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 (Commpihora 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 herbo-mineral 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 (Commpihora 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      | Compiphora mukul     | Gum       | 10 mg    | BPN     | Page No. 212 |
| 5       | Saindhav Lavana     | N.A                  | Mineral   | 10 mg    | RT      | Page No. 347 |
| 6       | Dalchini            | Cinnamomum zeylanicum| Bark      | 10 mg    | BPN     | Page No. 226 |
| 7       | Tamalpatra          | Cinnamomum tamala    | Leaves    | 10 mg    | BPN     | Page No. 228 |
| 8       | Elaichi             | Ammomum subulatum    | Seed      | 10 mg    | BPN     | Page No. 221 |
| 9       | Nagkeshar           | Mesua ferrea         | Flower    | 10 mg    | BPN     | Page No. 230 |
| 10      | Aqu. Ext of Suntha  | Zingiber officinale  | Root      | 10 mg    | BPN     | Page No. 14  |
| 11      | Aqu. Ext of Mire    | Piper nigrum         | Seed      | 10 mg    | BPN     | Page No. 17  |
| 12      | Aqu. Ext of Pimpli  | Piper longum         | Fruit     | 10 mg    | BPN     | Page No. 19  |
| 13      | Aqu. Ext of Kanchnar| Bauhinia veriegata   | Leaves and stem | 20 mg  | BPN     | Page No: 337 |
| 14      | Aqu. Ext of Gulvel  | Tinospora cordifolia | Leaves and stem | 20 mg  | BPN     | Page No: 269 |
| 15      | Aqu. Ext of Bhrungraj| Eclipta alba        | Leaves and stem | 20 mg  | BPN     | Page No: 429 |
| 16      | Aqu. Ext of Beheda  | Terminalia bellirica| Fruit     | 20 mg    | BPN     | Page No. 9   |
| 17      | Aqu. Ext of Amala   | Phyllanthus embelica | Fruit     | 20 mg    | BPN     | Page No:10  |
| 18      | Aqu. Ext of Harda   | Terminalia chebula   | Fruit     | 30 mg    | BPN     | Page No:7    |

**Excipients**

- 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 ± 25°, 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 calculated.

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 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 - 5µm
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)

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/cm²)            | 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.
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

|                          | Kanchnar 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
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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