جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی

IFDA
سازمان غذا و دارو

بسم الله الرحمن الرحیم

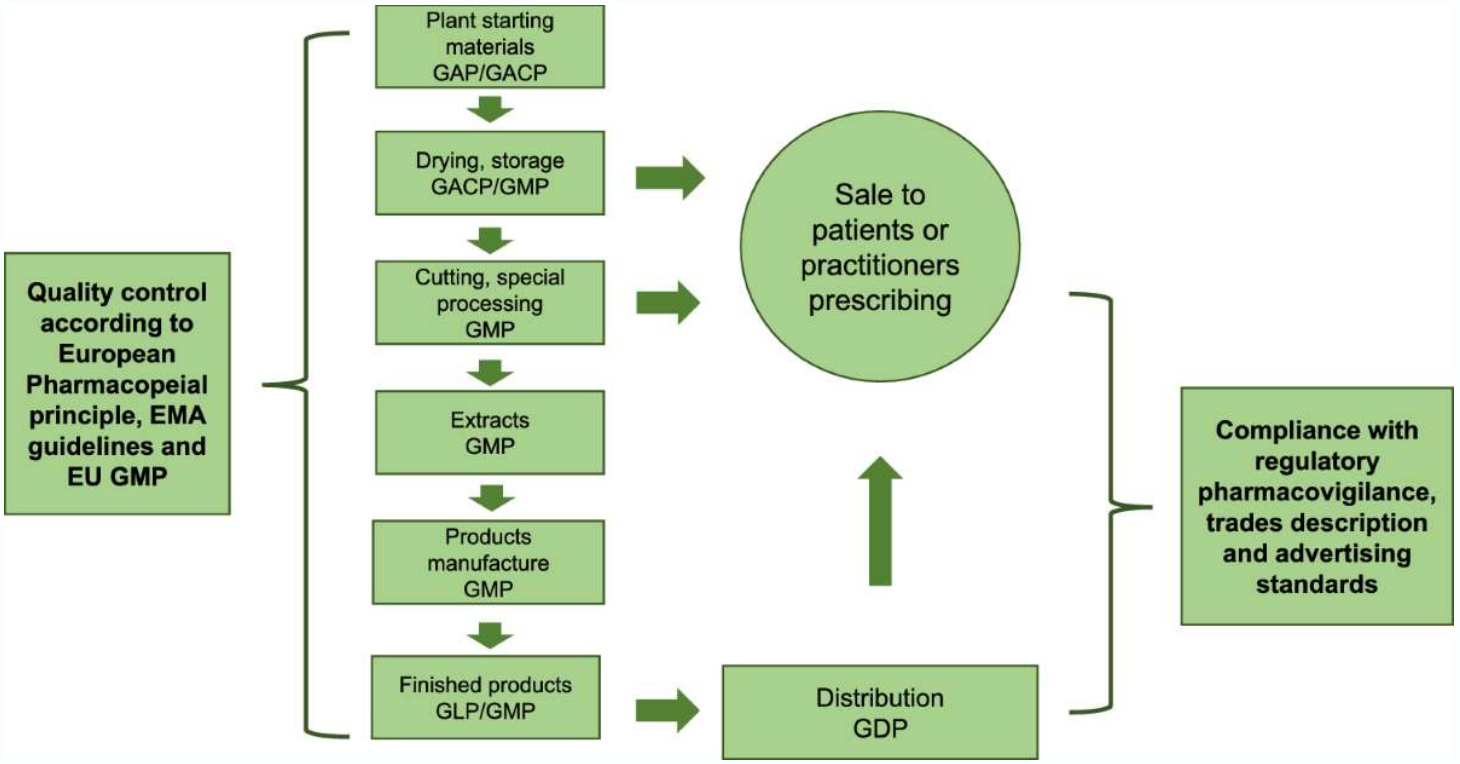
Modern Technological Approaches for Quality Control in new herbal medicine: challenges and solutions

Concerns:

- Medical experts and regulatroy authorities are concerned that certified nutraceuticals are still rare in the market
- Most raw materials used for the manufacture of nutraceuticals are imported and therefore offer no quality control
- Not much data available on how the herbal and botanical ingredients-that go into the manufacture of nutraceuticals-are produced
- Nutraceuticals clearly affect physiology but they are not submitted to testing process as rigorously as pharmaceutical drugs

