Agilent Solutions

for

Traditional

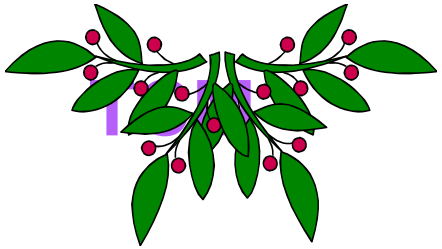
M

Ramaswami.R, General Manager-CAG

Agilent Technologies India.

Traditional Medicine in India

- Thousands of Plants are the basic resources or raw materials involved in Traditional Medicine
- Most of the products from India are marketed as “Food Supplements” and not medicines.
- Acceptability of these products as medicines need to be established by robust process, standardization and validation for incremental revenue growth.



Pharm. Industry

Collaborative Effort

Industry/Academia/University

1. Identify TCM active Component
2. Screen New Drug

Pharmaceutical Industry

1. Screen New Drug
2. Take Quality Control

Raw Material

- percentage of active/harmful component
- pesticide residual
- heavy metals

Final Drug Product

- percentage of active/harmful component
- heavy metals

Inspect of Drug Control/ Govt. Authority

1. Supervise Product Quality
2. Audit Chemical Additive

Agilent Application on TM

1. TM sample preparation & column selection
2. TM raw materials quality control(contaminant
3. LC/MS application on TM fingerprint library
4. Illegal chemical additives in TM
5. Innovative approach of TM analysis---2D LC/M

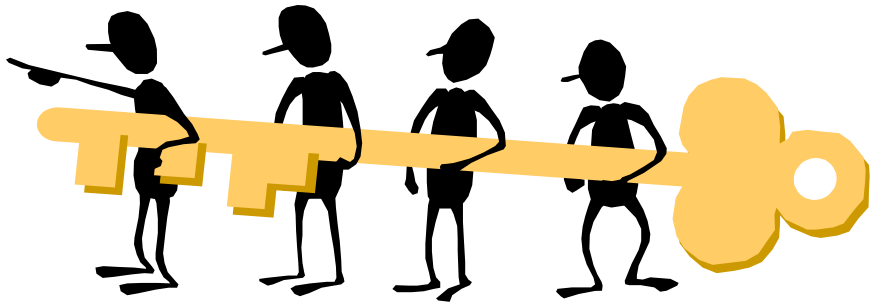
Appropriate column

Characters required by column fo M

- no tailing of basic compounds - ultra pure & low metal silica gel packing
- retain acid and base enough - high tolerance for wide mobile phase pH ran
- hydrophobic and hydrophilic compounds exist simultaneously - high queous mobile phase
- method reproduction - column life time long enough, efficiency decreasing owly
- Collect/isolate purified TM ingredient - seamless scaling-up from Analytica rep

Contaminants in TM

1. **mycotoxin**(HPLC, LC/MS)
   - aflatoxinB1, B2, G1, G2 and M1
   - patulin
2. **pesticide residue**(HPLC, LC/MS, GC-FPD/NPD/ECD/MSD)
   - Organophosphorous pesticide
   - Organochlorine pesticide
   - Carbamate
3. **heavy metals** (ICP-MS)
   - Al, Mg, Sb, Mn, As, Hg, Cd, Ni, Ca, K, Cr, Se, Cu, Na, Fe, Tl, P
     Sn, Li, Zn
4. **PHAs** (GC/MS)
5. **PCBs**(GC/MS)



Heavy metal assay needed ---TM nutrition

Growing from soils, TM plant absorbs harmful heavy metals such as As, Hg and Pb which employ fairly negative impact on human body metabolism. It can also help to check presence of useful elements in plants.

LC/MS on TM fingerprint library

TM matrix is fairly complex

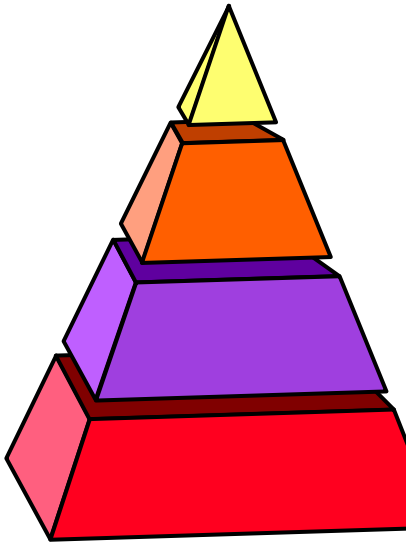
1. Employ multilevel mass spectrum to speculate on unknown structures from compounds known (same nuclear parent) ---Herbal Epimedii , Ginseng Saponin

2. Neutral loss screen ---Milkvetch Root

3. Extract Ion Chromatogram--- Herbal Epimedii

4. TIC fingerprint comparison--- Ginkgo Biloba L. Injection, Cordyceps, Mailuonin Injection

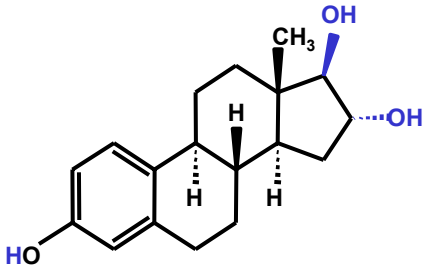
5. Positive/Negative ionization mode to complementary qualitative evaluate---Salvia Miltiorrhiza Bge.



