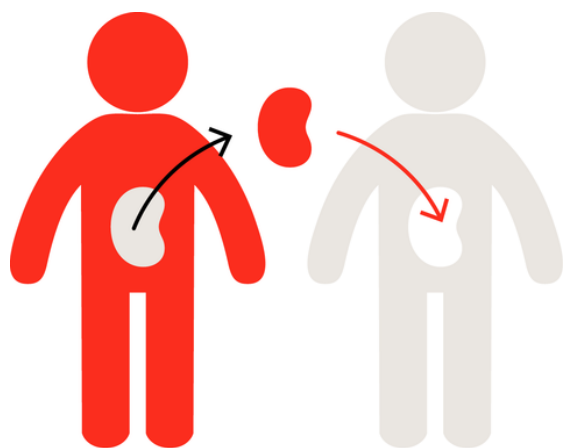


بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ



# Herbal Medicines



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**Associate Professor of Pharmacognosy**  
**Tabriz University of Medical Sciences**



# Herbal medicines... Harmless ?

- **Nowadays popular form of therapy**
- **Being natural & therefore harmless**



# Problems

- Allergic Reactions
- Toxic Reactions
- Mutagenic Effects
- Drug Interactions
- Contaminations
- Adverse Effects
- Mistaken Plant Identities



# Allergic Reactions

## □ Hypersensitivity reactions:

- Transient dermatitis >>> anaphylactic shock

i. Royal jelly → Bronchospasm

ii. Yohimbine → Lupus-like syndrome

iii. Cmpbor & Lvander & Jasmin

# Toxic Reactions

➤ **Flavonoids**



Hemolytic anemia  
Chronic diarrhea  
Severe nephropathy  
Colitis

➤ **Valerian root**



Liver toxicity & Acute hepatitis

Alkylating agents >>> inhibit thymidine incorporation into DNA  
>>> impaired mitochondrial function