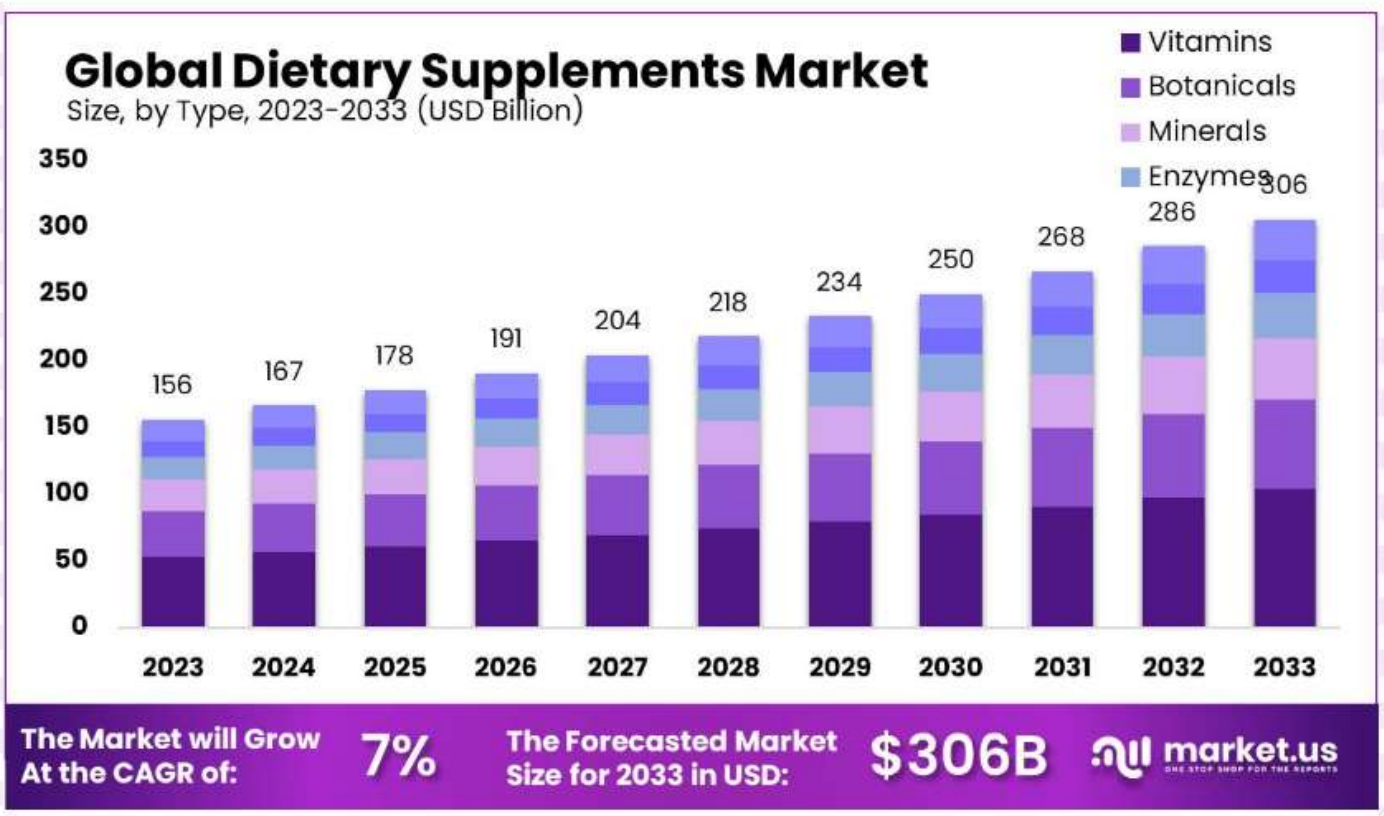
Quality control in herbal medicine

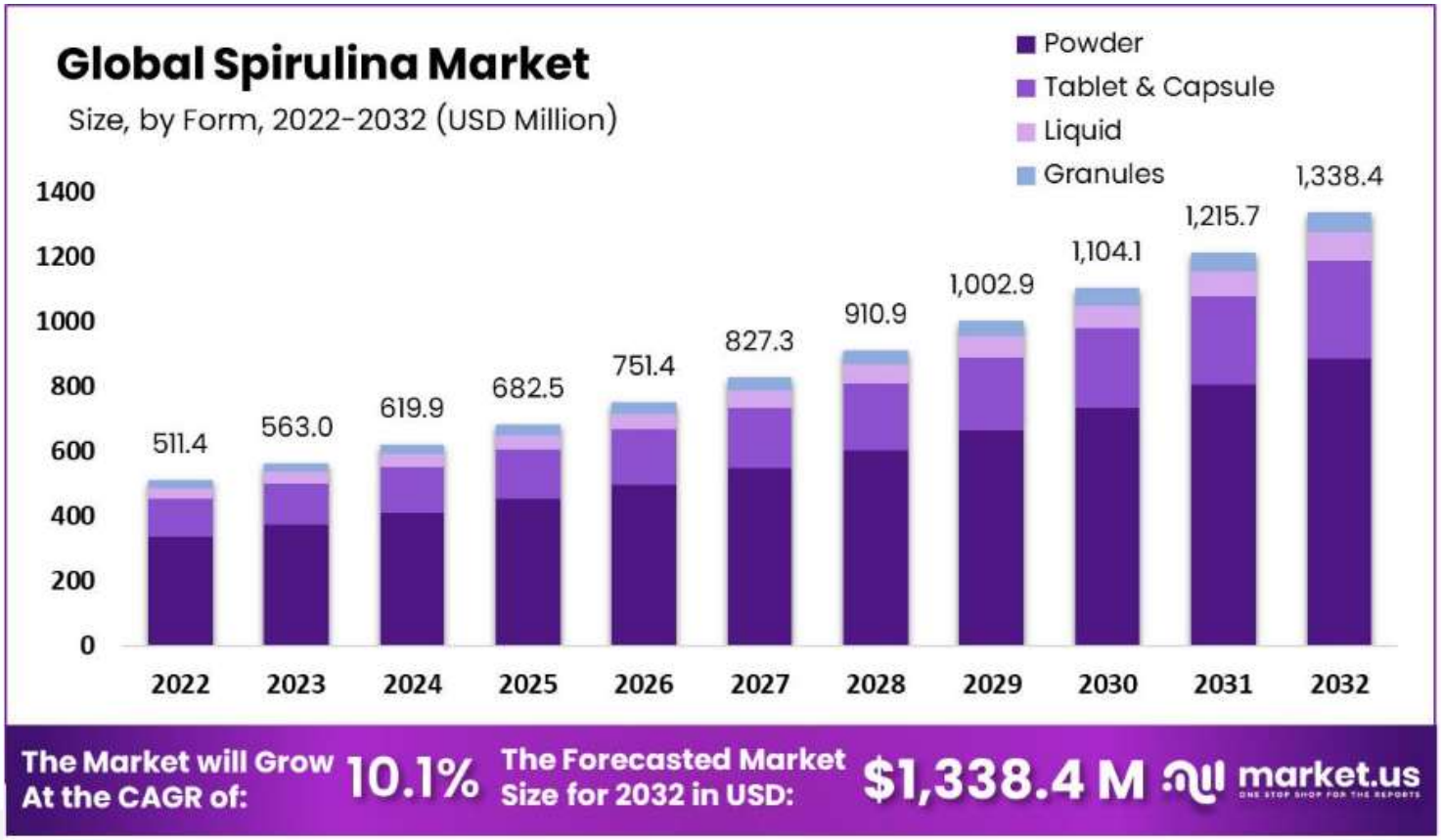
- Good Agricultural and Collection Practices (GACP)
- Good Plant Authentication and Identification Practice (GPAIP)
- Good manufacturing practice(GMP)
- Good laboratory practice(GLP)


Quality control according to European Pharmacopeial principle, EMA guidelines and EU GMP
Plant starting materials GAP/GACP
Drying, storage GACP/GMP
Cutting, special processing GMP
Extracts GMP
Products manufacture GMP
Finished products GLP/GMP
Sale to patients or practitioners prescribing
Distribution GDP
Compliance with regulatory pharmacovigilance, trades description and advertising standards

Why rising popularity

- The increased interest in healthy living
- Growing desire for natural cures
- Consumer demands are changing to preventive therapies for chronic disease


Global Dietary Supplements Market
Size, by Type, 2023-2033 (USD Billion)
Vitamins
Botanicals
Minerals
Enzymes
350
300
250
200
150
100
50
0
156
167
178
191
204
218
234
250
268
286
306
2023
2024
2025
2026
2027
2028
2029
2030
2031
2032
2033
The Market will Grow At the CAGR of:
7%
The Forecasted Market Size for 2033 in USD:
$306B
market.us


