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QUANTITATIVE DETERMINATION AND STANDARDIZATION OF ELECTROLYTES BY FLAME PHOTOMETRY FROM B.P.C. CAPSULE

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ABSTRACT

B.P.C. Capsule is one of the most popular herbal medicines in Indian market consumed by hypertensive patients**.** It contains electrolytes, Trace elements, essential elements, trace metals,minerals, alkaloids, steroids, organic compounds and toxic elements, besides that it also contains enzymes, proteins, and other Inorganic elements which are naturally present in herbal medicines**.** The B.P.C**.** Capsule contains electrolytes like Sodium (Na) and Potassium (K)**.** The daily requirement of Sodium (Na) and Potassium (K) is in micrograms. Diseases occur due to their deficiency and toxicity due to overdose**.** These Elements can bind to vital cellular components and interfere with their normal functions**.** In human being these elements can cause severe physiological and adverse health effects**.** Hence, it is utmost necessary to determine them quantitatively because it mostly affects cardiovascular and renal system**.** Therefore, it is thought necessary about the efficacy and standardization of B.P.C. Capsule**.** There is no proper method to detect the accurate concentration of essential elements, minerals, electrolytes, and Inorganic elements present in herbal medicines**.** Herbal medicines require standardization with implementation and constant review of technical standards of production and effective quality control methods.These Elements can be determined quantitatively and can be validated by using modern technique such as Flame photometry**.** Therefore it is necessary to promote this study in the view of the importance of results for both individual and social field.

KEYWORD: B**.** P**.** C**.** Capsule, trace elements, Sodium (Na) and Potassium (K), Herbal medicine, Standardization, Quality control, Flame Photometry**.**

INTRODUCTION

Hypertension, coronary heart diseases and diabetes mellitus are major rapidly growing health issues of present generation which are resultant of sedentary lifestyle, lack of physical activities, and unhealthy fast food consumption both in developing as well as developed countries. World Health Organization (WHO) states that around 85-95% of the world's population use traditional herbal medicines.[1] Most of them use herbal medicines for their less toxicity and minimal side effects like Herbal Tablet of B.P.C. capsule (Details Given in table number -1). Herbal medicines have become more popular as alternative and supplementary remedies in recent years.

Herbal medicines in Ayurveda are derived from roots, leaves, fruits, bark, seeds, etc. These medicines are now available in different forms like tablets, elixirs, Tonic, and powders.[2] Contamination or adulteration of herbal medicines by toxic metals, essential elements, trace elements and insect debris[3] remains major concern. The poor-quality control of these medicines can lead to health hazards like anemia due to destruction of red blood cells. Thus it is of grave importance to consider various parameters such as dosage, stability, toxicity, chemical factors, pesticide residues, toxin contents, heavy metals contamination and patient**'**s age(Adult or Children)before its therapeutic use **.**It is important to follow the quality control norms to standardize the herbal medicines.

World health Organization gives some guidelines[4] for the preparation of herbal medicines and lists some methods for the standardization of herbal medicines[4], also gives maximum permissible limit of heavy metals[5] and quality-control norms. Various instrumental methods like HPLC (High Performance Liquid Chromatography) techniques[6], GC (Gas Chromatography)[6], Electrophoresis and TLC (Thin Layer Chromatography)[6], XRPD (X ray Powder Diffraction)[7], Flame photometry are reported for the standardization of herbal medicines. These instrumental methods have successfully maintained the quality and standards of herbal medicines so as to bring reliable beneficial therapeutic effects. Flame Photometry method has high degree of sensitivity and specificity towards essential elements like sodium and potassium. Thus flame photometry can be used in quality control and standardization of herbal medicines.

MATERIALS AND METHODS

Table 01: Capsule details with company name and contents as per label.

Sr. No	Brand and Company Name	Medicines Name	Plants as per label *
1	Peekay pharma (Mfg. Lic No-25D/10/88)	B.P.C. capsule	Sarpgandha, Lahasun, Arjunchhal Ex, GuggulAshwagJatamansi,Naandha,Isabgol,Brahmi,Jatamansi,Nagarmotha, Shankpushi,Kapoor kachri, Badi ilaichi

Sampling*:* In the present study the marketed herbal tablets B.P.C. Capsule was selected for the analysis. The brand names of the medicines, license number and the plants used as per company's label are included (Table 01).

Figure 01: B. P. C. Capsule sample.

