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# ANALYTICAL PROFILING AND STANDARDIZATION OF T.RENAL PLUS TABLET: AN AYURVEDIC POLYHERBAL PROPRIETARY COMPOSITION

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## ABSTRACT

**Introduction** T. Renal Plus is an Ayurvedic poly-herbal preparation containing a blend of herbs including *Harad, Amla, Baheda, Sonth, Marich, Pippali, Motha* etc. in a specific proportion. The formulation is a unique combination of herbs that are useful in the patients affected with chronic kidney disease (CKD). Analytical profile of a composition is extremely important for determining the quality of the medicine. The present study was aimed to establish and standardize the analytical profile of T. Renal Plus tablet for its quality assurance. **Methods** Organoleptic characteristics and Physico-chemical analysis were carried out at the testing laboratory of Shri Ayurveda Seva Sadan, Firozabad, U.P. **Results** Organoleptic characters for both the raw herbs as well as final product were found tobe same as the specified standards. Physicochemical analysis revealed 6.60% LOD, 11.19% Total Ash, 1.79% Acid Insoluble Ash, 26.68% Alcohol soluble extractive, 41.2 % Water soluble extractive, 2.8 kg/cm$^2$ hardness, 411.5 mg average weight, 0.44% friability and 49.3 minutes of disintegration time. **Conclusion** Analytical profiling of T. Renal Plus Tablet including organoleptic characters andphysicochemical parameters have established that the tablet is having standard quality. This provides the preliminary data for the analytical profile of T. Renal Plus Tablet.

**KEYWORDS:** T. Renal Plus, Analytical profile, Ayurvedic herbal tablet, Physico-chemical parameters.

## INTRODUCTION

Inclination of people towards organic products, safety and cost effectiveness are among the key factors due to which herbal medications are in increasing demand for basic healthcare around the globe. Quality control of herbal medications is an important factor in determining the standardized quality of a product. Therefore, choosing the proper kind of plant material with therapeutically effective chemicals is the most important task. Herbal medications are produced on a large scale, but manufacturers encounter numerous challenges, including low- quality raw materials, lack of raw material authentication, absence of standards, improper standardization methodologies for individual medications as well as formulations and lack of quality control standards.

Increased global shift towards herbal medication in past years has been observed evidently but consumers also prefer to choose the quality products with pre-set standards. In view of this, Ministry of AYUSH, Government of India has laid down some specific parameters for both raw as well as finished products in official standard book i.e. The Ayurvedic Pharmacopoeia of India (API) to ensure the quality finished product for its consumers. Therefore, for the proper standardization of a finished product it is necessary to evaluate both raw material as well as finished product. Hence, this study was planned with the aim to develop and standardize the analytical profile of Ayurvedic poly-herbal formulation T. Renal-Plus by assessing its quality control parameters including Description, Organoleptic characteristics, Loss on Drying, Total Ash, Acid-insoluble ash, Alcohol-soluble extractive, Water-soluble extractive, Hardness, Average weight, Friability test and Disintegration Time.

## MATERIALS AND METHODS

Identification and authentication of raw materials is the primary step in standardizing the analytical profile. Therefore, all the raw materials purchased from the authorized vendor along with their COA were selected. Proper identification and assessment was done on the basis of physcio-chemical characteristics as described in API. After that, the end product i.e. T. Renal Plus tablet

was analyzed on the basis of quality control parameters described in API for *Vati* (Tablet). Three batches of T. Renal Plus tablet, 3 kg each, were prepared under similar conditions in manufacturing premises of Shri Ayurveda Seva Sadan Pharmacy, Firozabad, U.P. and all three batches were subjected to analysis to obtain standardized value for the required parameters.

The composition of T. Renal Plus is given below in Table 1.

