Standardization and Quality Control Parameters Required for Ayurvedic Medicines

Prepared for:

Directorate General of Drug Administration
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STANDARDIZATION OF QUALITY CONTROL PARAMETERS FOR AYURVEDIC MEDICINES

Introduction:

With the ever-increasing use of Ayurvedic medicines and the global expansion of the Ayurvedic medicines market, safety of these medicines has become a major concern for both the health authorities and the public in many countries. The World Health Organization (WHO) developed a strategy on traditional (Ayurvedic) medicines for the period 2002–2005 (WHO Traditional Medicine Strategy: 2002–2005), and this was subsequently implemented under the WHO Medicines Strategy covering the period 2004-2007. One of the major objectives of this document is to ensure the safety, efficacy and quality of Ayurvedic medicines.

The quality of Ayurvedic medicines has direct impacts on their safety and efficacy among the consumers. There are many control measures for Ayurvedic medicines, and first important step is to control the quality of medicinal plants and Ayurvedic materials. However, this is a very complicated and difficult task as it involves many different factors, such as the environment and agricultural practices.

WHO has developed a series of technical guidelines and documents relating to the safety and quality assurance of medicinal plants. These include, Guidelines on good agricultural and collection practices (GACP) for medicinal plants and Quality control methods for medicinal plant materials.

In the recent time, China is a major producer and exporter of Ayurvedic medicines in the world and India is an associate partner with China. They try to maintain the safety and standard quality parameters as per guidelines of the WHO and other international health organizations. Recently, the Department of AYUSH, Ministry of Health and Family Welfare, Government of India formulated a protocol for testing of Ayurvedic medicines. They emphasized on various quality parameters for testing of single and combined formulation as per requirements of the WHO and other International Health Agencies

It is known that about 70% of active ingredients of Ayurvedic medicines are either plant materials or plant products, nearly 10% of active ingredients are of animal origin and the remaining 20% of active ingredients are crude minerals & chemicals. The crude minerals and chemicals should be standardized in pre-formulation stages while the finished products should be standardized according to the conventional pharmacopeial methods and DGDA guidelines.

From above discussion, it is clear that medicinal plants have played key roles in preserving the health of millions of people. There is a growing focus of the importance of medicinal plants in the traditional (Ayurvedic) health care system in solving health related problems. Now, we are considering the Ayurvedic medicines as a developing sector in Bangladesh and try to set up standard quality control parameters according to the international health safety requirements.

Standardization of Ayurvedic Drugs:

Standardization of drugs means conformation of its identity and determination of its quality, purity and safety. Phytotherapeutic agents or Phytomedicines are standardized Ayurvedic preparations comprising of complex mixtures of one or more plants which are used in many countries for the treatment of various diseases. According to the WHO definition, Ayurvedic (herbal) drugs contain plant parts or plant materials in the crude or processed form as the active ingredients plus certain excipients.

Basically the standardization of the Ayurvedic plant materials will be based on raw materials and the finished products. The raw materials ~~are~~ includes-

1) Crude plants, plant parts and plant products
2) Mineral/ crude minerals, and
3) Animal organ(s) or part(s) of animal or of animal origin.

The Ayurvedic finished product includes-

1) Arka/Distillates
2) Asava & Arishta
3) Avaleha
4) Churna (fine powder)/ Kvatha churna-coarse powder
5) Lepa (Medicated wax /cream)
6) Netra bindu / Anjana (Eye drops)
7) Vartti
8) Pishti (Processed fine powder)
9) Ghansatva / Plant extract
10) Ghrta and Taila (Medicated oil and ghee)
11) Guggulu
12) Vati/Gutika/ Modaka (Tablet/Pills)
13) Syrup~~s~~ / Sharbat
14) Bhasma / Sindura
15) Mandura

16) Rasayoga
17) Lauha
18) Capsule

Here, the most important factors are plant materials & plant products and try to find out the ways and means to ensure the quality of finished products. Total quality of products depends on quality raw materials and quality in processing, starting from cultivation of raw materials to finished products distribution. In this case, the major roles will be played by the manufacturers, vendors or suppliers and or importers in ensuring the availability and use of quality plant materials.