Global Spirulina Market
Size, by Form, 2022-2032 (USD Million)
Powder
Tablet & Capsule
Liquid
Granules
1400
1200
1000
800
600
400
200
0
511.4
563.0
619.9
682.5
751.4
827.3
910.9
1,002.9
1,104.1
1,215.7
1,338.4
2022
2023
2024
2025
2026
2027
2028
2029
2030
2031
2032
The Market will Grow At the CAGR of: 10.1%
The Forecasted Market Size for 2032 in USD: $1,338.4 M
market.us

Modern QC technologies

- ensure herbal medicines are:
- safe,
- effective
- consistent

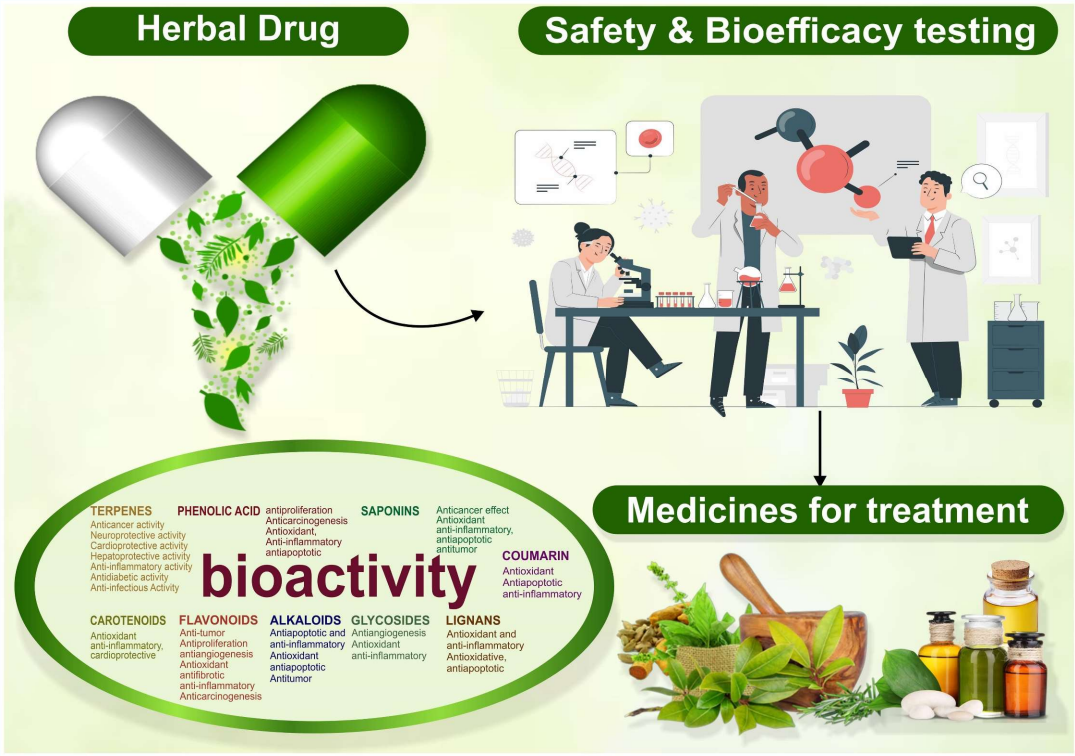
Combining analytical chemistry, genomics, and AI can eliminate adulteration and contamination

•Authentication & Standardization

a. DNA Barcoding
Identifies plant species using genetic markers, Prevents adulteration

b. High-Performance Thin-Layer Chromatography (HPTLC)
Separates and quantifies active compounds (e.g., alkaloids, flavonoids),Ensures batch-to-batch consistency.