**Table 1: Composition of T. Renal Plus Tablet.**

| Each 400 mg tablet contains- | | | |
|---|---|---|---|
| **Ingredients** | **Botanical name** | **Part Used** | **Quantity** |
| *Badi Harad* | *Terminalia chebula* | Fruit | 1 part |
| *Bahera* | *Terminalia bellirica* | Fruit | 1 part |
| *Amla* | *Emblica officinalis* | Fruit | 1 part |
| *Sonth* | *Zingiber officinale* | Rhizome | 1 part |
| *Kali mirch* | *Piper nigrum* | Fruit | 1 part |
| *Pippali* | *Piper longum* | Fruit | 1 part |
| *Motha* | *Cyperus rotundus* | Rhizome | 1 part |
| *Pippalimool* | *Piper longum* | Root | 1 part |
| *Bimbi* | *Coccinia indica* | Fruit | 1 part |
| *Gokhru* | *Tribulus terrestris* | Whole plant | 20 parts |
| *Shuddha Guggulu* | *Commiphora mukul* | Oleo-resin | 9 parts |

All the raw materials used in this formulation were subjected to following testing parameters to ensure their quality.

1. Description[1]
2. Foreign matter[2]
3. Total ash[3]
4. Acid insoluble ash[4]
5. Alcohol soluble extractive[5]
6. Water soluble extractive[6]

Samples from three batches of finished product i.e. T. Renal Plus tablet were also subjected to analysis to evaluate their quality and efficacy and were tested on following parameters.

1. Description[1]
2. Loss on Drying[2]
3. Total Ash[3]
4. Acid insoluble ash[4]
5. Alcohol soluble extractive[5]
6. Water soluble extractive[6]
7. Hardness
8. Average weight
9. Friability test
10. Disintegration time

The standard procedure was adopted from API for all the analytical testing except Hardness, Average weight, Friability test and Disintegration time of the tablet. In-house testing protocols were adopted for these methods. Details of which are described below.

- **Hardness** This test is generally applicable to compressed tablets/*Vati*. Procedure- A potable equipment known as 'Monsanto hardness tester' was used to test the hardness of *Vati*. The tablet was placed between the jaw and nozzle in edgewise position. Adjust the scale by sliding, so that zero on the scale coincides with the pointer. Tighten the screw knob till the tablet breaks and note the value on the scale. Repeat the process for three times to obtain an average value.

- **Average Weight/Weight Variation** This ensures proper implication of GMP and content uniformity of the formulation. **Procedure-** Take 20 tablets and weigh them separately. Calculate average weight and compare the individual tablet weight to the average. Then, compare the obtained values with the maximum % difference allowed as per set standards.
- **Friability Test** An important measure to ensure proper storage, transportation, packing and handling prior usage. **Procedure-** 10 tablets were taken and weighed together accurately. Place the tablets on the arm of drum in friability test apparatus androtate it at 25 rpm for 4 minutes. Then, remove the tablets and de-dust the loose powder from them carefully and weigh them again. Percentage of loss was calculated with the corresponding weight. The process was repeated thrice to avoid any error.

- **Disintegration Time** To evaluate the breakdown period of a tablet. Procedure- Disintegration tank was filled with distilled water till the mark. In each of the 1 l beaker, 750 ml of distilled water was filled. Temperature of the beaker was set to 37°C ± 0.5°C and timing was set at 60 minutes. One tablet was poured into each tube of the apparatus and tube was covered with disc. This set-up was introduced into the beaker water and apparatus was turned on. The time at which the tablet completely disintegrates in the water was noted.

## OBSERVATIONS AND RESULT

General description i.e., colour, odour and taste of all the herbs was found to be in accordance with the standard specifications mentioned for each herb. The average

values for the testing parameters along with its arrived pecifications arementioned in Table 2.