Definition of Plant materials and Products:

Crude drugs:
In the Ayurvedic Systems of Medicine comprising of Ayurveda, drugs of plant, animal and mineral origin, are used in their natural or so called "Crude" forms singly or in their mixture or in combination, to make a compound preparation of formulation. Nearly 90 per cent of the Crude drugs are obtained from the plant sources while about 10 per cent of the drugs are derived from animal and mineral sources. The drugs of plant origin especially of herbaceous nature are frequently used as whole plant; otherwise their parts such as Root, Stem, Leaf, Flower, Seed, Fruit modifications of Stem and Root, Bark of a Stem or Root, Wood, and their Exudates or Gums, etc. constitute single drugs in the Indian Systems of Medicine.

Ayurvedic medicines:
These include herbs, Ayurvedic raw materials, Ayurvedic preparations and finished products.

Herbs:
Herbs include crude plant materials such as leaves, flowers, fruits, seeds, stems, woods, barks, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

Ayurvedic raw materials:
Ayurvedic raw materials are either whole plants or parts of medicinal plants in the crude state. They include herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir baking with honey, alcoholic beverages or other materials.

Ayurvedic preparations:
Ayurvedic preparations are the basis for finished Ayurvedic products and may include comminuted or powdered Ayurvedic materials, or extracts, tinctures and fatty oils, expressed juices and processed exudates of Ayurvedic materials. They are produced with the aid of extraction, distillation, expression, fractionation, purification, concentration, fermentation or

other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.

Finished Ayurvedic products or Ayurvedic medicinal products:

These are medicinal products containing as active substances inclusively Ayurvedic drugs or Ayurvedic drug preparations. They may consist of Ayurvedic preparations made from one or more herbs. If more than one herb is used, the term mixed herbal product can also be used. They may contain excipients in addition to the active ingredients. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients, which are not of plant origin (e.g. mineral materials and animal materials). Generally however, finished products or mixed products to which chemically defined active substances have been added, including synthetic compounds and/ or isolated constituents from Ayurvedic materials, are not considered to be herbal.

Medicinal plant:

A medicinal plant is any plant, either growing wild or cultivated, and used for its medicinal properties.

Related definitions:

Odour:

The "odour" is examined by directly smelling 25g of the powdered drug contained in a package or when freshly powdered. If the odour is discernible the sample is rapidly transferred to an open container and re-examined after 15 minutes. If the odour persists to be discernible, it is described as having odour.

Taste:

The "taste" of a drug is examined by taking a small quantity of 85 mesh powdered materials by a tip of moist glass rod and applying it on tongue previously rinsed with water. This may not be done in case of poisonous drugs, indicated in the monograph.

Contamination:

The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter, into or onto a starting material, intermediate product or finished herbal product during production, sampling, packaging or repackaging, storage or transport.

Cross-contamination:

Contamination of a starting material, intermediate product or finished product with another starting material or unformulated materials or product during product manufacturing.

Foreign matters:

Material consisting of any or all of the followings:

- parts of the medicinal plant material or materials other than those named with the limits specified for the plant material concerned;
- any organism, part or product of an organism, other than that named in the specification and description of the plant material concerned;
- mineral admixtures such as soil, stones, sand, and dust; and glass, metal and plastics or any other extraneous materials. These may be loose or adhering to the ~~this~~ medicinal plant materials.

Pesticides:

Pesticides are defined as any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during production, storage, transport, distribution and processing. The term includes substances intended for use as a plant-growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers and plant nutrients.

Pesticide residues:

Pesticide residues are any specified substance in food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance.

Mycotoxins /Aflatoxins:

The presence of mycotoxins in plant material can pose both acute and chronic risks to health. Mycotoxins are usually secondary metabolic products which are non-volatile, have a relatively low molecular weight, and may be secreted onto or into the medicinal plant material. They are thought to play a dual role, firstly, in eliminating other microorganisms competing in the same environment and secondly, helping parasitic fungi to invade host tissues. Mycotoxins produced by species of the fungi including *Aspergillus*, *Fusarium* and *Penicillium* are the most commonly reported.

Mycotoxins comprise four main groups, namely, aflatoxins, ochratoxins, fumonisins and trichothecenes, all of which have toxic effects. Aflatoxins have been extensively studied and are classified as Group 1 human carcinogens by the International Agency for Research on Cancer.