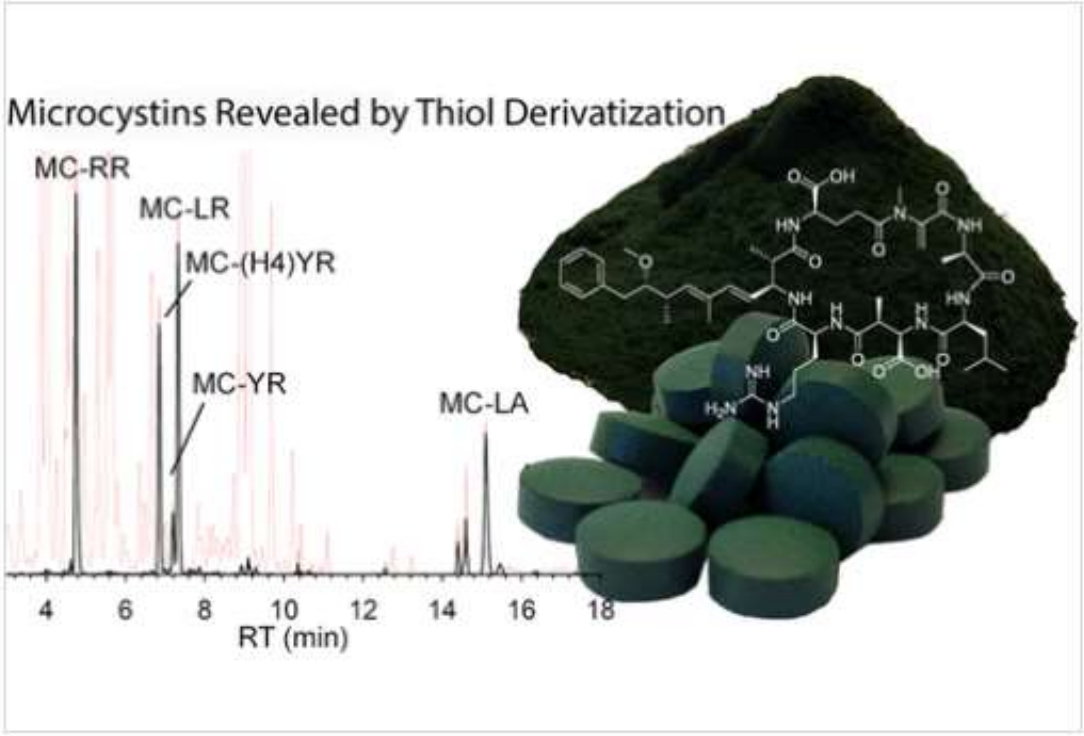
c. Liquid/Gas Chromatography-Mass Spectrometry (LC-MS/GC-MS)
Detects and quantifies multiple phytochemicals simultaneously.
Identifies bioactive compounds and contaminants (pesticides, heavy metals).
Profiling cannabinoids in Cannabis*-based medicines.


Herbal Drug
Safety & Bioefficacy testing
Medicines for treatment
bioactivity
TERPENES
Anticancer activity
Neuroprotective activity
Cardioprotective activity
Hepatoprotective activity
Anti-inflammatory activity
Antidiabetic activity
Anti-infectious Activity
PHENOLIC ACID
antiproliferation
Anticarcinogenesis
Antioxidant,
Anti-inflammatory
antiapoptotic
SAPONINS
Anticancer effect
Antioxidant
anti-inflammatory,
antiapoptotic
antitumor
COUMARIN
Antioxidant
Antiapoptotic
anti-inflammatory
CAROTENOIDS
Antioxidant
anti-inflammatory,
cardioprotective
FLAVONOIDS
Anti-tumor
Antiproliferation
antiangiogenesis
Antioxidant
antifibrotic
anti-inflammatory
Anticarcinogenesis
ALKALOIDS
Antiapoptotic and
anti-inflammatory
Antioxidant
antiapoptotic
Antitumor
GLYCOSIDES
Antiangiogenesis
Antioxidant
anti-inflammatory
LIGNANS
Antioxidant and
anti-inflammatory
Antioxidative,
antiapoptotic

Contaminant Detection

a. Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
Detects toxic heavy metals (As, Pb, Cd, Hg).
Ensures compliance with WHO/FDA limits.
- Example: Screening Ayurvedic* medicines for lead contamination.
b.PCR & Next-Gen Sequencing (NGS)
Detects microbial contaminants (bacteria, fungi).
Prevents infections from poorly processed herbs.
Identifying E. coli* or Salmonella in herbal powders.
C.Enzyme-Linked Immunosorbent Assay (ELISA)
Detects allergenic compounds (e.g., gluten, nuts,Microcystin).
Ensures safety for sensitive consumers.