The average values for the testing parameters along with its arrived specifications are mentioned in Table 2.

| Parameters | ForeignMatter | | Total Ash | | Acid Insoluble ash | | Alcohol soluble extractive | | Water soluble extractive | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Herbs** | **T.R** | **A.S** | **T.R** | **A.S** | **T.R** | **A.S** | **T.R** | **A.S** | **T.R** | **A.S** |
| *Badi Harad* | 0.86% | NMT 1% | 2.71% | NMT 5% | 0.76% | NMT 5% | 51.33% | NLT 40% | 71.77% | NLT 60% |
| *Baheda* | 0.58% | NMT 2% | 2.65% | NMT 7% | 0.23% | NMT 1% | 18.78% | NLT 8% | 43.13% | NLT 35% |
| *Amalaki* | 1.7% | NMT 3% | 4.22% | NMT 7% | 1.21% | NMT 2% | 52.66% | NLT 40% | 62.11% | NLT 50% |
| *Sonth* | 0.10% | NMT 1% | 4.16% | NMT 6% | 0.23% | NMT 1.5% | 15.46% | NLT 3% | 20.57% | NLT 10% |
| *Kali mirch* | 0.37% | NMT 2% | 1.87% | NMT 5% | 0.19% | NMT 0.5% | 16.85% | NLT 6% | 19.1% | NLT 6% |
| *Pippali* | 0.37% | NMT 2% | 1.94% | NMT 5% | 0.17% | NMT 0.5% | 15.66 | NLT 6% | 17.89% | NLT 6% |
| *Motha* | 0.77% | NMT 2% | 5.51% | NMT 8% | 1.26% | NMT 4% | 16.19% | NLT 5% | 26.99% | NLT 11% |
| *Pippalimoola* | 0.13% | NMT 2% | 2.21% | NMT 5.5% | 0.089 % | NMT 0.2% | 11.48% | NLT 4% | 19.37% | NLT 12% |
| *Bimbi* | 0.61% | NMT 2% | 12.73 % | NMT 21% | 1.03% | NMT 2% | 7.13% | NLT 3% | 24.77% | NLT 14% |
| *Gokhru* | 1.04% | NMT 2% | 5.88% | NMT 15% | 1.10% | NMT 2% | NMT 14.99% | NLT 6% | 24.88% | NLT 10% |
| *Guggulu* | 2.43% | NMT 4% | 3.16% | NMT 5% | 0.22% | NMT 1% | 29.21% | NLT 27% | 60.88% | NLT 53% |

**T.R-** Test Result, **A.S-** Arrived Specification, **NMT-** Not More Than, **NLT-** Not Less Than

While analyzing description of T. Renal Plus Tablet, color of the tablet was found to be black with pleasant odour and bitter taste. These observations were found to be similar in all three batches.

T. Renal Plus tablet was tested on 10 parameters including Description, Loss on drying, Acid insoluble ash, Alcohol soluble extractive, water soluble extractive, hardness, average weight,friability test and disintegration time. Following observations were made regarding the tested parameters T. Renal Plus Tablet as described in Table 3.

**Table 3: Analytical profile of T. Renal Plus Tablet.**

| S.no. | Parameters | Result | | | | Specifications |
|---|---|---|---|---|---|---|
| | | **B1** | **B2** | **B3** | **Average** | |
| 1. | Loss on drying | 6.50% | 5.69% | 7.63% | 6.60% | - |
| 2. | Total Ash | 11.17% | 10.37% | 12.03% | 11.19% | - |
| 3. | Acid insoluble ash | 1.66% | 1.86% | 1.85% | 1.79% | - |
| 4. | Alcohol soluble extractive | 27.85% | 23.65% | 28.55% | 26.68% | - |
| 5. | Water soluble extractive | 39.38% | 43.92% | 40.30% | 41.2% | - |
| 6. | Hardness | 3.0kg/cm$^2$ | 2.5kg/cm$^2$ | 3.0kg/cm$^2$ | 2.8kg/cm$^2$ | NLT 2.5 kg/cm$^2$ |
| 7. | Average weight | 413.20 mg | 408.10 mg | 413.20 mg | 411.5 mg | 380 to 420 mg |
| 8. | Friability test | 0.48% | 0.38% | 0.48% | 0.44% | NMT 1% |
| 9. | Disintegration time | 47 mins | 54 mins | 47 mins | 49.3 mins | NMT 60 mins |