Raw Material Processing for Product Manufacturing:

All drug materials of plant, animal & mineral origin, being used in the manufacture of Ayurvedic medicine, procured locally & by importation, should invariably kept in the quarantine, as per existing procedure followed by pharmaceutical manufacturing companies in Bangladesh.

For quality control of starting drug materials and finished products of plant origin, any two or all of the following Quality Control Tests should be carried out:

01. Identification tests: (a) Macroscopic & Microscopic
    b) Qualitative phytochemical
    (c) TLC/ HPTLC/ HPLC
    (d) Tests for chemicals, pesticides, heavy metals, microbes, etc.
02. Quantitative tests of one or more marker substance(s), for example Alkaloids, Glycosides, Flavonoids, etc.

Over all the quality control parameters of the raw materials and finished products will included the following tests:

a) PHARMACOGNOSTIC
- Taxonomical
- Morphological
- Anatomical
- Biological
- Biochemical
- Biotechnological

b) PHYSICO-CHEMICAL
- Ash values
- pH
- Hardness
- Disintegration time
- Elemental composition

c) PHYTOCHEMICAL
- Extractive values
- Chemical profiling
- TLC/ HPTLC/ HPLC fingerprinting
- Markers
  - Bio-active
  - Biological
  - Chemical
- HPTLC/ HPLC- based

d) MICROBILOGICAL ANALYSIS

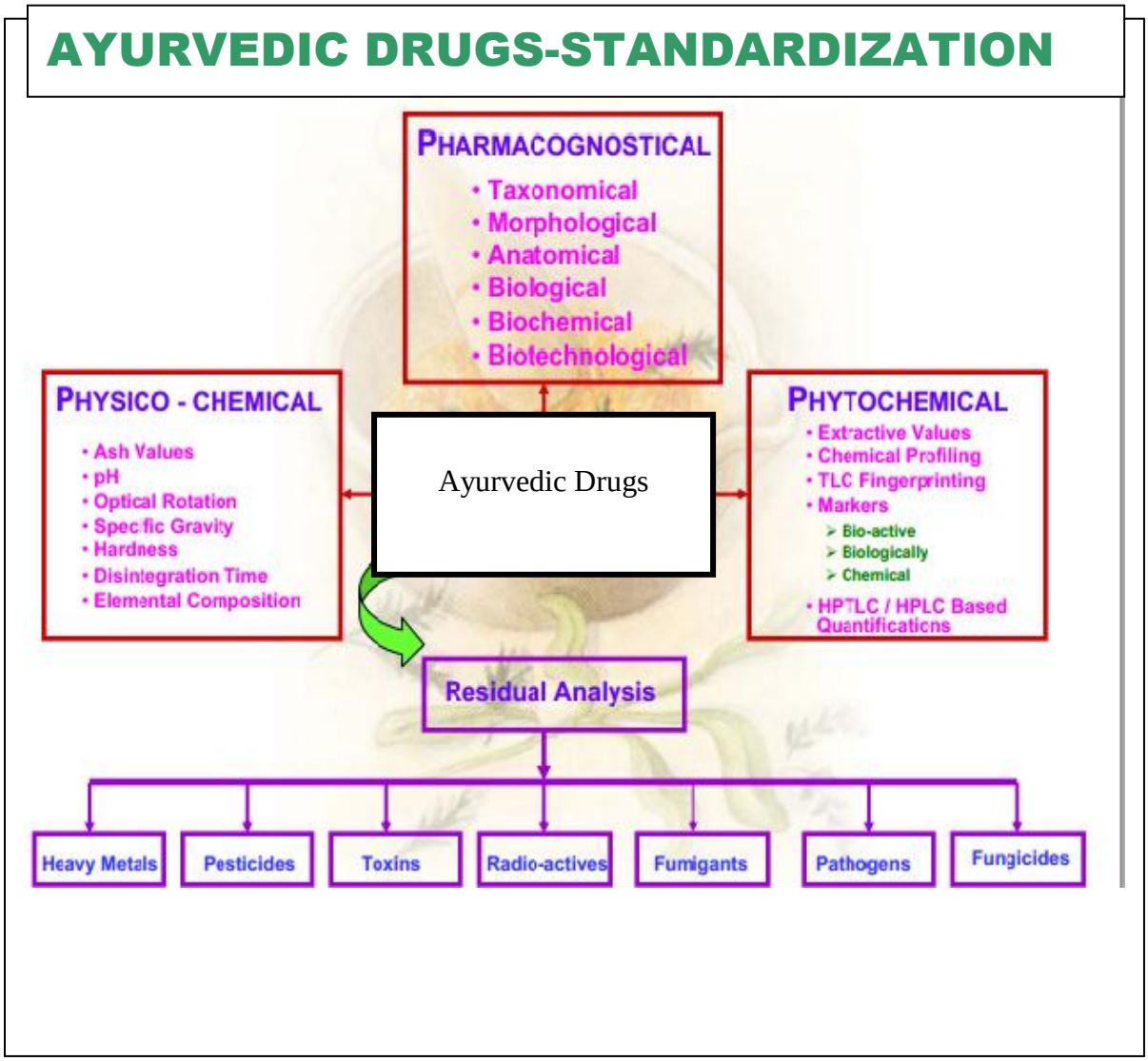
- Total viable count
- Presence of pathogenic organisms
  - *Escherichia coli*
  - *Salmonella* sp.
  - *Staphylococcus aureus*
  - *Pseudomonas* sp., etc.