Is Spirulina Dangerous?
Side-Effects...
686 × 386


Microcystins Revealed by Thiol Derivatization
MC-RR
MC-LR
MC-(H4)YR
MC-YR
MC-LA
4
6
8
10
12
14
16
18
RT (min)

Background: Why Was USP <2251> Created?

1. **Rise of Adulteration in Supplements**

2. **Regulatory Gaps**

3. **Need for Standardized Testing**

Development of USP <2251>

- **2016–2018: Initial Discussions**

- **2019: Proposal and Pilot Testing**

- **August 1, 2020: Official Adoption**
- **USP <2251> was formally incorporated into USP–NF**

Key Requirements of USP <2251>

1. Analytical Method Validation
- Labs must validate methods to ensure they can reliably detect adulterants (e.g., HPLC, LC-MS/MS).
2. Categories of Adulterants
- Focus on three major groups:
- Pharmaceutical drugs (e.g., sildenafil, tadalafil, NSAIDs).
- Anabolic agents (e.g., steroids, SARMs).
- Stimulants (e.g., DMAA, DMHA, amphetamines).
3. Quality Control
- Requires positive/negative controls, limit of detection (LOD) studies, and cross-lab reproducibility.

Impact of USP <2251>

Industry Compliance

- Supplement manufacturers and testing labs now follow standardized protocols.
- Helps companies avoid FDA warnings (e.g., FDA's "Operation Supplement Safety").
- Global Influence
- While USP is U.S.-focused, other regions (e.g., Europe, via EMA/EFSA) have referenced it for anti-adulteration strategies.
- Ongoing Updates
- USP revises the chapter periodically (e.g., adding new adulterants like phenibut or kratom alkaloids).

Add the following:

·⟨2251⟩ ADULTERATION OF DIETARY SUPPLEMENTS WITH DRUGS AND DRUG ANALOGS

DIETARY SUPPLEMENT ADULTERATION CATEGORIES

The following major categories of adulterated DS are recognized:

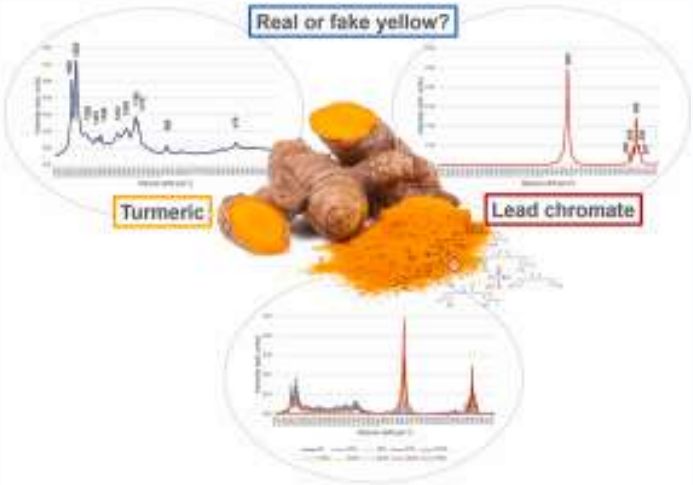
- **Sexual Enhancement:** This category is also referred to as the Erectile Dysfunction (ED) category. It encompasses a functionally coherent group of adulterants, including several approved drugs, their numerous approved and unapproved analogs, synthetic intermediates, and derivatives. Their functionality is manifested by selective inhibition of phosphodiesterase type 5 enzyme (PDE5), which hydrolyzes cyclic guanosine 3,5-monophosphate (cGMP); this group of drugs is frequently identified as PDE5 inhibitors. Screening methods for DS adulterated with ED drugs are presented in *Appendix A*.
- **Weight Loss (WL):** This category comprises a functionally and chemically diverse collection of compounds that include stimulants, laxatives, diuretics, anorexiants, and psychoactive drugs. Although stimulants constitute an important segment of WL adulterants, the oral anorexiant sibutramine dominates this category, frequently in combination with phenolphthalein, a laxative. Methods for analysis of DS adulterated with WL drugs will be addressed in Appendix B (to come).
- **Sports Performance Enhancement (SPE):** These compounds constitute the third major category of adulteration. Professional and amateur athletes are targeted with designer anabolic steroids and stimulants, which are systematically banned by the World Anti-Doping Agency. Functional and structural diversity, synthetic proclivity of the adulterators, and the generally small amounts of the infringing substances required to elicit a therapeutic effect make this category especially challenging to address. These supplements are customarily formulated in protein- and fat-rich matrices, thereby further complicating detection. For these reasons, GC- and LC-MS[n] techniques constitute primary analytical methodologies within this category. Analysis of DS adulterated with SPE drugs will be addressed in Appendix C (to come).

