



Research Article

PREPARATION AND EVALUATION OF HERBOMINERAL FORMULATION - SEPTIPAT 250 TABLET

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ABSTRACT

Ayurveda is the oldest system of medicine. Ayurvedic, herbal and herbo-mineral preparations are used for the treatment of chronic and degenerative diseases with less side-effects. Septipat - 250 Tablet is a compound herbomineral formulation widely used in Ayurvedic clinical practice as natural antibiotics, which has a tendency to kill the bacteria and give health and hygiene. Septipat - 250 Tablet consists of *Kanchnar (Bauhinia variegata)*, *Gulvel (Tinospora cordifolia)*, *Shuddha Guggul (Commiphora mukul)*, *Nagakaeshar (Mesua ferrea)* and four mineral ingredients *Tamra bhasma*, *Mandur bhasma*, *Shadgun Kajjali* and *Saindhav Lavana*. The detailed evaluation of this Patented and Proprietary Product was studied for the following parameters: physico-chemical, elemental assay and HPLC analysis of the product. The parameters were found to be sufficient and set as reference specification for the Septipat - 250 Tablet quality control study.

KEYWORDS: Herbomineral formulation, natural antibiotics, Septipat-250 Tablet, *Kanchnar*, *Shadgunkajjali*.

INTRODUCTION

The word antibiotics mean medicine that can destroy harmful bacteria in the body or limit their growth. Natural products which has a tendency to kill the bacteria and give health as well as hygiene are called natural antibiotics i.e., Ayurvedic Antibiotics. The primary benefits of using plant-derived medicine are relatively safer than synthetic drugs^[1].

Septipat -250 Tablets is one of the herbomineral preparations widely used as Ayurvedic Antibiotic in Primary Stage of Infections, reducing the spread of infection, reduces weakness found in infections. Septipat - 250 Tablet consists of *Kanchnar (Bauhinia variegata)*^[2], *Gulvel (Tinospora cordifolia)*, *Shuddha Guggul (Commiphora mukul)*, *Nagakaeshar (Mesua ferrea)* and four mineral ingredients *Tamra bhasma*, *Mandur bhasma*, *Shadgun Kajjali* and *Saindhav Lavana*. *Kanchnar* has anti-bacterial, anti-fungal, anti-malarial, pain reducing, swelling reducing, cytotoxic, fever reducing and thyroid hormone regulating properties. In Ayurveda, the *Kanchnar* tree is used extensively for treating skin and glandular diseases, leprosy, intestinal worms, tumours, wounds.

Kanchnar (Bauhinia variegata) was widely used in traditional medicine to treat a wide range of complaints. The phytochemical constituents of *Kanchnar* contain terpenoids, flavonoids, and tannins,

saponins, reducing sugars, steroids and cardiac glycosides. The pharmacological studies showed that *Kanchnar* is antioxidant, antimicrobial, anti-inflammatory, nephroprotective, hepatoprotective, antiulcer, immune-modulating, wound healing effects.^[3]

Shuddha parad^[4] and *Shuddha Gandhak* mixed and triturated without adding any liquid to convert it into smooth blackish powder *Kajjali*. Depending on the ratio of mercury and sulphur, there are different types of *Kajjali*. *Shadguna kajjali* contain 1 part of mercury and 6 parts of sulphur. The addition of extra quantity of sulphur in the *Shadguna kajjali* is supposed to counteract the toxicity of mercury. *Kajjali*^[5] is antibacterial and play an important role of bioavailability enhancer (*Yogvahi* property).

The present study focus on the evaluation of Septipat - 250 Tablet and to set the same as specification for future reference.

MATERIALS AND METHODS

Collection and Authentification of raw material

Herbal ingredients were collected from the authentic sources. All herbal raw drugs were authenticated by Technical Staff of Koral Pharma, Nashik based on Ayurvedic guidelines. Mineral ingredients are collected from authentic sources.