e) RESIDUAL ANALYSIS

- Heavy metals
- Pesticides
- Toxins
- Radio-active substances
- Fumigants
- Fungicides

SUMMARY OF AYURVEDIC DRUGS STANDARDIZATION AND QUALITY CONTROL PARAMETERS:

(Table needs some corrections- please see my marked copy of the draft)



Types of Ayurvedic Medicines/ Medicinal Products and Quality Control Parameters

1. Crude Ayurvedic materials

Quality control parameters-

- Authentication-

Each and every step of the following factors needs to be authenticated

- area of the collection,
- parts of the plant collected,
- the regional situation,
- botanical identity,
- microscopic characteristics, and
- histological analysis.

If all or some parts of the parameters can authenticate the material, then authentication procedures should be considered as accomplished.

2.0 Mineral origin:

Identification and relevant chemical tests as per specifications be conducted.

3.0 Animal organ or part of animal

Needs authentication and identification of animal, collection procedure, part of the animal or its organ, and histological analysis.

Plant materials are processed as follows:

- Authentication of the plants material,
- Keeping herbarium specimen(s) for comparison and identification,
- Assay of the liquid/dry extract is required considering at least one marker compound, whenever possible.

Assay procedure includes any of the following:

- Titrimetric procedure (wherever possible),
- Chromatographic evaluation, e.g. TLC/ HPTLC/ HPLC/ GC, etc.
- Spectrophotometric evaluation e.g. UV, IR, etc.
- Microbiological assay,
- Total viable load (as described in the BP, USP or other official monographs or WHO guidelines enclosed in the appendix),
- Presence of pathogenic organisms as described in the BP, USP or other official monographs or WHO guidelines enclosed in the appendix),
- Evaluation of safety
- Assay/ detection for the presences of heavy metals, e.g. Lead, Arsenic and Mercury,
- Assay/ identification for the presences of pesticides.

TEST CRITERIA OF AYURVEDIC RAW MATERIALS

1. **Tests parameters and specifications for crude Ayurvedic plant materials are as follows:**

Sl. No.	Tests
1.0	Identification
	-Macroscopic
	-Microscopic
	-Powder characteristics
2.0	Loss on drying at 105 ^{o}C
3.0	Total-ash
4.0	Acid-insoluble ash
5.0	TLC/ HPTLC- profile with marker substance(s) (wherever possible)
6.0	Water-soluble extractive
7.0	Alcohol-soluble extractive
8.0	Assay by suitable methods (if possible)
9.0	Test for heavy/Toxic metals -Mercury -Lead -Cadmium -Arsenic
10.0	Microbial contamination -Total bacterial count -Total fungal count
11.0	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
12.0	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
13.0	Test for Aflatoxins (B1, B2, G1, G2)
Note: Tests 1, 2 and 5 (Spot test on TLC/ HPTLC under UV lamps / Phytochemical tests) are mandatory.	

