plant cannot be applied directly on skin ,so a suitable formulation is required for application. As the formulation F32 complies with all the parameters of an ideal gel , it can compete with any herbal market formulation. In –vivo experiments need to be carried out using animal model to make it suitable for application on human skin.

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Author Profile

Manisha Singh received B. Pharma & M.Pharma degree from Maharshi Dayanand University, Rohtak in 2010 & 2012 respectively. She is currently working as a Lecturer in Ganpati Institute of Pharmacy and got best Academic Teacher Award for 2013-14 session.