➤ ***Aristolochia spp.***



Renal fibrosis & failure

➤ **Pyrrolizidine alkaloids**



Hepatotoxicity & Liver cancer

# Mutagenic Effects

## ☐ Anthranoid laxatives

- *Aloe spp.*, *Cascara spp.*, *Frangula spp.*, *Rhubarb senna*

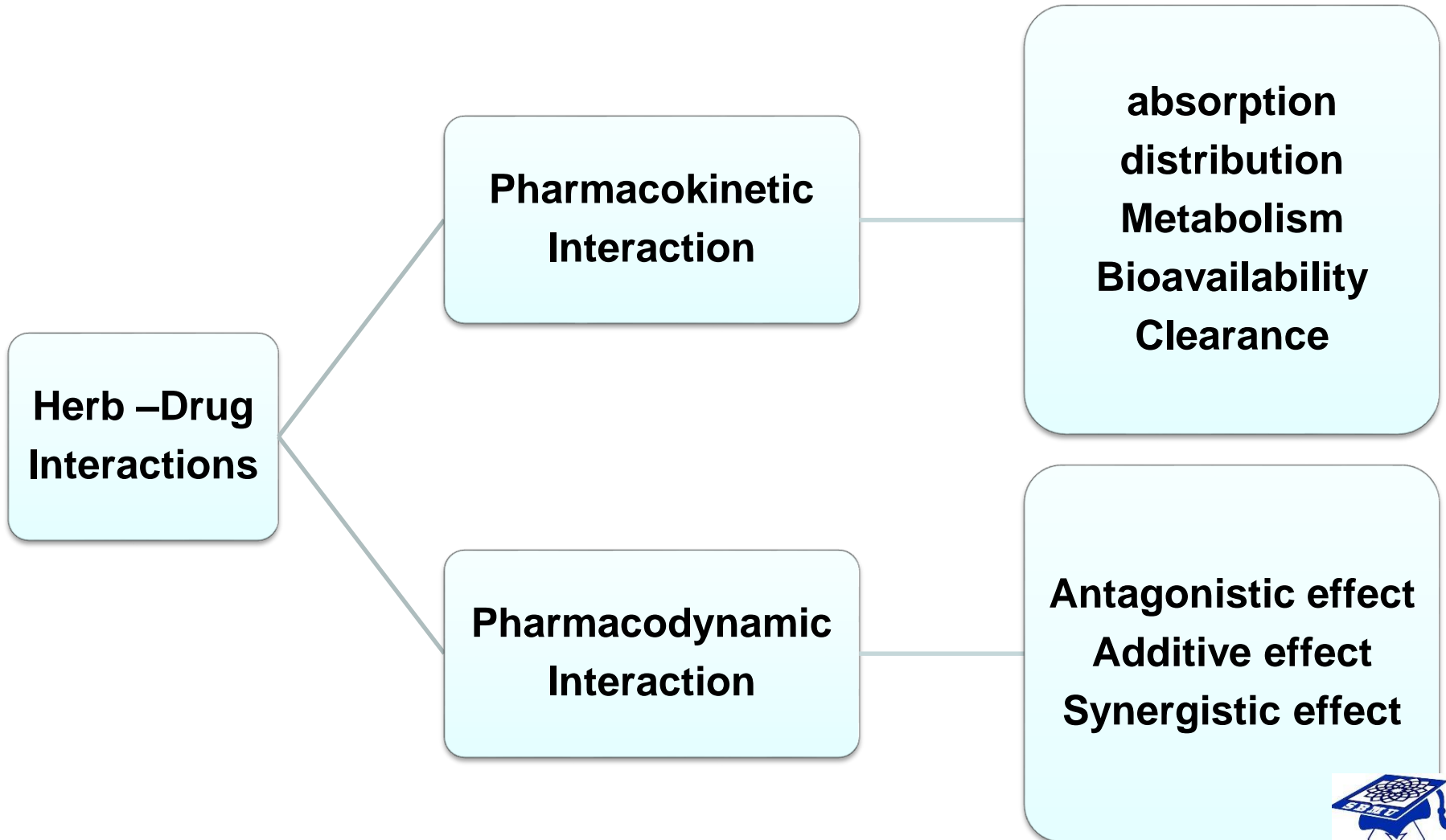
Long term usage  
(10-30 years)

**Colorectal cancer**

☐ Capsaicin → High regular doses

**Gastric cancer**

# Herb - Drug interactions





# Challenges in Assessing Herb-Drug Interactions

- **Complex mixtures of bioactive entities**
- **Chemicals content & Potency depends on many factors:**
  - Climate
  - Soil condition
  - Harvesting
  - Season
  - Drying
  - Storage
  - Preparation & extraction method
  - Part of plant
  - etc.

# Contamination

## ❖ Heavy metals

Arsenic – Mercury – Cadmium – Lead – Thallium & etc.

## ❖ Synthetic drugs

NSAIDS & Benzodiazepines & etc.

# Mistaken plants

**Inadvertently**

**OR**

**Done deliberately**

Could become much more complex by confusing terminology

- i. English common name or names**
- ii. Translation of a foreign name**
- iii. Latinized pharmaceutical name**
- iv. Scientific name**
- v. Brand name**



