8TH OXFORD INTERNATIONAL CONFERENCE ON SCIENCE OF BOTANICALS (ICSB) AND WORKSHOP SPONSORED ON IN INDIAN SYSTEMS OF MEDICINES

on 6th – 9th April, 2009

Presentation by

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www.indianmedicine.nic.in
Introduction to Indian Systems of Medicine & Status of Regulatory Laws and Pharmacopoeial Quality Standards of Drugs
OFFICIALLY RECOGNIZED SYSTEMS OF INDIAN MEDICINE

- Ayurveda
- Yoga & Naturopathy (Drugless therapy)
- Unani
- Siddha

System of Holistic Medicine
AYURVEDA (Medicine)

• Documented 5000 B.C.
• 3 Doshas, 5 Elements, holistic principles of nature
• Health is equilibrium of all functional elements
• 1000 Medicinal plants, 58 minerals, 54 animal products
• Individualized, safe, Promotive Preventive, & Curative therapy.
• Strengths in the management of Chronic debilitating diseases.
• 18 Specialties of Ayurveda are taught at UG/PG level.
SIDDHA (Medicine)

- Traditional system of medicine developed in Southern India.
- 3 Doshas, 5 elements, holistic principles.
- Specialized in Iatrochemistry and Mercurial preparations.
- The treatment is individualistic.
- Strengths in the treatment of Psoriasis, arthritis and maternal health problems.
UNANI (Medicine)

- Origin from Greek physician Hippocrates (460 – 377 BC).
- 4 humors – Dam (blood), Balgham (phlegm), Safra (yellow bile), Sauda (Black bile) & 4 temperaments.
- Diagnosis through examination of Nabz (pulse), Baul (Urine), Baraz (Stool).
- Treatments – İlağ  Tadbeer (Regimental therapy), İlağ  Bid  Gīza (Dietotherapy), İlağ  Dawa (Pharmacotherapy) and Jarahat (Surgery).
- Strengths in the treatment of Vitiligo, skin disorder, digestive disorders etc.
ORIGIN OF AYURVEDA

Ayurveda has Divine Origin

Ayu+Veda; Ayu= Life, Veda= Knowledge

- Lord *Brahma* created Ayurveda along with the creation of mankind and universe
- Since the history of mankind, *Ashtang Ayurveda* eight specialties of Ayurveda are in practice in one or the other way.
- *Vedas* (5000 B.C.) describe about 100 plants and treatment of various diseases
- Charka Samhita (800 B.C)- Treatise on Internal Medicine
- Sushruta Samhita (500 B.C)- Treatise on Surgery, Eye & ENT
In India Surgery was very advance; even transplantation of head in human beings has been referred in Indian literature.
From India Ayurveda along with Buddhism Spread to Tibet - Himalyan States, China, Japan, Korea, Mongolia, Myanmar, Srilanka, Singapur, Thailand and other parts of the world and was transformed in various Traditional Medical System of these Countries. Fundamental of These traditional System are common

Lord Buddha- A Great Exponent of Ayurveda
**PURUSH LOK SAMYA**

Human being is a replica of universe:

- Human being - Universe
- Microcosm - Macrocosm
- Five elements - Space, Air, Fire, Water & Earth
- *Vatta, Pitta, Kapha* - Air, Sun & Water- Earth
- Jeev-*Atma* (Soul) - Parmatma (Braham) (consciousness) (super consciousness)

Human being and environment around are very much similar and are inter-dependent
Ayurveda Concept – Modern Technology

Holistic Concept of Health
HUMAN BEING
Soul+Intellect+Mind+Body

<table>
<thead>
<tr>
<th>Food: Human body - Three Dosha:</th>
<th>Drugs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>V Vatta V</td>
<td>P Pitta P</td>
</tr>
<tr>
<td>P Kapha K</td>
<td></td>
</tr>
</tbody>
</table>

Five elements:

<table>
<thead>
<tr>
<th>S Space S</th>
<th>A Air A</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>A</td>
</tr>
</tbody>
</table>
STATE OF HEALTH

A state of equilibrium and functional balance of body components and happiness of mind & soul

- **Sam-Dosha** - Vatta, Pitta & Kapha [Humours]
- **Sam-Agni** - Biological fire
- **Sam Dhatu** - Body tissues
- **Malkriya** - Normal excretion of wastes - urine, stool, sweat etc.
- **Prasannatmendriya Manah** - Normal functions of Five motor and Five sensory organs and
- Happiness of mind & soul

Equilibrium of all these factors is health.
PRAKRITI

(Body, Mind, Temperament)

• Prakriti is decided at the time of fertilization
• Sperm+ovum+mental state of couple and environment
• Genetically constituted body, mind, personality

Body constitution

• Types: Vata type (V), Pitta type (P), Kapha type (K), VP, VK, PK or VPK
• Mental Temperament- Types: Satvik (S), Rajsik (R), Tamsik (T), SR, ST, RT, SRT

Generally Prakriti is mixture of all the three dosha but one
CONCEPT OF AGNI (BIOLOGICAL FIRE)