Ingredients

Sr. No.	Ingredient	Botanical Name	Part used	Quantity	Ref No.	Page No.
1	Tamra Bhasma	N.A	Mineral	10 mg	RT	Page No 413
2	Mandur Bhasma	N.A	Mineral	10 mg	RRS	Page no. 112, 113
3	Shadguna Kajjali	N.A	Mineral	10 mg	RT	Page No. 124
4	Shuddha Guggul	<i>Compiphora mukul</i>	Gum	10 mg	BPN	Page No. 212
5	Saindhav Lavana	N.A.	Mineral	10 mg	RT	Page No. 347
6	Dalchini	<i>Cinnamomum zeylanicum</i>	Bark	10 mg	BPN	Page No. 226
7	Tamalpatra	<i>Cinnamomum tamala</i>	Leaves	10 mg	BPN	Page No.228
8	Elaichi	<i>Ammomum subulatum</i>	Seed	10 mg	BPN	Page No. 221
9	Nagkeshar	<i>Mesua ferrea</i>	Flower	10 mg	BPN	Page No.230
10	Aqu Ext of Suntha	<i>Zingiber officinale</i>	Root	10 mg	BPN	Page No.14
11	Aqu. Ext of Mire	<i>Piper nigrum</i>	Seed	10 mg	BPN	Page No:17
12	Aqu. Ext of Pimpli	<i>Piper longum</i>	Fruit	10 mg	BPN	Page No:19
13	Aqu. Ext of Kanchnar	<i>Bauhinia veriegata</i>	Leaves and stem	20 mg	BPN	Page No: 337
14	Aqu. Ext of Gulvel	<i>Tinospora cordifolia</i>	Leaves and stem	20 mg	BPN	Page No:269
15	Aqu. Ext of Bhrungraj	<i>Eclipta alba</i>	Leaves and stem	20 mg	BPN	Page No:429
16	Aqu. Ext of Beheda	<i>Terminalia bellirica</i>	Fruit	20 mg	BPN	Page No. 9
17	Aqu. Ext of Amala	<i>Phyllanthus embelica</i>	Fruit	20 mg	BPN	Page No:10
18	Aqu. Ext of Harda	<i>Terminalia chebula</i>	Fruit	30 mg	BPN	Page No:7
	Excipients			Q.S.		
	Gum Acacia			Q.S.		
	Starch			Q.S.		
	Di Calcium Phosphate			Q.S.		

BPN- *Bavprakasa nighantu*^[7], RT-*Rastarangini*^[8], RRS- *Rasaratna samucchya*^[9]

METHOD OF PREPARATION

All the above mentioned ingredients are taken in the mentioned proportions, mixed them well, converted into granules and punched into tablets using Clit 16 station Tablet compression machine with punch size-12/32.

QUALITY CONTROL OF SEPTIPAT- 250 TABLETS**Physico-chemical Evaluation**

Physico-chemical evaluation of formulation was determined for loss on drying, hardness, thickness, diameter, friability, disintegration test, average weight, total ash, acid insoluble ash and water soluble extractive values were done as per Indian Pharmacopoeia method.

Hardness

The tablet required certain strength to withstand mechanical shock. Hardness was studied by using hardness testing apparatus (Monsanto Hardness tester)^[6].

Friability

The mechanical strength of the tablets were evaluated using the Roche friabilator and the percent friability determined as per India Pharmacopoeia^[3].

Disintegration time

The time required for the Septipat -250 Tablet to disintegrate was determined was found as per IP.

Average weight

Twenty tablets were weighed individually and collectively. Average weight per tablet was calculated from the total weight. Then the weights of individual tablets were compared with the average weight to determine weight variation^[3].

Total Ash

Accurately weighed 2 to 3g of the air-dried crude drug in a tared platinum or silica crucible and incinerated, gently at first, and gradually increase the temperature to $675 \pm 25^\circ$, until free from carbon, cool and weighed. The crucible was cooled in a desiccator, the ash weighed and the percentage of ash with reference to the air-dried crude drug was calculated³.

Acid insoluble ash

The ash was boiled with 25ml of 2M hydrochloric acid for 5 minutes, the collected insoluble matter in a Gooch crucible was washed with hot water, ignited, cooled in a desiccator and weighed. The percentage of acid-insoluble ash was calculated on the dried drug basis.