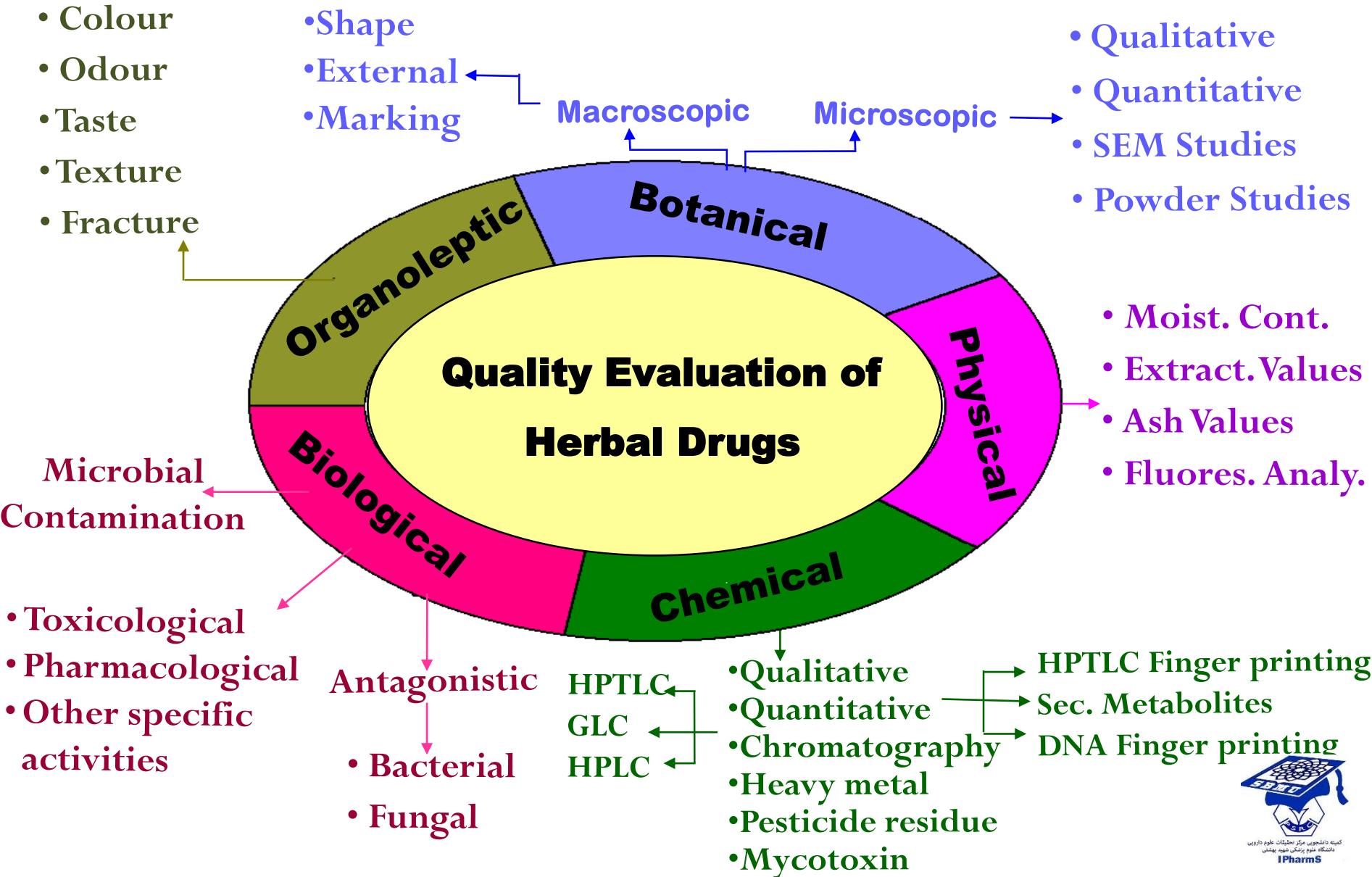
# World Health Organization

- **WHO** is a specialized agency of the United Nations (UN) that is concerned with international public health

# WHO Guidelines for Quality Control & Standardization of Herbal Drugs

- **Control**
- **Safety**
- **Efficacy**
- **Evaluation**
- **Standardisation**

# Standardization & Quality evaluation of herbal drugs



# Standardization of herbal drugs crude plant parts/plant material

## Definition:

- name of plant
- part of plant
- Nature/condition of material: whole, powdered, fresh, dried, etc

## Authentication/confirmation of:

- Correct geographical origin
- Correct stage of growth

## Absence of foreign matter:

- other plant parts or materials
- soil, stones, dust
- insects and other animal matter (as determined by microscopy, macroscopy, chromatography)