Normal Agni

Food

Essence of digested products (Mala)

Waste

normal excretion

Nutrition to body tissue

Organs

Tissues

Cells

-Nutrition of Panchbhoota

Balance of Dosha – VPK - Health
CONCEPT OF AMA (Toxic metabolites due to improper digestion)

Abnormal Agni (abnormal biological fire)

Food

Improperly digested food products

improper accumulation of wastes products

- Malnutrition of the body tissue
- Formation of Ama (toxic food products)
- Toxic metabolites
- Stimulates – auto-immune complex

(Ama) - (Starting of pathological process) DISEASE
Various diseases caused due to *Ama* (Toxic metabolites due to improper digestion)

- Dyspepsia (*Agnimandya*) & G.I.T. disorders
- Hyperacidity – peptic ulcer (*Amalpitta*)
- Irritable Bowl Syndrome & Colitis (*Samgrahni*)
- Liver disorders
- Joint disorders (*Amavata*)
- Allergic disorders (various skin disorders)
- Bronchial asthma (*Amma effecting Respiratory System*)
- Diabetes mellitus (*Amma Effecting Metabolism*)
CONCEPT OF SROTAS - PURIFICATION [Purification of micro-macro channels of circulation]

- Whole of the human body is made up of Srotas
- These channels are both large and small eg.
- Intestines, Bronchi, Ureters, Arteries, Veins,
- Capillaries
- Various types of fluids circulate through these channels
- Srotas are at Intracellular & intercellular tissues, organs & at systems level
- Disease is caused by accumulation of waste products in the channels of circulation
- Obstruction in the SROTAS cause disease
PRINCIPAL CONCEPT OF
AYURVEDIC TREATMENT

A three phase approach of curing a disease:

1. **Samshodhana** (Purification): Elimination of 
dosha, toxins etc. from the body by various 
processes e.g., sweating, emesis, purgation etc.

   Fasting, Sun Bath

2. **Samshamna** (Pacification): Neutralizing the 
dosha/toxins with the help of medicine/food.

3. **Nidan Parivarjana**: To avoid causative factors 
of the disease, Through Diet & Behavior
REGULATORY LAWS

- Indian Medicine Central Council (IMCC) Act, 1970 - For Education & Clinical practices
- Drugs & Cosmetics Act, 1940
- Drugs & Magic Remedies (Objectionable Advertisements) Act
- Biodiversity Act
- Wild Life Protection Act
- Indian Forests Act
• Indian Medicine Central Council (I.M.C.C.) Act 1970
• Central Government is vested with powers to grant permission for opening of new colleges, increase of admission capacity and starting of new or higher courses of study.
• Central Government grants permission on the basis of recommendations of State Government, affiliating university and regulatory council and availability of infrastructure as per prescribed norms.
LEGAL REGULATION FOR CLINICAL PRACTICE

• Indian Medical Central Council (I.M.C.C.) ACT 1970 for Ayurveda, Siddha & Unani practitioners.

• Registration of practitioners is mandatory.

• Registration requires possession of recognized medical qualification.

• Qualifications awarded by universities are included in the Act with the approval of Central Government.
REGULATION OF AYURVEDA SIDDHA & UNANI DRUGS

• Separate chapter and rules for Ayurveda, Siddha and Unani drugs in Drugs & Cosmetics Act, 1940.

• Drug Technical Advisory Board for matters related to quality control and standardization

• Drugs Consultative Committee for securing uniform administration of the legal provisions in different states.
Contd…

• Licensing of manufacturing units and drugs mandatory.
• Central Government empowered to prohibit manufacture and sale of certain drugs in public interest.
• Government Drug Analysts Qualifications and Duties.
• Appointment of Drug inspectors.
• Penalty for manufacture, sale etc. of drugs in contravention of Act.
• To prescribe methods of drug testing and analysis.
• Listing of schedule E drugs – poisonous materials.
• Definition of misbranded, adulterated and spurious drugs for punitive action.
• Compulsory Good Manufacturing Practices (GMP).
• Labeling/Packing provisions.
• Recognition of private and public drug testing laboratories for sample analysis.
• Compulsory testing and Certification for export.
QUALITY STANDARDS OF DRUGS

AYURVEDIC PHARMACOPOEIA OF INDIA

• Ayurvedic Pharmacopoeia Committee (APC), Siddha Pharmacopoeia Committee (SPC) & Unani Pharmacopoeia Committee (UPC) notified by the Government approves the pharmacopoeial standards.

• Scientific institutions / laboratories undertake basic work of standardization.