2.0 **Test parameters and specifications for minerals are as follows:**

Sl. No.	Test
1.0	Description
	Color
	Odor
	Taste
2.0	Identification
3.0	pH
4.0	Loss on drying at 105 ^{o}C
5.0	Foreign matters
6.0	Solubility
7.0	Test for heavy/Toxic metals -Mercury -Lead -Cadmium -Arsenic
8.0	Test for Aflatoxins (B1, B2, G1, G2)
9.0	Assay
Note: Tests 1, 2, 3, 5 and 6 are mandatory.	

3.0 Test parameters and specifications for animal or its organ as raw materials in Ayurvedic Medicines:

Test	**Specification**
Appearance	Qualitative evaluation of the animal source, its organ, parts of organ, etc. to be used.
Identification	Must comply with standard specifications
Characteristics	May be evaluated according to its characteristics
Histology	Must comply with standard specifications
Microbial contamination test	Total aerobic microbial count: $<10^7$CFU/g or CFU/ml
	Total combined yeast and mold count: $<10^5$ CFU/g or CFU/ml
	Specific pathogen:
	Escherichia coli: $<10^3$ CFU/g or CFU/ml
	Salmonella sp.: Nil (1g or 1ml)
	Staphylococcus aureus: Nil (1g or 1ml)
	Clostridia: Nil (1g or 1ml)
	Pseudomonas sp.: Nil
	(According to the type of organisms specifications should match with those of standard monograph)
Aflatoxins/Mycotoxins	Should follow standard monograph (BP/USP/WHO/EMA guidelines); i.e. Aflatoxin B1: Not more than 2μg/kg, Sum of Aflatoxins B1, B2, G1, G2): not more than 4μg/kg
Pesticide residues	Must comply with the recommended standard monograph (USP/WHO/EMA guidelines)
Heavy metals	Arsenic: 5ppm; Lead: 10ppm; Cadmium: 0.3ppm; Mercury: Nil; Copper: Nil
Assay	Quantitative measure of the marker compound(s) in the test sample in comparison to reference standard(s), whenever possible.
Note: Tests for identification, appearance, **histology** and microbial contamination -shall be performed.	

TEST CRITERIA OF FINISHED PRODUCTS

Finished Ayurvedic products or Ayurvedic medicinal products

The finished herbal product may be of following types-

a. Solid: Powder (Dusting, Effervescent/non-effervescent), tablet (Coated/non-coated), capsule (Hard/soft gelatin, HPMC, coated/non-coated/gastro-resistant),

b. Liquid: Syrup, (Syrups, Arka/ Distillate, Asava & Arishta, Ghansatva, etc.),

c. Semisolid: Cream, Ointment,

d. Suppository: Considered for the future,

1.0 ANALYTICAL SPECIFICATIONS OF ARKA/DISTILLATES

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	pH
3	Volatile matter
4	Specific gravity at 25 ^{o}C
5	Clarity test
6	Identifications (TLC/ HPTLC/ HPLC/ GC or by any suitable methods)
7	Assay (for marker compounds) by any suitable methods
8	Test for heavy metals: -Lead -Cadmium -Mercury -Arsenic
9	Microbial contamination: -Total bacterial count -Total fungal count
10	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
11	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
Note: Tests 1, 2, 4, 6 and 9 are mandatory.	

2.0 ANALYTICAL SPECIFICATIONS OF ASAVA AND ARISHTA (FERMENTED LIQUIDS)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	pH
3	Specific gravity at 25 ^{o}C
4	Total solids
5	Alcohol content -test for methanol
6	Reducing sugar
7	Non-reducing sugar
8	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
9	Total acidity
10	Test for heavy metals: -Lead -Cadmium -Mercury -Arsenic
11	Microbial contamination: -Total bacterial count -Total fungal count
12	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
13	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
Note: Tests 1-9 **and 11** are mandatory.	

3.0 ANALYTICAL SPECIFICATIONS OF AVALEHA (SEMI SOLIDS)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
	Taste
2	Loss on drying at 105 ^{o}C
3	Total ash
4	Acid-insoluble ash
5	pH(4-6.5)
6	Total solid
7	Fat content
8	Reducing sugar
9	Total sugar
10	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
11	Test for heavy metals: -Lead -Cadmium -Mercury -Arsenic
12	Microbial contamination: -Total bacterial count -Total fungal count
13	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
14	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
15	Test for Aflatoxins (B1, B2, G1, G2)
Note: Tests 1, 2, 5 and 12 are mandatory.	