Water soluble extractive value %

The ash was boiled for 5 minutes with 25 ml of water, collected the insoluble matter in a Gooch

RESULT AND DISCUSSIONS

Organoleptic parameters: *Rupa* (colour), *Rasa* (taste), *Gandha* (odour) and *Sparsha* (touch)

Table 1: Organoleptic parameters of Septipat tablet

	Parameters	Observation
1	Colour	Grey
2	Odour	Pungent
3	Taste	Slightly Bitter
4	Touch	Smooth

Table 2: Physico-chemical parameters of Septipat 250 Tablet (Mean value N=3)

Parameters	Results
Loss on drying %	6.24
Hardness (Kg/cm ²)	2
Thickness(mm)	4.35
Diameter(mm)	9.78
Friability (%)	0.1
Disintegration time(min)	6.48
Average weight(mg)	312
Total Ash(%W/W)	29.5
Acid insoluble ash(%W/W)	5.57
Water soluble extractive% value%	7.24

Friability is 0.1% shows tablet strength is good enough. Disintegration time 6.48 min indicates tablet is very effective as its disintegration time is very fast. Total ash 29.5% and Acid insoluble ash 5.57% indicates presence of inorganic material within the limit.

crucible, washed with hot water, and ignited for 15 minutes at a temperature not exceeding 450°C . Subtracted the weight of the insoluble matter from the weight of the ash; the difference in weight represents the water-soluble ash. Calculated the percentage of water-soluble ash on the dried basis.

Elemental Analysis

The elemental analysis of formulation was done by using ICP-OES as per Indian Pharmacopoeia method.^[3]

HPLC Analysis

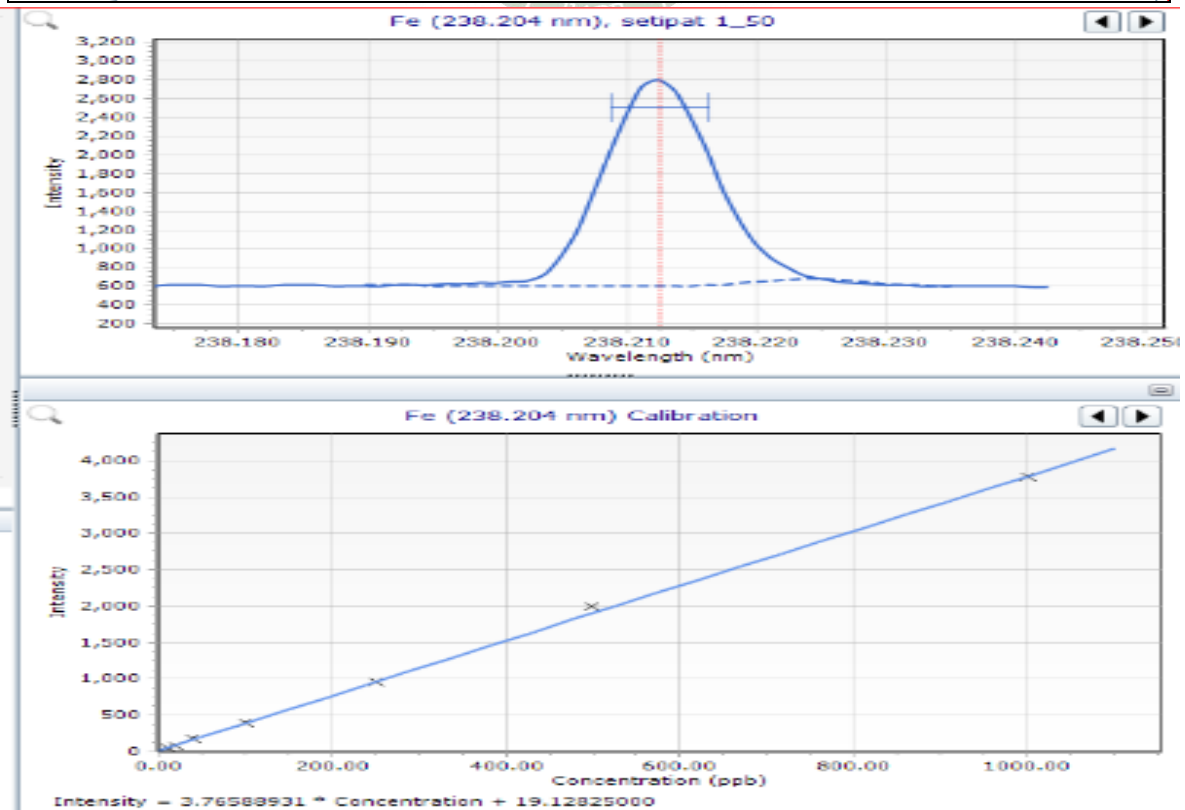
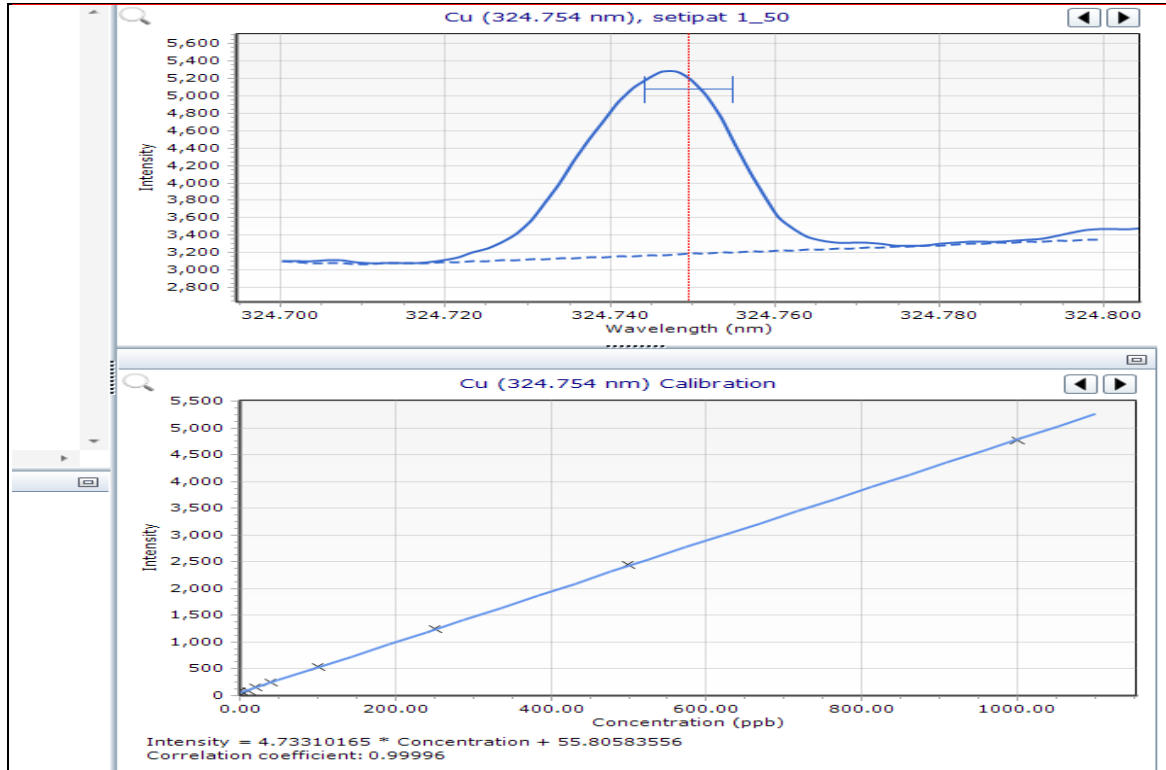
HPLC analysis was done for the formulation with the following-chromatographic conditions.