Turmeric Contamination

- Issue: 2023 FDA recall due to lead (Pb) levels >30 ppm in Indian-sourced turmeric.

- Root Cause: Adulteration with lead chromate for color enhancement.

- Solution: Supplier audits + mandatory ICP-MS testing for imports.



Summary

Company Announcement Date:
December 16, 2024

FDA Publish Date:
December 16, 2024

Product Type:
Dietary Supplements

Reason for Announcement:
Product contains undeclared diclofenac and dexamethasone

Company Name:GNMART Inc

Brand Name: Force Forever

Product Description: Dietary Supplement

Summary

Company Announcement Date:
December 16, 2024
FDA Publish Date:
December 18, 2024
Product Type:
Drugs
Reason for Announcement:
Product contains undeclared Metformin and Glyburide
Company Name:
Shoppers-Plaza
Brand Name:
Fouzee
Product Description:
SugarLin Herbal Formula Herbal Dietary Supplement

Company Announcement Date:
December 13, 2024
FDA Publish Date:
December 13, 2024
Product Type:
Food & Beverages
Foodborne Illness
Reason for Announcement:
Product contains toxic yellow oleander.
Company Name:
Motivate Me Ashley, LLC
Brand Name:
VidaSlim
Product Description:
VidaSlim Brand 90-day, 30-day and 7-day Original Root, Root Plus, and Root Capsules & VidaSlim Hot Body Brew D

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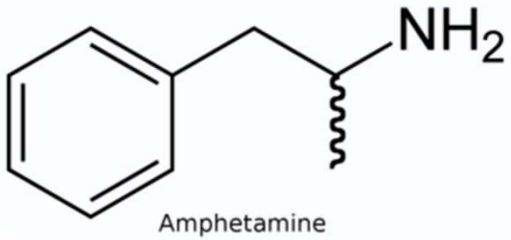
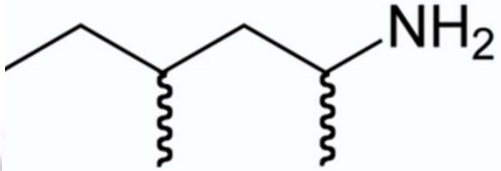
Summary

Company Announcement Date:
November 04, 2024
FDA Publish Date: November 06, 2024
Product Type: Dietary Supplements Drugs
Reason for Announcement:
Undeclared Sildenafil and Diclofenac
Company Name:
VitalityVita
Brand Name:
VitalityVita
Product Description:
Marketed as Dietary Supplement

Pre-workout
USPlabs
methylhexan amin
liver transplant



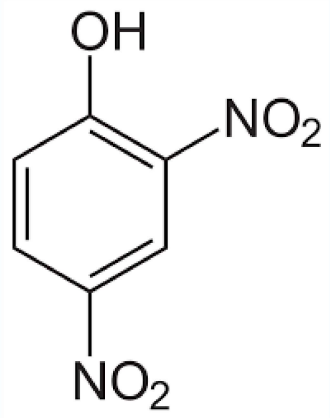
Amphetamine



Methylhexaneamine

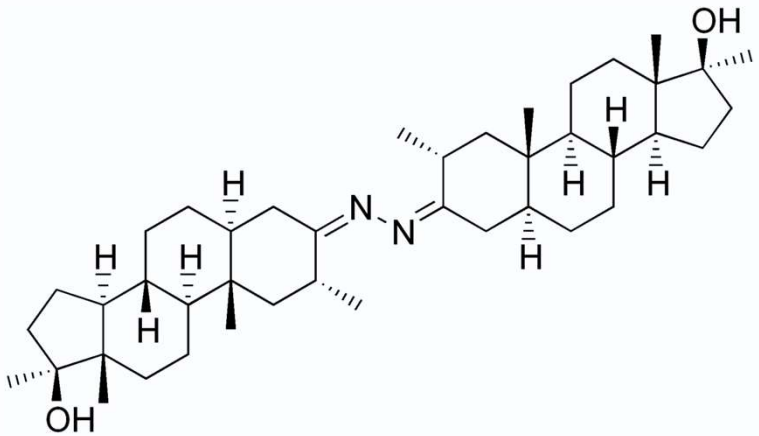
dnp2.webp

substance DNP is often marketed as a slimming or weight loss aid and has sadly resulted in 33 deaths across the UK to date.