METHODS

Method for the Flame Photometry

Code numbers namely F1 is assigned for B.P.C. Capsule**.** By taking the weight of tablet on digital balance tablet sample is then gently ground to fine powder using mortar and pestle and packed in butter paper until the analysis**.** To determine the concentration of Sodium and Potassium, a wet digestion of the powder sample is done as per the new method developed**.**Table number 02 shows the weight of samples and dilution**.** Each sample is placed separately in 100 mL round bottom flask and 3 mL concentrated sulphuric acid is added**.** The mixture kept for 30 minutes at room temperature**.** After 30 minutes 4 mL of 30%hydrogen peroxide is added to the round bottom flask and allowed to cool at room temperature**.** The sample is then refluxed with Sulphuric acid at 190^{o}C for 40 minutes**.** The sample is cooled down to room temperature**.** 2 mL of 30**%**hydrogen peroxide is added and the solution heated once again until the digest is clear upon cooling**.** It is filtered through Whatman No**.** 42 filter paper and transferred quantitatively to a 25-mL volumetric flask by adding distilled water**.**

The concentration of Electrolytes Sodium (Na) and Potassium (K) in the final solution are determined by using Elico Flame Photometer CL 378**.**

Instrument Configuration

Table 02: Instrument Specification for Flame Photometry.[8]

Sr. No	Parameter	Sodium (Na)	Potassium (K)
1	Sensitivity	0.5 ppm	0.5 ppm
2	Range	1-100ppm, 0-200mEq	1-100ppm, 0-100mEq
3	Linearity	Better than 2% repeatability, better than 1% CV for 20 consecutive samples for Na and K	
4	Flame System	LPG and Oil free dry air	
5	Power requirement	90-260 V AC, 43-63 Hz, 1ϕ, Max. 65VA	

Table 03: Detected Elemental concentration in ppm by Flame Photometry.

Sr. No	Samples	Elemental concentration in ppm	
		Na	K
1	B.P.C. Capsule	2.8	7.0

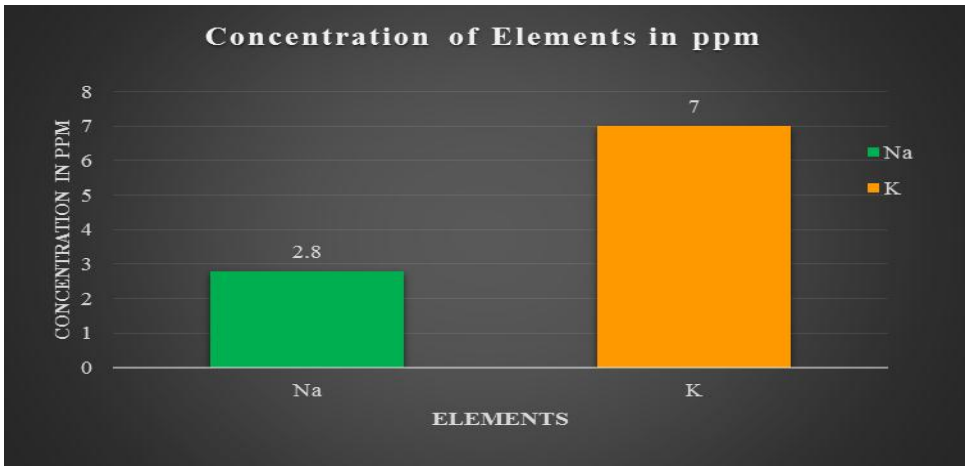

Figure - 02- Graphical representation of concentration of elements.

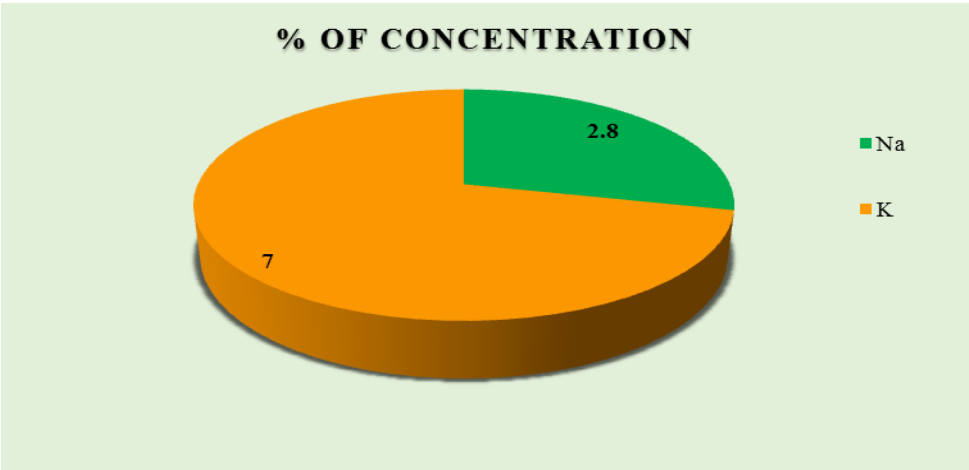

Figure-03-Graphical representation of Percentage concentration of elements

RESULT AND DISCUSSION

Biological Application[9]

Sodium

Sodium plays important role in controlling the total amount of water in the body. It is also important for regulating blood volume and maintaining muscle and nerve function. Sodium is mostly found in blood, plasma, and lymph fluid. Imbalance in sodium concentration may cause hypertension and increased risk of heart disease.

