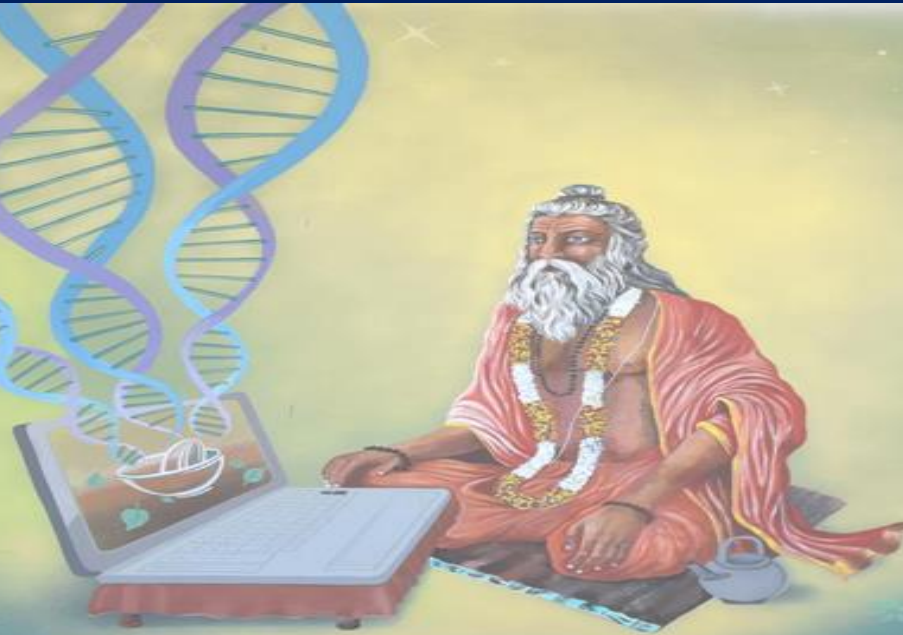


Quality Considerations for Global Recognition of Indian Herbal Medicines - A Critical Appraisal

KLE AYURVEDA
Tradition
Technology
Innovation



By
PROF. (DR.) CHANDRAKANT KOKATE
Vice – Chancellor
KLE University
(Accredited "A" By NAAC)
Belagavi– 590 010, Karnataka

Herbal Drug Industry – Some Facts

- ❖ Fastest growing industry
- ❖ Europe leads world market followed by Asia and North America
- ❖ Within Europe, Germany leads the market, followed by France, Italy, UK & Spain
- ❖ Annual per capita consumption in Germany is US \$ 42.9
- ❖ World Bank estimated Global Trade in M & AP & their products at US \$ 5 Trillion by 2050 A.D
- ❖ Global Market today is around \$ 70.5 Billion with average annual growth of 10-12 %

Global Market for Herbal Drugs (2011–12)

Total \$ 80 Billion (Approx.) Annual Growth Rate
around 12 % Global Share of Market

Continent	Percentage
Europe Union	45%
Rest of Europe	04%
Asia	19%
North America	10%
Others	22%

Herbal Medicine: Indian Context

- Around us \$ 3500 million worth Herbal medicines annually
- Approximately 1200 single ingredient and 10500 Polyherbal formulations registered
- 65 % of herbal medicines categorized as Ayurvedic medicines (time - tested)

Why Herbals ?