• Experts of Ayurveda, Unani, Siddha phytochemistry, pharmaceutical science, pharmacognosy, inorganic chemistry and medicinal plants are associated.
THE AYURVEDIC PHARMACOPOEIA OF INDIA

Volume - V

First Edition

Goverment of India
Ministry of Health and Family Welfare
Department of Ayurveda, Yoga-Naturopathy, Unani, Siddha & Homoeopathy (AYUSH)
New Delhi
Published Pharmacopoeias and Formularies

- Ayurvedic Pharmacopoeia: 540 monographs (7+2 Vol) + 101 formulations
  Ayurvedic Formulary(2 vol.): 636 formulations

- Siddha Pharmacopoeia: 76 monographs

- Siddha Formulary: 248 formulations

- Unani Pharmacopoeia (5 vol): 240 monographs

- Unani Formulary(5 Vol.): 812 formulations

- Essential drug lists published.
THE
AYURVEDIC
PHARMACOPOEIA
OF
INDIA

PART - II
VOLUME - II
First Edition
(FORMULATIONS)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA
AND HOMOEOPATHY (AYUSH)
NEW DELHI
<table>
<thead>
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<th>Year</th>
<th>No. of drugs</th>
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<tr>
<td>1. Ayurvedic Pharmacopoeia of India Vol. I</td>
<td>1986</td>
<td>80</td>
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<tr>
<td>2. Ayurvedic Pharmacopoeia of India Vol. II</td>
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<td>78</td>
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<td>3. Ayurvedic Pharmacopoeia of India Vol. III</td>
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<td>4. Ayurvedic Pharmacopoeia of India Vol. IV</td>
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<td>68</td>
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<td>5. Ayurvedic Pharmacopoeia of India Vol. V</td>
<td>2006</td>
<td>92</td>
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<td>6. Ayurvedic Pharmacopoeia of India Vol. VI</td>
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<td>101</td>
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<tr>
<td>7. Ayurvedic Pharmacopoeia of India Vol. VII</td>
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<td>21</td>
</tr>
<tr>
<td>(Minerals and Metals)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (Single drugs) =</td>
<td></td>
<td>540</td>
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## Unani & Siddha Pharmacopoeia

<table>
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<tr>
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<th>Title</th>
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<tbody>
<tr>
<td>1.</td>
<td>Unani Pharmacopoeia of India-Vol I</td>
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<td>2.</td>
<td>Unani Pharmacopoeia of India-Vol II</td>
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<tr>
<td>3.</td>
<td>Unani Pharmacopoeia of India-Vol III</td>
<td>53</td>
</tr>
<tr>
<td>4.</td>
<td>Unani Pharmacopoeia of India-Vol IV</td>
<td>50</td>
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<td>5.</td>
<td><strong>Unani Pharmacopoeia of India-Vol V</strong></td>
<td>52</td>
</tr>
<tr>
<td>6.</td>
<td>Siddha Pharmacopoeia of India</td>
<td>73</td>
</tr>
</tbody>
</table>
## Unani & Siddha Formularies

<table>
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<tr>
<th></th>
<th>Unani Formulary of India- Vol</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Unani Formulary of India- Vol I</td>
<td>441 Formulations</td>
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<tr>
<td>2.</td>
<td>Unani Formulary of India- Vol II</td>
<td>102 Formulations</td>
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<tr>
<td>3.</td>
<td>Unani Formulary of India- Vol III</td>
<td>103 Formulations</td>
<td></td>
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<tr>
<td>4.</td>
<td>Unani Formulary of India- Vol IV</td>
<td>166 Formulations</td>
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<tr>
<td>5.</td>
<td>Unani Formulary of India- Vol.V</td>
<td>179 Formulations</td>
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</tr>
<tr>
<td>6.</td>
<td>Siddha Formulary of India</td>
<td>250 Formulations</td>
<td></td>
</tr>
</tbody>
</table>
COMPONENTS OF AYURVEDIC, SIDDHA & UNANI MEDICINES

- Plants: 90-95%
- Minerals: 1-2%
- Metals: 1-2%
- Animal Byproducts: 1-2%
- Marine Products: 1-2%

These are used in single and multiple ingredients formulations.
Standardization of Raw drugs and Ayurvedic formulations
Standardization of Herbal Ayurvedic Drugs
For Global Competitiveness:

**Raw materials**
- Authentication
- Physico, chemical, biological limits
- Storage conditions
- Size/shape/right quality
- Chromatographic fingerprint

**Process**
- Material/energy inputs
- Operational uniformity
- Safety and occupational health
- Intermediate quality [in process quality control]
- Chromatographic fingerprint

**Product**
- Organoleptic
- Chromatographic fingerprint
- Assay [Chemical / biological]
- Storage stability
- User safety
- Packaging and labelling
- Physico chemical properties
STANDARDIZATION
HERBO-MINERAL
FORMULATIONS

Plant based Drugs

Animal by Product

Metals & Minerals
AIMS

CONTROL OF PRODUCT QUALITY IN TERMS OF:

- Identity
- Purity
- Strength

• PLANT DRUGS -> UNPROCESSED PLANT PARTS AS DRUGS (PD)
Pharmacopoeial Standards of Ayurvedic Drugs

Reference: Pharmacopoeia of India (API) Monograph

1. Official name of the drug: Sanskrit/Ayurvedic

2. General Introduction:

3. Synonyms e.g., Regional names etc.

4. Description:
   (a) Macroscopic description
   (b) Microscopic (Pharmacognostic), description
       - Root
       - Flower
       - Stem
       - Fruit
       - Leaf
       - Seed