# Standardization of herbal drugs crude plant parts/plant material

**Microscopic characteristics confirming identity:**

- qualitative features
- quantitative features, (e.g. stomatal number)

**Radioactive contamination limits:** arising from environmental pollution or microbial decontamination procedures

**Assay:** for materials containing constituents of known therapeutic activity, or known unique (marker) compounds.

Non-specific assay methods for groups of compounds may be used where specific

assay methods are not available for single compounds



# Processed plant materials/non-plant materials (extracts, tinctures, comminutions etc.)

**Definition:** liquid, solid, etc

**Organoleptic characteristics:**

- Macroscopy
- Smell
- Taste
- Texture
- Colour

**Chromatographic profile using more than one method:**

- to confirm presence of unique compounds (markers)
- to confirm characteristic TLC chromatogram
- to confirm characteristic HPTLC chromatogram (TLC + densitometry = HPTLC)

# Processed plant materials/non-plant materials (extracts, tinctures, comminutions etc.)

**Water content** (for hygroscopic materials):

**Ash values:** indicate extent of contamination with inorganic material. Determined by incineration. Values include acid insoluble and sulphated ash

**Volatile matter:** for plants containing volatile oils:

- Determined by steam
- Distillation

**Powdered material:** test method and acceptable limits for particle size, distribution

# continued...

If the product is a mix of plant materials, the supplier must provide evidence that each component plant has been individually tested.

**Heavy metal limits:** from environmental pollution and pesticides

**Microbial contamination limits:** microbial contamination arises from cultivation, harvesting, processing and storage:

- confirmation of absence of *E. coli*, *S. aureus*, *P. aeruginosa* and
- *Salmonella*
- limits for aflatoxins (fungal toxins)

# continued...

**Residual solvents from processing**

**Pesticide residue limits:** arising from cultivation (FAO and WHO limits)

**Extractive values:** extraction by different solvents indicates proportion of polar and non-polar components

**Assay:** for materials containing constituents of known therapeutic activity, or known unique (marker) compounds;

- Non-specific assay methods for groups of compounds may be used where specific assay methods are not available for single compounds

<http://www.fda.gov.ir/>

# اداره کل امور فرآورده های طبیعی، سنتی و مکمل

وزارت بهداشت، درمان و آموزش پزشکی | تماس با ما | RSS | درباره ما | ۱۳۹۸، سال رونق تولید

English | جستجو

سازمان غذا و دارو

پایش مصرف | آزمایشگاه | تجهیزات و ملزومات پزشکی | **طبیعی، سنتی و مکمل** | آرایشی و بهداشتی | دارو | غذا | خانه

