Post-Covid Immunity Claims -Ayush Kwath and Ministry Endorsed Formulas Scientific Validity Check

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***Abstract*—The SARS CoV 2 virus causing the COVID19 pandemic has increased the sense of urgency of prevention and supportive treatment to limit acute infection and alleviate long-term outcomes (post-acute sequelae of SARS CoV 2 infection, PASC/Long COVID). In this respect, the Ministry of AYUSH in India approved the use of immunity-promoting preparations, such as Ayush Kwath, Chyawanprash and AYUSH-64. The given assertions are criticized in the current paper on the basis of critical analysis of Ayurvedic concepts, phytochemical, action, and the available scientific body of evidence.**

Ayurveda views immunity as Vyadhikshamatva (resistance to diseases), Ojas (vital essence), Agni (digestive/metabolic fire) and Rasayana (rejuvenative therapies). Ayush Kwath is a combination of Tulsi, Dalchini, Sunthi, Krishna Marich, which contains phytoconstituents that include eugenol, cinnamaldehyde, gingerols and piperine, which have been reported to possess antiviral, anti-inflammatory, antioxidant, and bioenhancing effects. Amla-based polyherbal Rasayana, Chyawanprash, is claimed to possess adaptogenic and immunomodulatory effects, whereas AYUSH-64 which was created to address malaria had antiviral, anti-inflammatory and thrombolytic effects.

The immunomodulatory and protective properties of these herbs are supported by laboratory and pre-clinical research, and show the down-regulation of pro-inflammatory cytokines, regulation of the innate and adaptive immune systems, and the gut-immune axis. However, strong clinical evidence is still lacking. The AYUSH-64 trials have demonstrated faster recovery and lower hospitalisation in mild-to-moderate cases of COVID-19 and community-based administration of Ayush Kwath and Chyawanprash have proposed prophylactic effects. But, due to methodological limitations such as a small sample size, lack of blinding, and lack of biomarker evaluation, definitive conclusions are limited.

The regulatory provisions laid down by the Food Safety and Standards Authority of India (FSSAI) and the Central Council for Research in Ayurvedic Sciences (CCRAS) allow functional claims that the products improve the immunity, but the assertions stated are disease-specific either preventive or curative are highly successful. In turn, even though AYUSH interventions have potential, they need to be supported by serious randomized controlled trials that can confirm their efficacy.

Finally, AYUSH-approved formulations were implemented culturally relevant and affordable to reach large groups of populations during the pandemic. However, to be included in the modern health systems, they require strong evidence-based validation and optimization of population-health outcomes.

***Index Terms*—COVID -19; post-COVID immunity; AYUSH; Ayush Kwath; Chyawanprash; AYUSH-64; Ayurveda; Immunomodulation; Herbal formulations; Clinical validation.**

I. INTRODUCTION TO POST COVID HEALTH CHALLENGES

COVID-19 stands for Corona virus disease 2019, an infection caused by recently discovered viral species called SARS-CoV-2 (severe acute respiratory syndrome- Corona Virus- 2), a novel contagion belongs to large family of viruses known to cause illness ranging from the common cold to more severe diseases like SARS & MERS. SARS-CoV-2 is an RNA virus, with a Spike like Protein (s-protein) on its surface that binds to receptors on human cells mainly ACE2 receptors which allows virus to infect the healthy cells. This virus is enclosed in a fatty outer membrane, that can be destroyed by soap, making handwashing an effective method of prevention. Most people recovered with mild/ moderate symptoms; however, some cases became severe, leading to pneumonia, organ failure, even death especially in vulnerable population like elderly individuals, people with chronic diseases and immunocompromised individuals.

The covid 19 pandemic has a significant impact on global health not only through the infections but also through the long-term effects in individuals effected

by COVID. These long-term effects followed after infection are termed as Post Acute Sequelae of SARS-CoV-2 Infection (PASC) or Long Covid. These are the significant public health concerns. (Nalbandian, 2021) Post covid symptoms are clinically heterogeneous that means they affect all the organs and organ system in the body not only respiratory system. Some of the common symptoms include long-term fatigue, chest pain, myalgias, palpitations, Brain fog, and neuropsychiatric manifestations such as depression, anxiety, and insomnia (Carfì, 2020) (Davis, 2021). These symptoms can be seen more than 12 weeks after infection. These symptoms do not depend on the severity of the infection. We can see these symptoms even in the individuals with mild infection or asymptomatic also. (Sudre, 2021).

The underlying mechanisms of Long COVID is influenced by multiple factors which are still under investigation. Understood mechanisms include persistent viral reservoirs, immune dysregulation, microvascular thrombosis, autonomic nervous system dysfunction, and post-viral fatigue syndrome-like states. (Proal, 2021). Additionally, proofs suggest that COVID triggers pre-existed non communicable diseases like cardiovascular diseases, kidney diseases, diabetes, liver failure, psychological disorders due to the inflammation caused by infection (Xie, 2022).

Mental health challenges are also increased after COVID due to the prolonged isolation, grief, economic instability, anxiety caused by spread of infection, Health problems. The World Health Organization (WHO, 2022) reported that there is 25% increase of mental health problems like depression and anxiety all over the world.