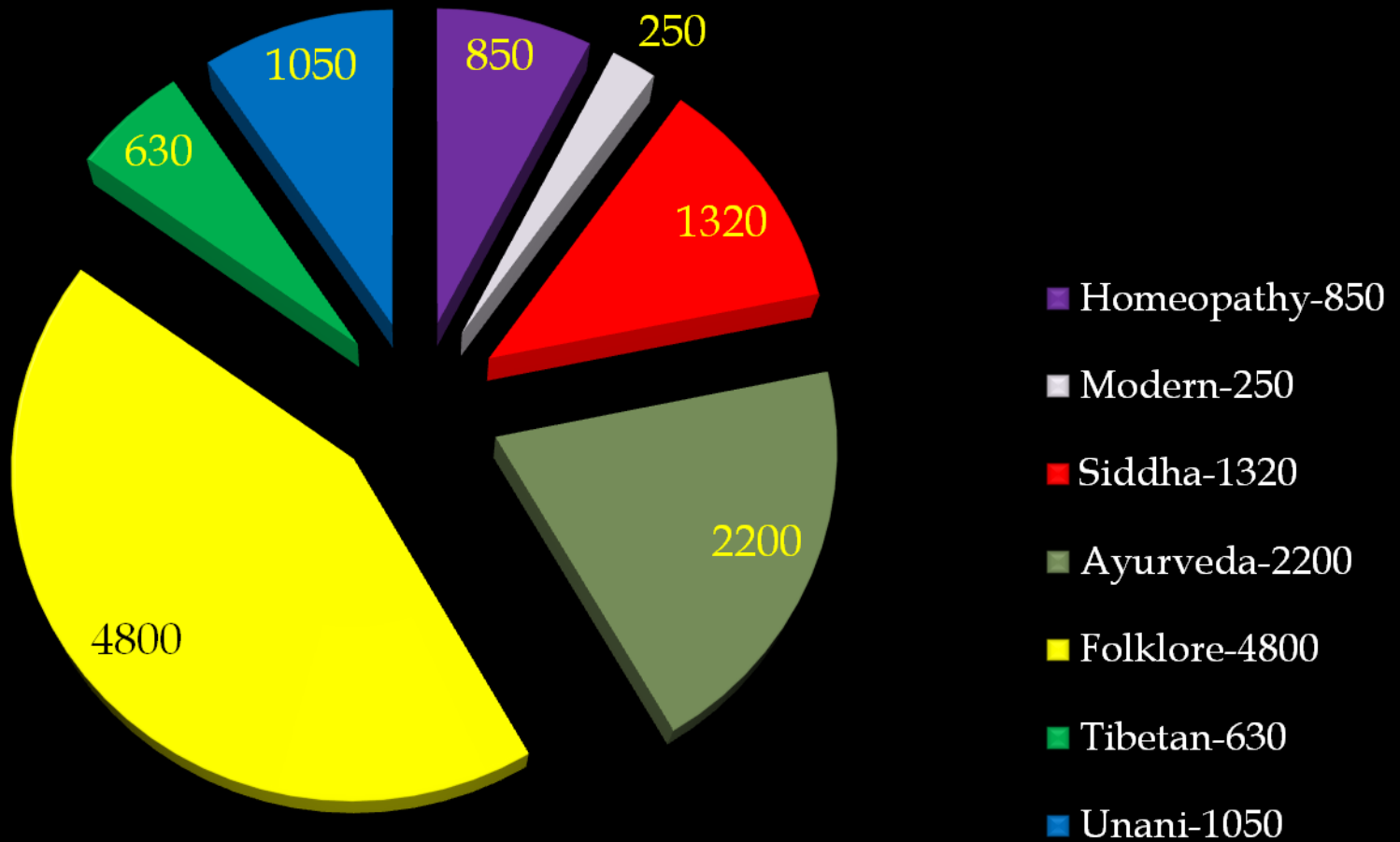
- Traditionally Established
- Economically Affordable
- Easy Procurement of Raw Material
- Green Pharmacy – Eco-friendly Products
- Comparatively Less Toxic
- Very Effective in Chronic Diseases

Indian Systems of Medicine

- ❖ **AYURVEDA**
 - ❖ **YOGA**
 - ❖ **UNANI**
 - ❖ **SIDDHA**
 - ❖ **HOMEOPATHY**
 - ❖ **NATUROPATHY**
 - ❖ **AMCHI (TIBETAN SYSTEM)**
- AYUSH**



Number of Medicinal Plants used in Indian Systems of Healthcare (11,100)



Ecosystem and Biodiversity in India

- One amongst top 12 mega - diversity countries in world
- Out of 18 hot spots of bio-diversity, 2 exist in India
- Fifteen Agro-Climatic Zones
- Twenty Five Biotic Provinces

Important Herbal Drugs Marketed in USA & Europe

Ginkgo, Garlic, Ginseng, St.John's Wort, Hops,
Passion Flower, Aloe-Vera, Senna, Rhubarb,
Isabgol, Soya, Isoflavones, Lycopene, Valerian,
Nutraceuticals and Herbal Antioxidants.

Global Demand for Plant – Derived Drugs

- **Terpenoids** - Taxoids, Steroids
- **Glycosides** - Flavonoids, Saponins,
Anthraquinones, Digitalis, Ginseng
- **Alkaloids** - Belladonna, Vinca, Camptotheca,
Poppy, Cinchona, Ergot, Rauwolfia,
Ipecac, Tobacco

Recent Herbal Drugs In World Market

- **Arteether – *Artemisia annua* – Antimalarial**
- **Galanthamine – *Galanthus woronowii* – Alzheimer's disease**
- **Nitisinone – *Callistemon citrinus* – prevents accumulation of toxic bioproducts in kidney and liver.**
- **Tiotropium – *Atropa bellonna* – in chronic obstructive pulmonary disease (as inhaled anticholinergic bronchodilator)**

Bioactive Ingredients As Emerging Nutraceuticals

- ❖ Bioactive Proteins & Peptides
- ❖ Dietary Fibres
- ❖ Phytochemical- Antioxidants
- ❖ Polyunsaturated Fatty Acids
- ❖ Pre and Probiotics

Important Indian Herbal Drugs for Global Trade

- ALOE – VERA



- ASHWAGANDHA



- CURCUMA



- GARLIC



- ISAPGOL



- LEMON GRASS



- AMLA



- BRAHMI



- DIOSCOREA



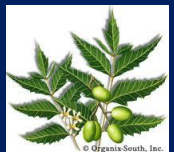
- HENNA



- KALMEGH



- NEEM



Continued....