4.0 ANALYTICAL SPECIFICATIONS OF CHURNA (FINE POWDER)/ KVATHA CHURNA (COARSE POWDER)

Sl. No.	Test parameters
1	Description
	Macroscopic
	Microscopic
2	Loss on drying at 105 ^{o}C
3	Total ash
4	Acid-insoluble ash
5	Water soluble extractive
6	Alcohol soluble extractive
7	Particle size (80-100 mesh for churna, 40-60 mesh for Kvatha churna)
8	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
9	Test for heavy metals: -Lead -Cadmium -Mercury -Arsenic
10	Microbial contamination: -Total bacterial count -Total fungal count
11	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
12	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
13	Test for Aflatoxins (B1, B2, G1, G2)
Note: Tests 1-8 and 10 are mandatory.	

5.0 ANALYTICAL SPECIFICATIONS OF LEPA (MEDICATED WAX/ CREAM/

POULTICE)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
	Consistency/ Uniformity of content
	Microscopic (if powdered drugs incorporated)
	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
2	Viscosity
3	pH (4-6.5)
4	Particle size (if powdered drugs incorporated) mesh size 125 - 150
5	Total fatty matter
6	Loss on drying at 105 ^{o}C
7	Spreadability
8	Test for heavy metals: -Lead -Cadmium -Mercury -Arsenic
9	Microbial contamination: -Total bacterial count -Total fungal count
10	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
11	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
Note: Tests 1-5, 7 and 9 are mandatory.	

8.0 ANALYTICAL SPECIFICATIONS OF PISHTI (PROCESSED FINE POWDER)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	Taste
3	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
4	Assay of element (s)
5	Loss on drying at 105 ^{o}C
6	Total ash
7	Acid- insoluble ash
8	Particle size -mesh size 125-150
9	Test for heavy/ toxic metals: -Lead -Cadmium -Mercury -Arsenic
10	Microbial contamination: -Total bacterial count -Total fungal count
11	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
12	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
13	Test for Aflatoxins (B_1, B_2, G_1, G_2)
Note: Tests 1-8 and 10 are mandatory.	

9.0 ANALYTICAL SPECIFICATIONS OF GHANSATVA/ PLANT EXTRACTS

Sl. No.	Test parameters
1	Description
	Colour
	Odour
	Taste
2	Loss on drying at 105 ^{o}C
3	Total ash
4	Acid- insoluble ash
5	pH
6	Water soluble extractive
7	Alcohol soluble extractive
8	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
9	Test for heavy/ toxic metals: -Lead -Cadmium -Mercury -Arsenic
10	Microbial contamination: -Total bacterial count -Total fungal count
11	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
12	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
13	Test for Aflatoxins (B_1, B_2, G_1, G_2)
Note: Tests 1-8 (spot test on TLC/ HPTLC under UV lamps/ Phytochemical tests) and 10 are mandatory.	

10.0 ANALYTICAL SPECIFICATIONS OF GHRTA AND TAILA (MEDICATED OIL AND GHEE)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	Weight / ml. (in case of taila)
3	Refractive index at 25 ^{o}C
4	Viscosity
5	Iodine value
6	Saponification value
7	Acid value
8	Peroxide value
9	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
10	Test for heavy/ toxic metals: -Lead -Cadmium -Mercury -Arsenic
11	Microbial contamination: -Total bacterial count -Total fungal count
12	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
13	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
14	Test for Aflatoxins (B_1, B_2, G_1, G_2)
Note: Tests 1-9 and 11 are mandatory.	

11.0 ANALYTICAL SPECIFICATIONS OF GUGGULU

Sl. No.	Test parameters
1	Description
	Colour
	Odour
	Taste
2	Loss on drying at 105 ^{o}C
3	Total ash
4	Acid- insoluble ash
5	pH
6	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
7	Water soluble extractive
8	Alcohol soluble extractive
9	Test for heavy/ toxic metals: -Lead -Cadmium -Mercury -Arsenic
10	Microbial contamination: -Total bacterial count -Total fungal count
11	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
12	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
13	Test for Aflatoxins (B_1, B_2, G_1, G_2)
Note: Tests 1-8 and 10 numbers are mandatory.	