**B1-** Batch 1, **B2-** Batch 2, **B3-**Batch 3, **Mins-** Minutes, **NLT-** Not Less Than, **NMT-**NotMore Than

## DISCUSSION

Prior formulating any composition, selection of correct and good quality raw material is the utmost important step. Today, manufacturing of Ayurvedic medicines has become more market oriented. Since, the demand is on surge, the collection of plants from forests or their natural habitats is mostly done by people who are not trained professionally to identify and distinguish them properly. As a result, mostly incorrect or substituted herb is received at the manufacturingsites. Also, when the herb reaches to the manufacturer in dry state, it becomes even more difficult to identify it properly on the basis of

organoleptic parameters.[7] Incorrect use of herb may result in the ineffective medicine or may produce adverse events as well. Hence identification of a plant plays a vital role and should be done by professionals. Organoleptic parameters of all the raw herbs used in this composition were similar to the standard parameters, which indicated the accurate and quality raw herb being used for composing this formulation.

After proper identification, to ensure the quality of the raw herb as well as formulation, certaintesting parameters are being enlisted by the regulatory authorities. Loss on drying or Moisture content of the drug is required to be checked. It should be at minimum level to discourage the growth of bacteria, yeast or fungi during the storage. The low values of this parameter indicates that the plant material is having appropriate standard, quality and stability. In-efficient drying process may lead to deterioration of the active phyto-constituents present in the drug during the storage period.[8] LOD for all the raw materials were found to be in accordance with the set parameters.

Other significant criteria for the detection of nature of material, authenticity of drug, impurities, adulteration, quality and purity of the test sample includes estimation of ash values (Total Ash, Acid-insoluble ash, water-soluble ash etc.). The Total Ash value determines the presence of impurities like carbonate, oxalate and silica. Water-soluble ash value of a drug indicates the content of inorganic compounds present in it. Acid-insoluble ash is done to determine the presence of silica, especially sand which indicates that whether the material is contaminated with earthy materials or not.[9] Values of these parameters were found to be in accordance withthe arrived specifications for the raw material and were found to be low for T. Renal Plus tablet indicating lesser presence of inorganic matter in the formulation.

Extractive values are considered as an important method to evaluate and identify the chemicalconstituents present in a drug and is also useful in the estimation of chemical proportions soluble in a particular solvent system.[10] The extractive values for a crude drug are also beneficial when the chemical composition of a drug is difficult to be estimated by any other method.[11] The amount of extract exhibited in a solvent system is an approximate measure of the amount of constituents that the drug contains. Drugs with higher water-extractive values determines the presence of various acids, sugars, in-organic compounds whereas drugs havinghigher alcohol-extractive values indicates the presence of phenolic, steroids, flavonoids etc.[12,13]

Other quality control parameters for the tablet such as hardness, friability test and disintegration test were performed for testing the quality profile of T. Renal Plus tablet. Parameters like hardness of the tablet and friability test are done to measure the physical strength of the tablet. This parameter is important with reference to both clinical as well as pharmaceutical point of views. It is important to determine these in order to establish the storage conditions, transportation, packaging and handling before usage.[14]

Disintegration time for a tablet is testing to analyze the mechanical breakdown period of the tablet into smaller pieces which provides a greater surface area and availability of the drug when administered by the patient. The action of the drug is primarily influenced by its disintegration time. Disintegration process is an integral parameter which ensures as well as maximizes the bioavailability of active pharmaceutical ingredient from the solid dosage form. When solid dosage form is taken, only the active pharmaceutical ingredient near the surface will be able to dissolve while the rest is passed through body metabolism as such with minimal absorption and may affect the efficacy of the medicine.[15]

All these analytical parameters for T. Renal Plus tablet were found to be at par with the arrivedspecifications.

## CONCLUSION

The above discussion indicates that all the raw herbs used in the composition as well as T. Renal Plus tablet on the basis of its analytical profile are found to be similar and in accordance to the API. Organoleptic characters, Total ash, Acid-insoluble ash, Water-extractive value, Alcohol-extractive value, Hardness, Friability and Disintegration time of the tablet are found to be within the specified range.

**Conflicts of Interest None Acknowledgement**

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