5. Powder - diagnostic features

6. Chemical constituents
Standards of Identity, Purity and Strength

Foreign matter - not more than.....%  
Total Ash - not more than.....%  
Acid insoluble ash - not more than....%  
Alcohol soluble extraction - not less than....%  

T.L.C. (IDENTITY TEST) (with method & description)

Assay method of major chemical constituent

Properties and Action:

(i) Rasa (Taste)  
(ii) Guna (Properties)  
(iii) Virya (Predominant action)  
(iv) Vipaka (Metabolic action)  
(v) Karma (Pharmacological action)
Test for Heavy Metals Limits

Microbial Load Limits

Aflatoxins

Important Formulations:

Therapeutic Uses:

Dose:

Authentic/Textual References
Outline of a pharmacopoeial monograph on mineral and metal-based raw drugs

- Title-Official Ayurvedic name and English name
- Definition
- Synonyms, Samskrta name/other languages
- Broad Classification
- Origin and Occurrence
- Physical Properties
- Chemical properties
- Assay of element metal
- Heavy metals and Arsenic
- Other elements (naturally appearing in the ore)
- Sodhana (purification/detoxification of material)
- Dose of Bhasma (calcinated material)
- Important formulations in which Bhasma is one of the ingredients
## Major Metals and Ores

<table>
<thead>
<tr>
<th></th>
<th>Name</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kanta Lauha</td>
<td>Iron Ore</td>
</tr>
<tr>
<td>2</td>
<td>Mandura</td>
<td>Iron Slag</td>
</tr>
<tr>
<td>3</td>
<td>Rajata</td>
<td>Silver Metal</td>
</tr>
<tr>
<td>4</td>
<td>Svarna</td>
<td>Gold Metal</td>
</tr>
<tr>
<td>5</td>
<td>Svarnamakshika</td>
<td>Copper Ore</td>
</tr>
<tr>
<td>6</td>
<td>Tamra</td>
<td>Copper Metal</td>
</tr>
<tr>
<td>7</td>
<td>Yashada</td>
<td>Zinc Metal</td>
</tr>
<tr>
<td>8</td>
<td>Banga</td>
<td>Tin Metal</td>
</tr>
<tr>
<td>9</td>
<td>Naga</td>
<td>Lead Metal</td>
</tr>
<tr>
<td>1. Abharaka</td>
<td>Mica</td>
<td></td>
</tr>
<tr>
<td>2. Gairika</td>
<td>Red Ochre</td>
<td></td>
</tr>
<tr>
<td>3. Gandhaka</td>
<td>Sulphur</td>
<td></td>
</tr>
<tr>
<td>4. Godanti</td>
<td>Selenite</td>
<td></td>
</tr>
<tr>
<td>5. Jawaharmohra</td>
<td>Serpentine</td>
<td></td>
</tr>
<tr>
<td>6. Khatika</td>
<td>Kaolinite</td>
<td></td>
</tr>
<tr>
<td>7. Tankana</td>
<td>Borax</td>
<td></td>
</tr>
<tr>
<td>8. Saindhava Lavana</td>
<td>Rock Salt</td>
<td></td>
</tr>
</tbody>
</table>
Concept of Shodhana (Purification & Detoxification of the Raw Drugs)

Objects to ensure Safety:

1. To remove the undesirous toxic effect of raw drugs.
2. To add additional properties to the drug.
3. To make the drug suitable as medicine.
4. The purification is done by various processes of mixing, boiling of the raw drug with other substances with specific properties, Drying etc.
5. Juices/decoctions of various herbs etc. is used.
Bhasma/Incineration
Compounds of minerals & metals

- Metals and minerals are converted in Micro-fine powder/Ash of various compounds like Oxides, Sulphides etc. These are herbo-metallic legends.

- This is archived by putting material on fire. One such cycle is called Puta

- The number of Puta required are according to nature of the Material (Heat-susceptibility) which may varies with metal from 30, 50, 100 upto 1000.

- Bhasma powders do not contain free metal in elemental form and the products are assimiable in human body quite safely.

  - Bhasmas & Rasaushadhes are fast acting potent medicines.

  - Pharmacopoeial standards of 21 Metals Minerals has been published
Concept of Bhasma and Rasaushadhasies
(Herbo-metallic formulations)

Conversion of Metals – into Herbo-metallic legends by rigorous processing

• Purification of metals with different material by grinding and heating etc,
• Burning of Metals into ashes by Furnaces.
• Trituration of Metal ash with the juice of medicinal plants repeatedly
• repeatedly burning into ashes 50-100 times
• Final product is free from elementary metal and suitable for medicinal purpose in a small dose.
KĀNTA LAUHA (Iron Ore)

- *Kānta Lauha* is an Iron ore containing magnetite, a ferric oxide (Fe$_3$O$_4$).
- **Broad Classification:** Oxide
### Physical Properties:

<table>
<thead>
<tr>
<th>Nature</th>
<th>Lump</th>
<th>Lustre</th>
<th>Metallic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Greyish black</td>
<td>Tenacity</td>
<td>Brittle</td>
</tr>
<tr>
<td>Streak</td>
<td>Reddish black</td>
<td>Transparency</td>
<td>Opaque</td>
</tr>
<tr>
<td>Cleavage</td>
<td>None</td>
<td>Hardness</td>
<td>5.5 to 6</td>
</tr>
<tr>
<td>Fracture</td>
<td>Uneven</td>
<td>Sp. Gr</td>
<td>5 to 6</td>
</tr>
<tr>
<td>Magnetism</td>
<td>Magnetic in nature</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Chemical Properties:

| Assay (Not less than) | 60% Iron (Fe) | | |
|-----------------------|---------------|-------------------|
| **Heavy Metals & Arsenic** (Not more than) | Arsenic = 2 ppm | Cadmium = 7 ppm |
| Other Elements may contain ± 20% of these limits | Zinc = 95 ppm | Manganese = 500 ppm | Silver = 5 ppm |
Kānta Lauha Shodhana (Detoxification)

- **Śodhana (Detoxification):** Shall not be used in formulations without subjecting it to śodhana.
- *Kānta Lauha* is used in the form of *bhasma* in Herbo-Mineral formulation.
  - Kantalauha-patra QS
  - Taila (Seed oil of *Seasamum indicum*) QS nirvapana - 3 times
  - Takra (Buttermilk from cow’s milk) QS nirvapana - 3 times
  - Kanjika (Sour rice gruel) QS nirvapana - 3 times
  - Gomutra (Cow urine) QS nirvapana - 3 times
  - Kulattha-Kvatha QS nirvapana - 3 times
    (Decoction of seeds of *Dolichos biflorus*)

Kanta Lauha is converted into Bhasma by putting on fire repeatedly (Puttas)

- **The number of Putta required for Bhasma- 60**
  *(Putta means repeated fire cycled to material)*
RAJATA (Silver metal)

- *Rajata* (Ag) is a silver-white metal available in the form of ingots.
- **Broad Classification**  Metal
### Physical properties:

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Granular, nuggets and feather like dendrites</td>
</tr>
<tr>
<td>Colour</td>
<td>Silver white, turning greyish black due to tarnishing</td>
</tr>
<tr>
<td>Streak</td>
<td>White</td>
</tr>
<tr>
<td>Cleavage</td>
<td>None</td>
</tr>
<tr>
<td>Fracture</td>
<td>Hackly</td>
</tr>
<tr>
<td>Lustre</td>
<td>Metallic</td>
</tr>
<tr>
<td>Tenacity</td>
<td>Sectile, ductile and malleable</td>
</tr>
<tr>
<td>Transparency</td>
<td>Opaque</td>
</tr>
<tr>
<td>Hardness</td>
<td>2.5 to 3.0</td>
</tr>
<tr>
<td>Sp. Gr</td>
<td>10.1 to 11.1</td>
</tr>
</tbody>
</table>

### Chemical Properties:

<table>
<thead>
<tr>
<th>Assay (Not less than)</th>
<th>98.5% Silver (Ag)</th>
<th>Heavy Metals &amp; Arsenic (absent)</th>
<th>Mercury</th>
<th>Lead</th>
<th>Arsenic</th>
<th>Cadmium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Elements</td>
<td>Copper=1.40 %</td>
<td>Sulphur=traces</td>
<td>Gold= 0.001%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>may contain ± 20% of these limits</td>
<td></td>
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</tbody>
</table>
RAJATA SHODHANA (Detoxification)

Samanya Shodhana (General Procedure)

Śodhana (Detoxification): Shall not be used in formulations without subjecting it to śodhana.

- **Rajata** is used in the form of *bhasma* in the Herbo-mineral formulation.
- **Rajata-patra** (Silver foils or turnings)
- **Taila** (Seed oil of *Seasamum indicum*) Q.S nirvapana - 3 times
- **Takra** (Buttermilk from cow’s milk) Q.S nirvapana - 3 times
- **Kanjika** (Sour rice gruel) Q.S nirvapana - 3 times
- **Gomutra** (Cow urine) Q.S nirvapana - 3 times
- **Kulattha-Kvatha** (Decoction of seeds of *Dolichos biflorus*) Q.S nirvapana - 3 times

Vishesha Shodhana (Specific Procedure)

- **Rajata-shuddha** (Detoxified silver metal)
- **Agastya svarasa** Q.S. for nirvapana – 3 times
  (Juice of leaves of *Sesbania grandiflora*)
- **The number of Putta required for Bhasma- 10**
  (Putta means repeated fire cycled to material)
Svarnamaksika (Copper Ore)

- *Svarnamaksika* is a copper ore containing Chalcopyrite (CuFeS2) mineral.
- Broad classification: Sulphide
### Physical Properties:

<table>
<thead>
<tr>
<th>Nature</th>
<th>Massive, smooth</th>
<th>Lustre</th>
<th>Metallic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Golden yellow</td>
<td>Tenacity</td>
<td>Brittle</td>
</tr>
<tr>
<td>Streak</td>
<td>Greenish black</td>
<td>Transparency</td>
<td>Opaque</td>
</tr>
<tr>
<td>Fracture</td>
<td>Uneven</td>
<td>Hardness</td>
<td>3 to 4</td>
</tr>
<tr>
<td>Sp. Gr</td>
<td>3.4 to 3.7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Chemical properties:

<table>
<thead>
<tr>
<th>Assay</th>
<th>5% Copper (Cu)</th>
<th>20% Iron</th>
<th>12% Sulphur</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Not less than)</td>
<td>Lead = 70 ppm</td>
<td>Arsenic = 1 ppm</td>
<td>Cadmium = 3 ppm</td>
</tr>
<tr>
<td>Heavy Metals &amp; Arsenic (Not more than)</td>
<td>Gold = 0.70 ppm</td>
<td>Silver = 48 ppm</td>
<td>Zinc = 800 ppm</td>
</tr>
<tr>
<td>Other Elements may contain ± 20% of these limits</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SVARNAMAKSHIKA SHODHANA (Detoxification)

- Şodhana (Detoxification): Shall not be used in formulations without subjecting it to şodhana
- Svarnamaksika is used in the form of bhasma in Herbo Mineral formulation.
- Suvarna makshika (Chalcopyrite)
- Nimbuka svarasa Q.S. for svedana (impregnation) (2–3 days)
  (Juice of fruits of Citrus limon)
- The number of Putta required for Bhasma- 10 (Putta means repeated fire cycled to material)
TĀMRA (Copper Metal)

- *Tamra* is the end product of the metallurgical process of Copper ore. It is available in the form of wires, sheets or rods of Copper which is produced by an electrolytic process.
- **Broad Classification**  Metal
### Physical properties:

<table>
<thead>
<tr>
<th>Nature</th>
<th>Plates, wires or rods; can be bent by hand</th>
<th>Lustre</th>
<th>Metallic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Copper red</td>
<td>Tenacity</td>
<td>Malleable</td>
</tr>
<tr>
<td>Streak</td>
<td>Copper red</td>
<td>Transparency</td>
<td>Opaque</td>
</tr>
<tr>
<td>Fracture</td>
<td>Hackly</td>
<td>Hardness</td>
<td>2.5 to 3.0</td>
</tr>
<tr>
<td>Cleavage</td>
<td>None</td>
<td>Sp. Gr</td>
<td>8 to 9</td>
</tr>
</tbody>
</table>

### Chemical Properties:

<table>
<thead>
<tr>
<th>Assay (Not less than)</th>
<th>99.5% Copper (Cu)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heavy Metals &amp; Arsenic (Not more than)</strong></td>
<td>Lead = 5 ppm</td>
<td>Arsenic = 1 ppm</td>
<td>Cadmium = 5 ppm</td>
</tr>
<tr>
<td>Other Elements may contain ± 20% of these limits</td>
<td>Zinc = 25 ppm</td>
<td>Silver = 10 ppm</td>
<td>Gold = 135 ppb</td>
</tr>
</tbody>
</table>
TAMRA SHODHANA (Detoxification)
Samanya Shodhana (General Procedure)

- Śodhana (Detoxification): Shall not be used in formulations without subjecting it to śodhana
- Tāmra is used in the form of bhasma in Herbo-Mineral formulation.
- Tamra-patra (Foils or turnings of copper)
- Taila (Seed oil of *Seasamum indicum*) QS nirvapana - 3 times
- Takra (Buttermilk from cow’s milk) QS nirvapana - 3 times
- Kanjika (Sour rice gruel) QS nirvapana - 3 times
- Gomutra (Cow urine) QS nirvapana - 3 times
- Kulattha-Kvatha QS nirvapana - 3 times
  (Decoction of seeds of *Dolichos biflorus*)

Vishesa Shodhana (Specific Procedure)

- Tamra- shuddha (Detoxified)
- Snuhi kshira (Latex of *Euphorbia neriifolia*) QS for lepana - 3 times
- Arka kshira (Latex of *Calotropis procera*) QS for lepana - 3 times
- Saindhava (Rock salt) QS for lepana - 3 times
- Nirgundi rasa (juice of leaves of *Vitex nigundo*) QS for quenching - 3 times
- *The number of Putta required for Bhasma- 10*
  *(Putta means repeated fire cycled to material)*
Pharmacopoeial Standards of Multiple Ingredient Ayurvedic Formulations

1. To develop SOP’s of manufacturing process of formulation
2. To develop standards of identity, purity and strength of ingredients & compound formulation
3. Pharmacognostic & chemical standardization Shelf life studies
4. Twenty Laboratories & manufacturing companies are working on SOP’s
5. Pharmacopoeial Standards of 101 formulation have been published.
6. Annual Target is 50 formulations per year to cover 500 most widely used formulations.
## DOSAGE FORMS OF AYURVEDIC FORMULATIONS