12.0 ANALYTICAL SPECIFICATIONS OF VATI/GUTIKA/ MODAKA (TABLET/ PILLS)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	Weight variation
3	Loss on drying at 105 ^{o}C
4	Disintegration time- Not more than 30 minutes - Not more than 60 minutes for guggulu tablets
5	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
7	Test for heavy/ toxic metals: -Lead -Cadmium -Mercury -Arsenic
8	Microbial contamination: -Total bacterial count -Total fungal count
9	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
10	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
11	Test for Aflatoxins (B_1, B_2, G_1, G_2)
Note: Tests 1-5 are mandatory.	

13.0 ANALYTICAL SPECIFICATIONS OF SYRUP / SHARBAT

Sl. No.	Test parameters
1	Description
	Colour
2	Odour
3	Total ash
4	Acid- insoluble ash
5	Water soluble extractive
6	Alcohol soluble extractive
7	pH
8	Total sugar content
9	Viscosity
10	Identifications (TLC/ HPTLC/ HPLC or by any suitable methods)
11	Test for heavy/ toxic metals: -Lead -Cadmium -Mercury -Arsenic
12	Microbial contamination: -Total bacterial count -Total fungal count
13	Test for specific pathogen *Escherichia coli* *Salmonella* sp. *Staphylococcus aureus* *Pseudomonas aeruginosa*
14	Pesticide residues -Organochlorine pesticides -Organophosphorus pesticides -Pyrethroids
Note: Tests 1, 2, 7 and 12 are mandatory. Determination of Propylene glycol, Glycerin and Sorbitol are mandatory to ensure safety.	

14.0 ANALYTICAL SPECIFICATIONS OF BHASMA/ SINDURA (CALX)

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	Identification- Chemically
3	Particle size : mesh size 200 - 300
4	Loss on drying at 105 ^{o}C
5	Total ash
6	Acid- insoluble ash
7	Water soluble ash
8	Assay of elements
9	Ayurvedic specifications
10	Lustreless (*Nishchandrica)*
11	Fine enough to enter the crevices of finger (rekha purnatva)
12	Floats on water (*varitara*)
13	Smokeless (*Nirdhoom)*
14	Tasteless (Niswadu)
15	Irreversible (Apunar bhav)
Note: Tests 1-7 are mandatory.	

17.0 ANALYTICAL SPECIFICATIONS OF LAUHA

Sl. No.	Test parameters
1	Description
	Colour
	Odour
2	Identification- Chemically
3	Particle size : mesh size 200 - 300
4	Loss on drying at 105 ^{o}C
5	Total ash
6	Acid- insoluble ash
7	Water soluble ash
8	Assay of elements
9	Ayurvedic specifications
10	Lustreless (*Nishchandrica)*
11	Fine enough to enter the crevices of finger (rekha purnatva)
12	Floats on water (*varitara*)
13	Smokeless (*Nirdhoom)*
14	Tasteless (Niswadu)
15	Irreversible (Apunar bhav)
Note: Tests 1-9 are mandatory.	

18.0 ANALYTICAL SPECIFICATIONS OF CAPSULE

Sl. No.	Test parameters
1	Description
	Colour
	Shape
2	Uniformity of dosage unit
3	Particle size : mesh size 80 - 120
4	*Identifications (TLC/ HPTLC/ HPLC/ UV/ IR or by any suitable methods)*
5	Loss on drying at 105 ^{o}C
6	Dissolution
7	Weight variation
8	Acid- insoluble ash
9	Water soluble ash
10	*Assay of elements (TLC / HPTLC/ HPLC / UV or by any suitable method)*
Note: Tests 1-7 are mandatory.	

Conclusions

The pharmaceutical sector is a rapidly growing and priority sector in Bangladesh. The alternative/ traditional systems of medicines comprising of the Unani, Ayurvedic, Homeopathic and Herbal medicines are widely used for primary health care by 80% of the population in this subcontinent. Therefore, modernization of alternative/ traditional medicines should be emphasized and accomplished to meet the international standards.

Immediate and concerted efforts should be taken to attain the quality of these products to such a level of high standards and ensure sustainably of the quality control and quality assurance systems. To meet the increasing demands of alternative/ traditional medicines research and development of these medicines is very important. For the development of the Ayurvedic/ alternative medicines collaborative research programs must be established between the industries and academia/ research institutions.

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