1. Equipment: Agilent Technologies HPLC 1200 Infinity
2. Mobile Phase: 0.1% Acetic Acid in water: MeOH (50:50).
3. Column Used: ODS Hypersil 100X2.1mm, Particle size - $5\mu\text{m}$
4. Extraction Solvent: Methanolic Water
5. Retention Time: 1.047 Min (Septipat 250) & 1.073 Min (Kanchanar).
6. (Acceptance Criteria for RT is ± 0.2 min)

Table 3: Elemental Assay of Septipat - 250 Tablets

	Element	mg/tab	Permissible limits mg/tab
1	Copper	2.77	2 - 6
2	Iron	3.48	2 - 6
3	Mercury	1.31	0.5 - 2
4	Sulphur	12.87	2 - 13

The elemental copper, iron, mercury and sulphur for the Septipat - 250 Tablet was within the permissible limit.



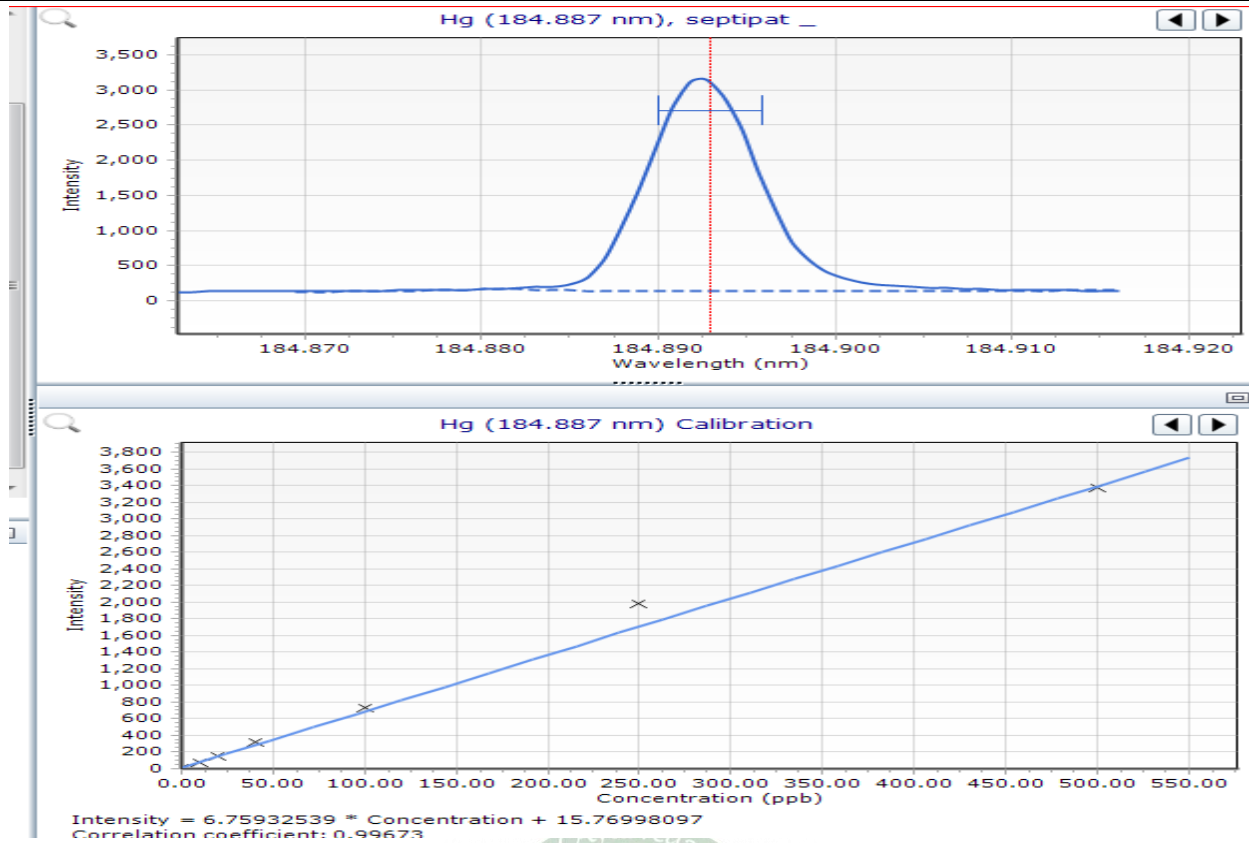


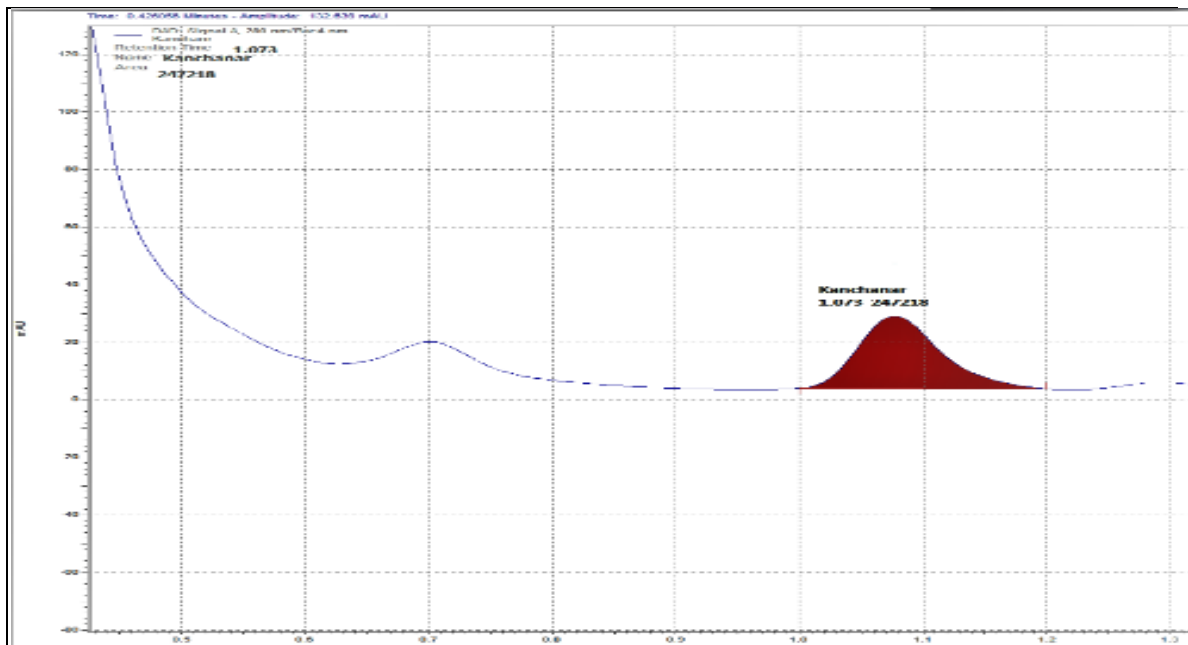
Figure 1: Standard calibration curve of copper, iron and mercury