- NUTMEG



- POPPY



- SAFFRON



- SENNA



- SHATAVARI



- TERMINALIA



- VIDANG



- PAPAYA



- RAUWOLFIA



- SANDALWOOD



- SHANKHAPUSHPI



- SOLANUM



- TULSI



- VINCA



Herbal Extract is Influenced by -

Plant Material Used

- ❖ Origin
- ❖ Nature of Plant Material
- ❖ Size of Plant Material
- ❖ Moisture Content
- ❖ Degree of Processing

Quality of Solvent

- ❖ Nature
- ❖ Polarity
- ❖ Concentration

Continued....

Manufacturing Equipment & Process

- ❖ Batch size
- ❖ Hydrostatic pressure
- ❖ Time
- ❖ Temperature
- ❖ Type of Extract

Critical Observations About Herbals

- **Misconception that all herbals are safe**
- **Mistaken use of wrong species**
- **Adulteration with other medicines and potent chemical substances**
- **Poor quality formulations**
- **Innate toxicity**
- **Interaction with other medicines**
- **Incorrect dosing**
- **False claims**
- **Misuse by healthcare providers and consumers**

Herbal Formulations: Problems Encountered for QC & QA

- ❑ **Clinical trial is not a regulatory requirement**
- ❑ **No emphasis on consistent quality**
- ❑ **Poor Pharmacovigilance product**
- ❑ **Analytical problems are acute**
- ❑ **Poorly designed protocols**
- ❑ **Poor documentation and statistically poor information**
- ❑ **Improper monitoring of quality of clinical trials**

Need of The Hour

3 C's

- **Comprehensive vision**
- **Conviction of abilities**
- **Commitment to objectives**

Basic Requirements for Crude – Drug Utility

- ♦ **Authenticity (Genuinity)**
- ♦ **Efficacy**
- ♦ **Validity (Clinical)**
- ♦ **Safety**
- ♦ **Microbial Load on Drug**
- ♦ **Pesticidal Residue on Drug**
- ♦ **Heavy Metal Content of Formulation**

Quality Parameters

- ❖ Clear Scientific Definition
- ❖ Proof of Identity
 - Macroscopic, Microscopic
 - Organoleptic, Diagnostic Features
 - Finger Print Chromatograms



Continued....

Quality Parameters

•Purity

- Moisture content
- Ash values
- Physical constants
- Extractive values
- Solvent residue (in case of extracts)
- Microbial material
- Heavy metals
- Pesticide residues
- Aflatoxins



Continued....

Quality Parameters

- Radioactivity suspected
- Adulteration / Substitution
- Content of Active Principles or Lead Markers
- Bio-activity Profile



Export Of Herbal Products [Mandatory Requirements]

- 1) NAME OF PRODUCT**
- 2) NAME OF COMPANY / MANUFACTURER**
- 3) MFG. LIC. NO. AND DATE**
- 4) COMPOSITION DETAILS**
- 5) DETAILS OF EXTRACTS USED IN PRODUCT**
 - NAME OF EXTRACT**
 - SOLVENT USED**
 - RATIO OF EXTRACT TO RAW MATERIALS**

Continued....

6) SAFETY LIMITS FOLLOWED

- ☐ **HEAVY METALS**
- ☐ **PESTICIDE RESIDUE**
- ☐ **MICROBIAL CONTENT**
- ☐ **ANY OTHER SAFETY TEST CARRIED**

7) HERBAL & MODERN DRUG INTERACTION

8) PHARMACOVIGILANCE TO STRENGTHEN CREDIBILITY OF HERBAL DRUGS

Good Practices for Better Results

- ❖ **Good Agricultural Practices (GAP)**
- ❖ **Good Storage Practices (GSP)**
- ❖ **Good Manufacturing Practices (GMP)**
- ❖ **Good Laboratory Practices (GLP)**
- ❖ **Good Clinical Practices (GCP)**

“ The Vision of providing affordable and effective healthcare to our entire population goes much beyond the capacity of any individual, institution or organization.

Technology is an important tool to give fast health care and we have to use it. ”

- Dr.A.P.J.ABDUL KALAM

At the inauguration of “The Charter for Pharma Vision-2020”,
unveiled at Chennai, 2003



KLE University, Belagavi

THANK YOU

Visit us @ www.kleuniversity.edu.in