Additionally vulnerable population like elderly people, people with multiple diseases that led to less immunity against infections, economically weaker sections affected a lot during the pandemic, that lead to need for equitable, multidisciplinary, and long-term health interventions.

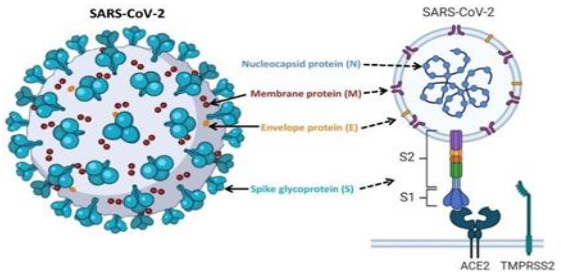


fig 1: SARS-CoV structure and binding to ACE 2 receptor

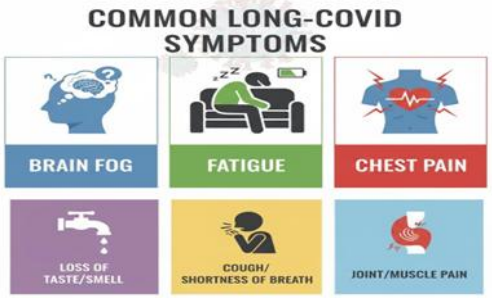


Fig 2: Common long covid symptoms

II. ROLE OF TRADITIONAL MEDICINE DURING PANDEMIC

Traditional medicine, especially Ayurveda and yoga, played a crucial role in India's COVID-19 response by offering preventive, promotive, and supportive healthcare options grounded in holistic principles. Based on olden ayurvedic texts and evidence presented in current literature works, traditional systems highlighted immunity improvement (Vyadhikshamatya), metabolic balance (Agni), detoxification (Shodhana), and mind-body balance. These principles were applied through structured regimens of herbs, dietary practices, respiratory therapies, lifestyle routines and yoga-based interventions.

The ministry of AYUSH actively promoted ayurvedic formulations using different methods like advisories, advertisements and state- level programs. Herbal preparations such as Ayush Kwath, Chyawanprash, Ashwagandha, Guguchi, and Amalaki were recommended for the immunity boosting and they also known for antiviral properties. (Zende, 2020) (Umesh, 2022). Steam inhalation (Swedana), gargling (Kavala), nasal oil application (Nasya), and rasayana therapies like Swarna Bhasma were implemented to increase the strength of the respiratory system and overall immunity (Mittal, 2020). These interventions were flexible and accessible, that help to reach both urban and rural population.

Table: Ayurvedic Interventions During COVID-19

CATEGORY	EXAMPLES
Immunity boosters	Guduchi, Ashwagandha, Amalaki, Tulsi, Ayush kwath
Rasayana Formulations	Chyawanprash, Brahma Rasayana, Swarna Bhasma
Respiratory support	Sitopaladi churna, Dashamula Kwatha, Go Jihvadi Kwatha
Mental Health Support	Yoga, Pranayama, Sudharshan kriya
External applications	Nasya (nasal drops), Swedana (steam), Kavala (gargle), Gandusha (oil pulling)
Paediatric support	Swarna Prashana

Ayurveda also offered structured protocols depending on an individual's exposure level or disease stage. Unexposed individuals were advised to follow daily routine and use Rasayana herbs to prevent illness caused by virus. People who had exposure or early symptoms were often given classical medicines such as Snjeevani vati, Chitrakadi vati, and Pippali rasayana. For those with mild symptoms, a warm herbal decoction made with spices was used to help manage fever, sore throat, and inflammation. Panchakarma procedures like Virechana were applied in suitable cases for detoxification and recovery support (Srivastava, 2020).

Moreover, Ayurvedic fundamental principles approached COVID-19 through the perspective of Janapadodhwamsa (epidemics) and Sankramika Rogas (infectious diseases). These principles emphasize the effect of environmental factors, poor sanitation, seasonal imbalances, and disturbed ethical conduct (Adharma) on public health. Thus, Ayurveda proposed an interdisciplinary approach combining physical, mental, and environmental care (Adluri, 2022). This included not only medicinal prescriptions but also councelling on ethical living, seasonal discipline (Rithucharya), and daily activities (Dinacharya).

Yoga-based practices played an ayurvedic therapies especially in supporting mental well-being and respiratory health. Pranayama and meditation helped reduce stress-related immune suppression and helped in improving lung function. These were very important during lockdown to cope with anxiety and isolation (Umesh, 2022). The combination of yoga and ayurveda helped to achieve to psychoneuroimmunological resilience that was required to prevent and recover from viral infections

Fig 3: Role of traditional medicine

States like Kerala, Gujarat, and Maharashtra successfully implemented traditional medicine in response to COVID-19. Community-based initiatives, online medical consultations, and homedelivery of AYUSH kits ensured broader access. Clinical trials were also started to prove effectiveness of traditional interventions, with a focus on safety, standardization, and pharmacological efficacy (Golechha, 2020).