<table>
<thead>
<tr>
<th>S.No</th>
<th>Dosage Form</th>
<th>No. of ingredients</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Swarasa (Expressed Juice)</td>
<td>1-3</td>
<td>5-10 ml</td>
</tr>
<tr>
<td>2.</td>
<td>Churna (Powder of the combination)</td>
<td>3-20</td>
<td>3-5 gm</td>
</tr>
<tr>
<td>3.</td>
<td>Kwath Churna (Coarse powder for making fresh decoction)</td>
<td>3-5 gm</td>
<td>10-30 gm</td>
</tr>
<tr>
<td>4.</td>
<td>Pravahi Kwath (Preserved decoction in liquid form- ready for use)</td>
<td>3-20</td>
<td>10-20 ml</td>
</tr>
<tr>
<td>5.</td>
<td>Asava and Arishta (Fermented liquids – multiple ingredients)</td>
<td>5-20</td>
<td>20-30 ml</td>
</tr>
<tr>
<td>6.</td>
<td>Arka (Distilled medicated water)</td>
<td>1-3</td>
<td>10-20 ml</td>
</tr>
<tr>
<td>7.</td>
<td>Avaleha (Jam like preparation)</td>
<td>10-50</td>
<td>5-10 gm</td>
</tr>
<tr>
<td>8.</td>
<td>Paka Khand (Confectionary like preparation)</td>
<td>10-25</td>
<td>5-10 gm</td>
</tr>
<tr>
<td>9.</td>
<td>Guggulu (Commiphora wittii based preparation)</td>
<td>5-20</td>
<td>1-3 gm</td>
</tr>
<tr>
<td>10.</td>
<td>Ghrita (Clarified butter based preparation)</td>
<td>5-20</td>
<td>5-10 gm</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Quantity</td>
<td>Formulation</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
<td>----------</td>
<td>-------------------</td>
</tr>
<tr>
<td>11.</td>
<td>Taila (Medicated/oil based preparation)</td>
<td>10-20</td>
<td>External QS</td>
</tr>
<tr>
<td>12.</td>
<td>Lepa (For external applications)</td>
<td>5-15</td>
<td>External QS</td>
</tr>
<tr>
<td>13.</td>
<td>Malhara (Ointment)</td>
<td>3-5</td>
<td>External QS</td>
</tr>
<tr>
<td>14.</td>
<td>Satva/Ghansatva extracts</td>
<td>1-3</td>
<td>1/2 - 1 gm</td>
</tr>
<tr>
<td>15.</td>
<td>Vati/Gutika (tablet/pill)</td>
<td>5-20</td>
<td>1/2 - 1 gm.</td>
</tr>
<tr>
<td>16.</td>
<td>Panaka (syrups)</td>
<td>5-15</td>
<td>10-20 ml</td>
</tr>
<tr>
<td>17.</td>
<td>Capsules</td>
<td>5-10</td>
<td>2</td>
</tr>
<tr>
<td>18.</td>
<td>Aaschayotana (Eye drops)</td>
<td>3-5</td>
<td>2-3 drops</td>
</tr>
<tr>
<td>19.</td>
<td>Karn bindu (Ear drops)</td>
<td>5-10</td>
<td>2-6 drops</td>
</tr>
<tr>
<td>20.</td>
<td>Nasaya (Nasal drops/ insuflation)</td>
<td>5-10</td>
<td>2-4 drops</td>
</tr>
<tr>
<td></td>
<td>Bhasma - <em>(Calcinated ash)</em>; (i) Mineral based ash (ii)(ii) Metal based ash</td>
<td>1-3</td>
<td>50-100 mg</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>21.</td>
<td>Lauh &amp; Mandora <em>(Iron ash based formulations)</em>;</td>
<td>5-20</td>
<td>1gm</td>
</tr>
<tr>
<td>22.</td>
<td>Ras Yoga (i) Kupipakva Rasayan &amp; Parpati - <em>(Special Metallic compounds with Sulphur)</em> (ii) Rasayoga – <em>(Herbo-mineral metallic formulations)</em></td>
<td>2-5</td>
<td>50-100 mg</td>
</tr>
<tr>
<td>23.</td>
<td></td>
<td>2-5</td>
<td>30-60 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5-20</td>
<td>125-250</td>
</tr>
</tbody>
</table>
### Srngyadi Curna

<table>
<thead>
<tr>
<th></th>
<th>Herbal Ingredient</th>
<th>Name</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Srngi (Karkata srngi)</td>
<td><em>Pistacia integerrima</em></td>
<td>Gl.</td>
</tr>
<tr>
<td>2</td>
<td>Prativisa</td>
<td><em>Aconitum palmatum</em></td>
<td>Rt. Tr.</td>
</tr>
<tr>
<td>3</td>
<td>Krsna (Pippali)</td>
<td><em>Piper longum</em></td>
<td>Fr.</td>
</tr>
</tbody>
</table>
TLC of Srngyādi Cūrṇa