The defendant had been selling this lethal substance to people across Europe and America on the dark web between June 2017 and July 2020

Blackstone Labs
All of the product
Dimethazine
Severe liver damage



گیرنده آندروژن Mebolazine چرخه حجیم آنابولیک آندروژن استروئید Dimethazine DMZ

جزئیات محصول:

محل منبع:	چین
نام تجاری:	Keray
گواهی:	ISO9001
شماره مدل:	میولازین

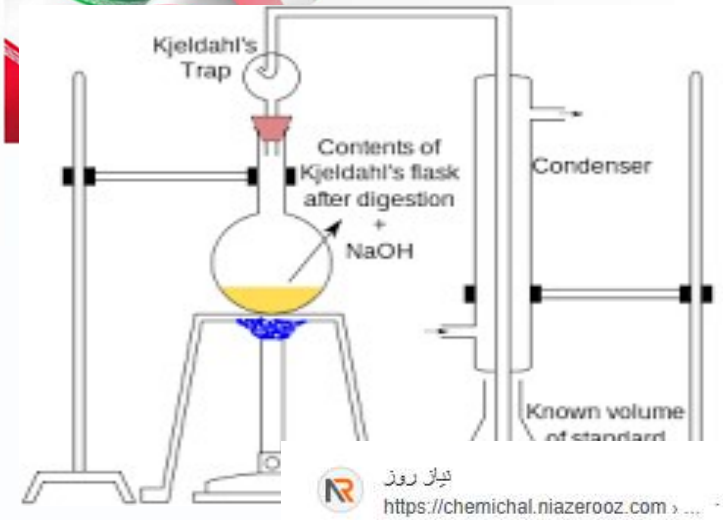
پرداخت:

مقدار حداقل تعداد سفارش:	10 گرم
قیمت:	Negotiable
جزئیات بسته بندی:	بسته بسیار محتاطانه
زمان تحویل:	ظرف 1 روز
شرایط پرداخت:	L/C، T/T، Western Union، MoneyGram
قابلیت ارائه:	200 کیلوگرم در ماه

مخاطب | گپ

Send Message

گیرنده آندروژن Mebolazine چرخه حجیم آنابولیک **تصویر بزرگ :**
آندروژن استروئید Dimethazine DMZ



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فروش پودر ملامین - صنایع شیمیایی - نیاز روز

فروش پودر ملامین. فروش پودر ملامین با قیمت مناسب کد مرک 808614 1کیلوگرم مرک ارسال به تهران و سراسر کشور در کمترین بازه زمانی جهت خرید و یا استعلام قیمت ...

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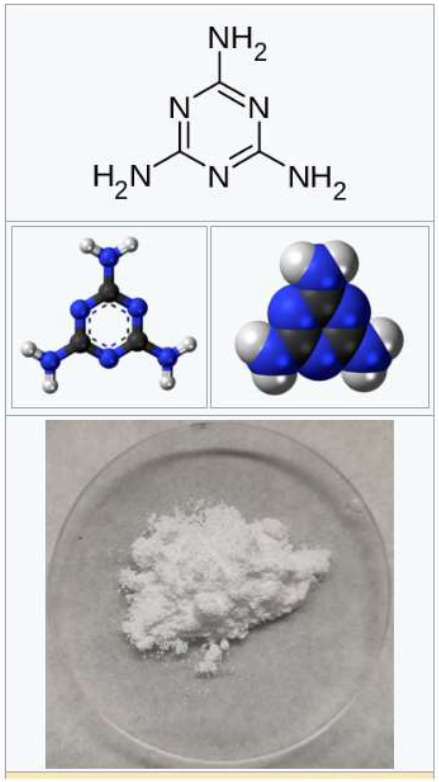
پودر ملامین درجه صنعتی 99.8٪ شیمیایی 1-78-108 Cas ...

محل منبع: چین. نام تجاری: Dr Aid. شماره مدل: پودر ملامین. قیمت: $1,200.00 - $1,600.00/Tons. جزئیات بسته بندی: کیسه های PE PP.

$1,200.00 to $1,600.00

بارپون شیمی

Melamine



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از توجه شما سپاسگزاریم