HPLC Profile

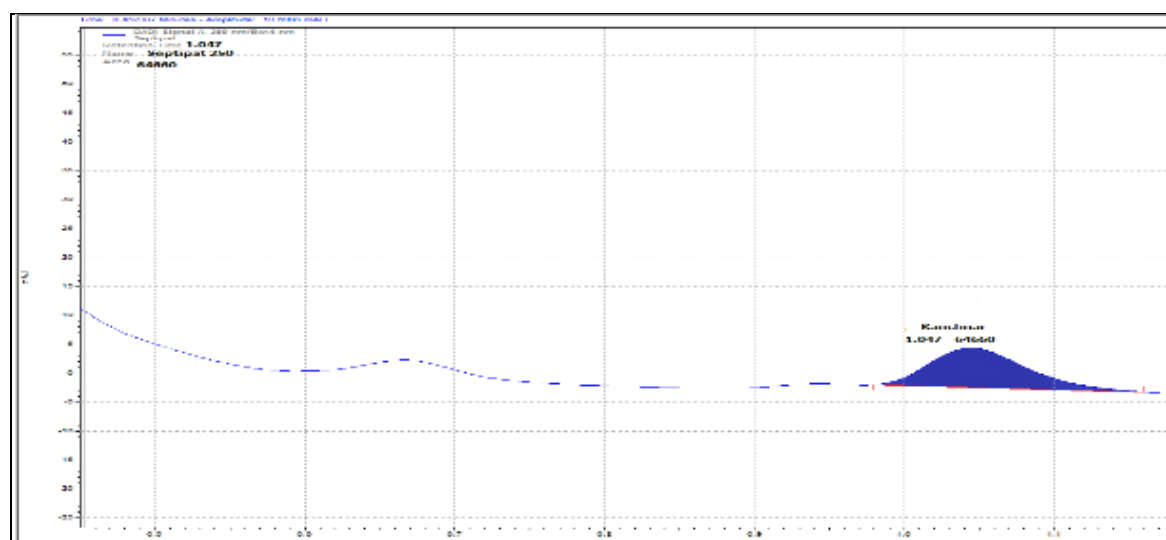
	<i>Kanchnar</i> raw	Septipat -250 Tablet
Retention time	1.073 Min	1.047 Min
Area	247218	64660

Retention Time: 1.073 Min (*Kanchnar*) and 1.047 Min (Septipat 250 Tablet)

The Acceptance Criteria for RT is ± 0.2 min so it clearly confirms the presence of *Kanchnar* in final formulation of Septipat -250 Tablet.



Chromatogram of *Kanchnar* raw material



Chromatogram of Septipat -250 Tablet

CONCLUSIONS

Standardization is very important aspect of every pharmaceutical preparation. The study reveals that sufficient quality control parameters were followed during the preparation of formulation. Organoleptic parameters, physicochemical analysis, elemental assay were carried out as per IP method. HPLC profile generated in this particular study can be considered as a preliminary tool for the presence of *Kanchnar* in Septipat-250 Tablet. Copper, Iron, mercury and sulphur indicates the mineral ingredients like *Tamra bhasma*, *Mandur bhasma*, *Shadgun kajjali* added in proper quantity in formulation.

Ayurvedic herbs have great potential as antimicrobial. The use of the herbo-mineral formulation Septipat – 250 Tablets play an important role to prevent or control the bacterial, fungal, antimicrobial infections due to presence of *Kanchnar* and *Shadguna kajjali*.

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