Under UV 254 nm

1- Prativisa (Root)  Alcoholic Extract
2- Pippali (Fruit)  Alcoholic Extract
3- Sryngyagi Curna  Alcoholic Extract
4- Srngi (Gall)  Alcoholic Extract

Mobile Phase – Toluene: Ethyl acetate: Formic acid (5:4.5:0.5)
Under UV 366 nm

1- Prativisa (Root) Alcoholic Extract
2- Pippali (Fruit) Alcoholic Extract
3- Sryngyagi Curna Alcoholic Extract
4- Srngi (Gall) Alcoholic Extract

Mobile Phase – Toluene: Ethyl acetate: Formic acid (5:4.5:0.5)
After Derivatization with Anisaldehyde - Sulphuric acid
Powder Microscopy of Srngyādi Cūrna
THIN LAYER CHROMATOGRAM OF CHITRAKADI VATI

Tracks:
- T1 - Ajamoda (Apium graveolens)
- T2 - Pippali (Piper longum)
- T3 - Chitraka (Plumbago zeylanica)
- T4 - Chitrakadi vati (RRL, Bhu)
- T5 - Chitrakadi Vati (Baidyanath)
- T6 - Chavya (Piper chaba)
- T7 - Sunthi (Zingiber officinale)
- T8 - Pippali mula (Piper longum - Root)
- T9 - Maricha (Piper nigrum)
- T10 - Hingu (Ferula assafoetida)

Solvent System:
- n-Hexane : Acetone
  - 7.5 : 2.5

Visualisation:
- Anisaldehyde - Sulphuric acid Reagent
HPTLC Fingerprinting of Chitrakadi Vati (RRL, Bhu) at 254 nm
THIN LAYER CHROMATOGRAM OF LASUNADI VATI

Tracks:
- \( T_1 \) – Lasunadi vati, RRL(Bhu)
- \( T_2 \) – Hingu (Ferula assafoetida)
- \( T_3 \) – Safeda jeeraka (Cuminum cyminum)
- \( T_4 \) – Maricha (Piper nigrum)
- \( T_5 \) – Pippali (Piper longum)
- \( T_6 \) – Sunthi (Zingiber officinale)
- \( T_7 \) – Lasunadi vati, Baidyanath

Solvent System:
- n-Hexane : Acetone
  - 7.6 : 2.4

Spray:
- Anisaldehyde - sulphuric acid reagent
HPTLC Fingerprinting of Lasunadi Vati (RRL, Bhu) at 254 nm
THIN LAYER CHROMATOGRAM OF MARICHYADI VATI

Tracks:
- $T_1$ – Marichyadi vati, RRL(Bhu)
- $T_2$ – Marichyadi vati, Baidyanath
- $T_3$ – Marichyadi vati, Without Jaggery,
- $T_4$ – Maricha ($Piper nigrum$)
- $T_5$ – Pippali ($Piper longum$)
- $T_6$ – Dadima ($Punica granatum$)

Solvent System:
Ethyl acetate : n-Hexane : Formic acid
4 : 6 : 0.1

Visualisation:
UV 254 nm
AROGYAVARDHINI VATI (Tablet)
Herbo metallic Formulations

1. Rasa (parada) suddha (Mercury) 1/44 parts
2. Gandhaka-suddha (Sulphur) 1/44 parts
3. Lauha-bhasma (Iron) 1/44 parts
4. Abhra (abhraka)-bhasma (Mica) 1/44 parts
5. Sulva (tamra)-bhasma (Copper) 1/44 parts
6. Haritaki (Terminalia C) 2/44 parts
7. Bibhitaka (Terminalia B) 2/44 parts
8. Amalaki (Emblica officinalis) 2/44 parts
9. Silajatu-suddha (Asphaltum) 3/44 parts
10. Pura (guggulu) –suddha(Oleo raisin) 4/44 parts
11. Citra (Eranda) 4/44 parts
12. Tikta (Katuka) (Picorrhiza) 22/44 parts
13. Nimba vrksa dalambha (Neem leaves) QS
14. (nimba)-svarasa (Neem leaves juice)

One Tablet 250 mg. contains 4 mg. Hgs and daily dose will contain 8 mg of HgS.
STANDARDIZED DRUG

Various Process → Multiple Ingredient

Diversity in Raw Material

Desired Activity
Rationale of Poly-herbal formulation in Ayurveda

Drug-Body interaction

Drug

↓

Crude

↓

Extract

↓

Molecules

→

Body

↓

Targets (receptors)

↓

Multiple targets
• Molecules follow specific pathway and act on specific receptor.

2. In Disease condition, multiple organ systems are involved.

3. Therefore, drug should have a multiple targeted action.

4. Internal chemical involvement significantly varies from person to person.

5. Combination of different herbs targets the different site of action.

6. Therefore, Ayurveda has emphasized biological standardization considering the individual Psycho-somatic make up.
Woods are Lovely Dark & Deep

But

I have Yet Promises to Keep

And

Miles to Go Ahead Before I Sleep

No More Never More

William Wordsworth
THANKS