Increasing incidence of hypertension and heart disease all over the world can be attributed to the rising occurrences of sodium imbalances.Sodium is the major extracellular positive ion. Excess sodium is excreted in the urine. The transport of sodium into and out of individual cells also plays a key role in critical body functions. Many physiological processes in the human body especially in the nervous system, smooth and skeletal muscles require electrical signals for communication. The movement of sodium is critical in the generation of these electrical signals. Therefore, Hyponatremia and Hypernatremia can lead to cellular malfunction which can be fatal. Increased sodium in the blood occurs whenever there is excess sodium in relation to water; it can lead to kidney diseases, loss of water and vomiting. A decreased concentration of sodium occurs whenever there is a relative increase in the amount of body water relative to sodium it causes liver, kidney, and heart diseases.

Potassium

Potassium is the major intracellular positive ion, which plays major role in regulation of heart rhythm and muscular functions. Hyperkalemia and Hypokalemia affect nervous system and cardiac function which may lead to arryhthmias. Kidneys play major role in potassium excretion, thus diseases which affects kidneys can lead to Hyperkalemia.

Imbalance in sodium and potassium ion concentration causes cardiovascular malfunction which further leads to hypertension, arrhythmias and strokes. It also leads to disturbance in pH which may lead to tissue and kidney damage.

Thus balance between sodium and potassium ion concentration is one of the necessary condition in order to maintain normal physiological function and eventually health.

Diluted sample is used for the further analysis on Flame photometer. As an electrolytes Sodium (Na) and Potassium (K) are great importance for life and the fluids which are present

in body.Detected accurate concentration of Electrolytes in selected samples by Flame Photometer are given in table number 03.

Table 4: LD 50 of the elements (The Merck Index, 1989).[10]

Sr. No	Elements	Compounds	LD50
1	Sodium (Na)	Sodium Chloride	3.75 g/kg orally in rat
2	Potassium (K)	Potassium Carbonate	1.87 g/kg orally in rat

Table 5: Airborne threshold limit of elements.[11]

Sr. No	Elements	Air Born Threshold Limits
1	Sodium (Na)	2.0 mg/m^3
2	Potassium (K)	2.0 mg/m^3

Table 6: Approximate elementary composition of the human body (Dry Weight Basis)[12]

Sr. No	Element	Percentage
1	Sodium (Na)	0.4
2	Potassium (K)	1.0

Limit of detection (LOD) and Limit of quantification (LOQ) for the Instrument

Development of Analytical method and validation are the most important factors for the preparation of drugs in pharmaceutical industry. Limit of detection and limit of quantification are two importance parameters in method of validation.[13]

Table 7: Validation and Confidence Limit with standard Deviation.

Sr. No	Observations	Concentration of Elements in ppm	
1	Element	Na	K
2	Mean	2.8888	7.378
3	SD	± 0.0512220	± 0.2849034
4	95%	± 0.05889437	± 0.32757812
5	99%	± 0.92361769	± 0.51372812

The elements Sodium (Na) and Potassium (K) are of great importance in living organism and these elements plays an important role in biochemical reactions.The requirement of these elements for human being is in grams or in micro grams in the form of essential elements and Minerals. The detected concentration of Sodium (Na) was **2.8 ppm.,** and Potassium (K) was **7.0 ppm**.The coefficient variance (CV) of the samples if less than one is considered as low variance and coefficient variance (CV) of the samples if greater than one is considered as high variance, in all samples very low coefficient variance (CV) is found. The detected

concentration of these elements is below the LD50 and below the air borne threshold limit and are not hazardous to human.

CONCLUSION

In the present study very low coefficient variance (CV) is found. All these values of electrolytes showed less toxicity in herbal medicines and are detected below LD50 and below the air borne threshold limit. A low standard deviation (SD) means that the data is very closely related to the average thus very reliable. Quantitative estimation of metals is done by atomic absorption spectrophotometer in Bhasma only, not in tablets therefore, the concentration of these elements is below the hazardous levels to the patient.The sensitive instrumental techniques of Flame Photometry are used in the present study can be made mandatory for the quality control and standardization of Herbal medicines.

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