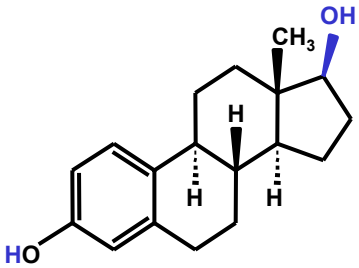
Illegal chemical additives in Traditional Medicine

Estrogenic Hormone Group

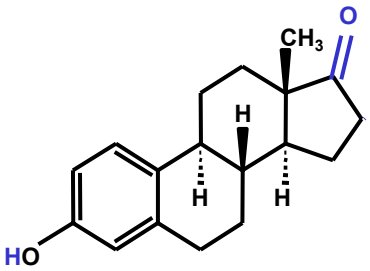
Develops a fast screening for the illicit adulterated chemicals in TCM



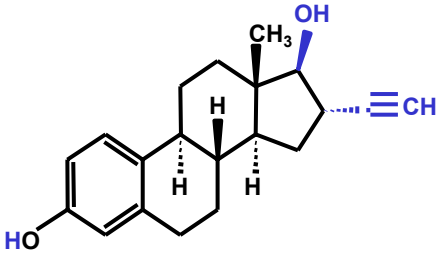
Estriol($C_{18}H_{24}O_3$, 288.4)



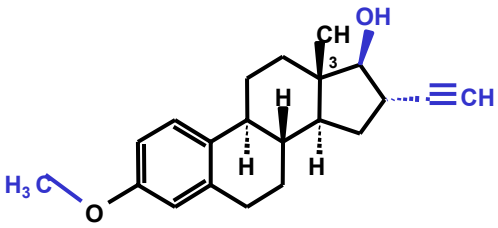
Estradiol($C_{18}H_{24}O_2$, 272.4)



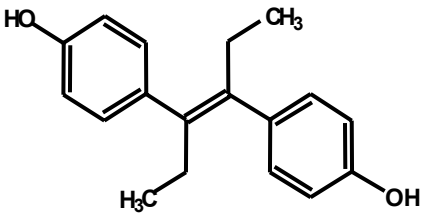
Estrone($C_{18}H_{22}O_2$, 270.4)



Ethinylestradiol($C_{20}H_{24}O_2$, 296.4)



Metranol($C_{21}H_{26}O_2$, 310.4)



Diethylstibestrol($C_{18}H_{20}O_2$, 268.4)

TM Solutions

LC/MS

ICP/MS

GC/MS

HPLC

CE

GC

Success Story

* Establishing Traditional Chinese Medicine (TCM) methods in the first Edition of Chinese Pharmacopeia with Chinese Pharmacopeia Commission (CPC).
* CPC Chairman acknowledging this work in his message and all solution configuration included in published Pharmacopeia.
* Work in progress for the second Edition now.
* CD available on all set methods using HPLC.

Agilent Technologies

THE ANALYSIS OF HERBAL MEDICINES & HEALTHCARE PRODUCTS

Analysis of Herbal Medicines and Healthcare Products Application Compendium from Agilent Technologies is a collection of applications on the analysis of traditional herbal medicines and healthcare products.

The applications are grouped according to the types of substances being analyzed. These include adulterants,pesticide residues, heavy metals, residual solvents, bioactive compounds and metabolites.

All applications featured in this compendium have been developed with complete solutions using Agilent analytical products, software and services.

The analytical techniques deployed include gas chromatography (GC), liquid chromatography (LC) and mass spectrometry (MS) as well as hybrid techniques such as GC/MS, LC/MS and ICP-MS. Further details about each solution can be found on xxxxxxxxxxxxxxxxxxxxxxxxxxx

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Agilent's History

- Agilent dates back to the earliest days of Hewlett-Packard, which started as a test and measurement company in 1939.
- On Nov. 1, 1999, Agilent started operating as an independent company.
- Agilent embodies historical commitment to innovation and contribution, uncompromising integrity, teamwork, trust and respect for the individual.

Bio Analytical Measurement

Value Proposition

We will help labs produce better results faster with:

- ❑ Broad portfolio of reliable products and workflow solutions
- ❑ Advice on applications and lab operations
- ❑ Easy to use, open software systems
- ❑ Responsive support, highest uptime and lowest cost of ownership

Our Measure is Your Success

Life Science & Chemical Analysis - India

Business Focus and Growth

- India is 3rd largest country of business in Asia by $ Revenue
- Highest and fastest growth rate
- LSCA business focused on:
  - Chemical analysis (Research Labs, Environmental, Food safety, Commercial Testing Labs, Traditional Medicine, Fine Chemicals etc)
  - Pharmaceutical analysis (drug development and drug manufacturing, QA/QC, CRO/CMO)
  - Genomics and Proteomics (Cancer Research, Agriculture…)

Agilent Facilities

- Sales, support and market offices in 7 cities
- More than 1,800 professionals
- World Class **"CENTRE OF EXCELLENCE"** customer training centre at Bangalore.
- Established **"GLOBAL R&D CENTRE"** in Bangalore.

World Class Agilent *Campus* at Manesar (near Gurgaon) ~ Mid 2010

Thanks !