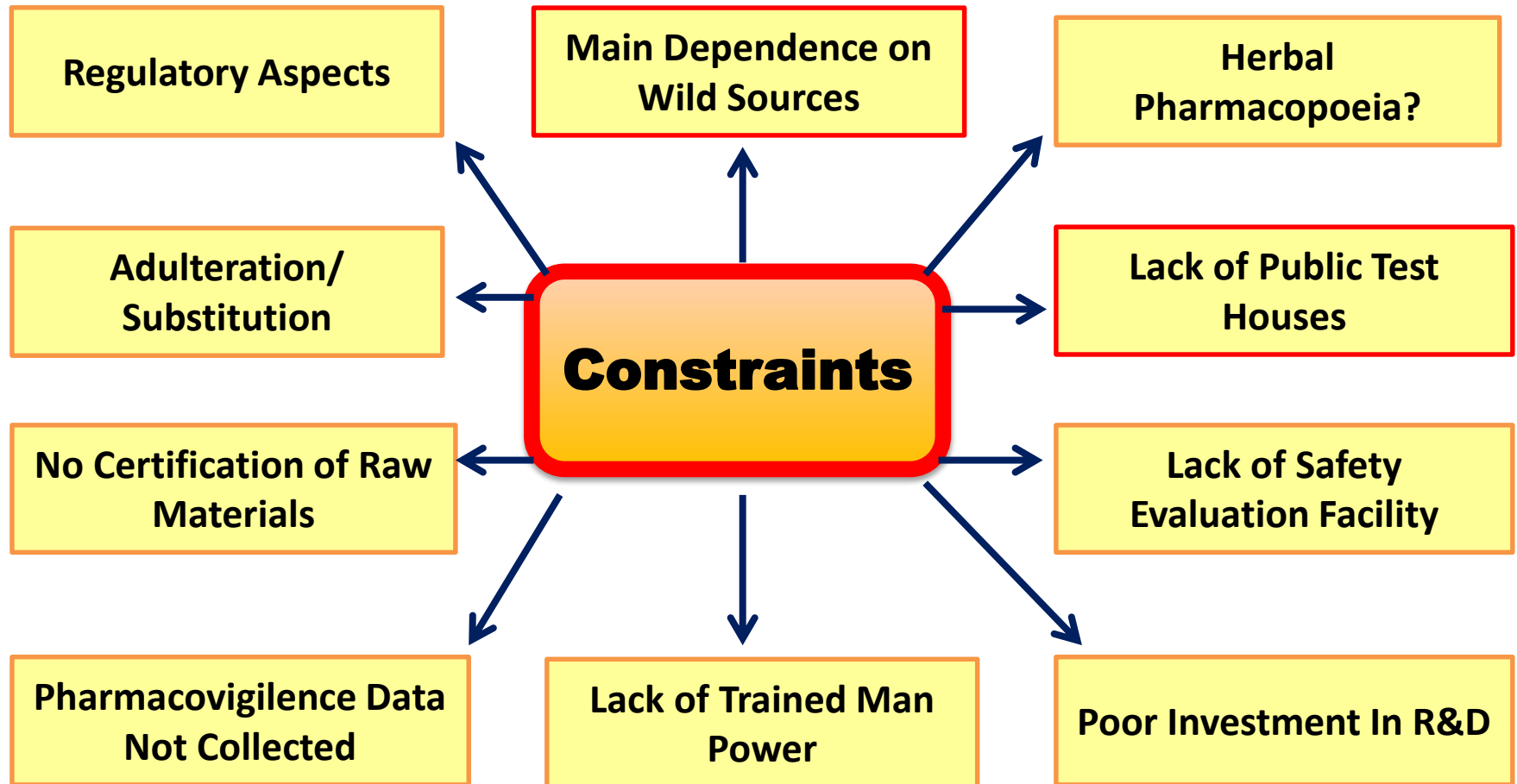
- اداره کل امور فرآورده های طبیعی، سنتی و مکمل
- درباره اداره کل
- اداره فرآورده های طبیعی
- اداره فرآورده های سنتی
- اداره مکمل های تغذیه ای
- اداره شیر خشک های رژیمی و غذاهای ویژه
- کمیته و کمیسیون ها ( اعضاء ، اساسنامه و ... )
- قوانین، ضوابط، مقررات و بخشنامه
- آمار و گزارشات ( ترخیص، ورود، فهرست فرآورده های دارای مجوز)
- آموزش
- سوالات متداول

طبیعی، سنتی و مکمل < اداره کل امور فرآورده های طبیعی، سنتی و مکمل



Iranian Herbal Pharmacopoeia.pdf

# Constraints in quality control of herbal drugs



# ➡ In conclusion:

- ✓ Herbal Medicines **Is Drug, Not Food !**
- ✓ Growing tendency in consumption
- ✓ Easily being traded via internet
- ✓ Strict controls over the Herbal productions
- ✓ Herbs **can not** be categorized as completely **harmful** or **beneficial**
- ✓ Randomized Clinical Trials are of an **Urgent Need**

*Thanks*

*for your attention*