In conclusion, traditional medicine served as a culturally accepted budget-friendly, and integrated support network in the course of the COVID-19. By offering lifestyle coaching, mental health support, immunity boosters and treatment approaches,

Ayurveda and Yoga helped close gaps in preventive care, especially at public level.

III. UNDERSTANDING AYUSH KWATH

AYUSH Kwath is an herbal tea that is promoted by the Ministry of AYUSH, Government of India, to boost the immunity and protect against common infections, especially during covid-19. It is not a medicine but it is a traditional remedy that is made using India spices that are known for their health benefits.

INGREDIENTS OF AYUSH KWATH

HERB	SCIENTIFIC NAME	KNOWN BENEFITS
TULSI (HOLY BASIL)	*Ocimum sanctum*	Immunity booster, antiviral, antistress
DALCHINI (CINNAMON)	*Cinnamomum zeylanicum*	Anti-inflammatory, antioxidant
SUNTHI (DRY GINGER)	*Zingiber officinale*	Supports digestion, anti-inflammatory
KRISHNA MARICH (BLACK PEPPER)	*Piper nigrum*	Enhances absorption of nutrients, antioxidant

Fig 4: Ayush kwath ingredients

These herbs are traditionally used in ayurveda and have been validated by modern science for many of their health promoting properties.

PREPERATION OF AYUSHKWATH:

1. Take 3 grams of the four herbs in powdered or crushed form.
2. Boil in 150 ml of water.
3. Reduce it to 100 ml
4. Strain and drink warm
5. Add jaggery or honey (optional)

Dosage recommendation given by **Ministry of** AYUSH is once or twice a day for general wellness.

HEALTH BENEFITS AND USES:

According to the traditional and scientific understanding AYUSH KWATH helps in

- Improve immune response.
- Fight seasonal infections like cold, cough, and sore throat.
- Support respiratory health.
- Enhance digestion and metabolism.
- Act as a preventive tonic for general wellbeing.

It is recommended for the use during monsoons, winter, or when immunity is in risk due to infection waves.

PRECAUTIONS TO BE TAKEN:

- Safe for adults when taken in moderation
- Should be avoided in high doses
- Should consult a doctor before giving to children, pregnant women or people with medical conditions
- Works best along with a healthy diet, sleep, exercise, and hygiene practice.

fig 5: Preparation of Ayushkwath

IV. OVERVIEW OF MINISTRY ENDORSED FORMULAS

Ministry of AYUSH have endorsed some other formulas other than Ayush kwath for immunity against COVID from different traditional medical practices like AYURVEDA, UNANI and SIDHA.

I. AYURVEDIC FORMULATIONS:

a. SANSHAMANI VATI (Tinospora cordifolia)

- System: Ayurveda
- Composition: Single-herb tablet made from the stem of Guduchi *(Tinospora cordifolia)*
- Pharmacological actions:

- Immunomodulatory: Enhances both innate and adaptive immunity.
- Antipyretic: Reduces fever through modulation of pro-inflammatory cytokines.
- Anti-inflammatory and Antioxidant: Lowers oxidative stress and inflammatory mediator levels.
- Evidence:
- In the AYURAKSHA trial, they included sanshamani vati in the preventive care of 47,827 Delhi police personnel resulted in 55.6% lower COVID-19 IgG positivity rate, better immunity, questionnaire scores and higher WHO-QOL BREF scores were observed when compared to control subjects.
- No adverse effects were reported during trial use.
- (Nesari, 2022), (Ahmad, 2021)

b. ANU TAILA

- System: Ayurveda
- Composition: Contains multiple herbs meant for nasal instillation; contains herbs like *Sesamum indicum* oil base, *Aegle marmelos, Cinnamomum camphora,* and *Cyperus rotundus.*
- Pharmacological actions:
- It lubticates and gives protection for nasal mucosa by reducing pathogen adhesion
- Gives relief from nasal congestion and supports respiratory function.
- Shows potential antiviral properties by changing mucosal immune.
- Evidence:
- In the AYURAKSHA trial, daily use of Anu thaila as nasal drops along with Sanshamani vati proved a potential prophylactic benefit and no adverse events.
- (Nesari, 2022)

c. AYUSH- 64

- System: Ayurveda
- Composition: Contains *Alstonia scholaris* (bark), *Picrorhiza kurroa* (rhizome), *Swertia chirayita* (whole plant), *Caesalpina crista* (seed pulp).
- Pharmacological actions:
- Firstly, it was formulated for the treatment of malaria, after the research I was proved to be having antiviral, anti-inflammatory, immunomodulatory effects.
- Hypothesis is that it may modulate cytokine production and reduce viral replication.
- Evidence:
- CTRI- registered trials in mild-to-moderate COVID-19 demonstrated faster recovery, reduced symptom

duration, and improved patient well-being was reported.

- (Ahmad, 2021) (Srivastava N. &., 2020)

d. AGASTYA HARITAKI

- System: Ayurveda
- Composition: It is a poly-herb formulation that contains *Terminalia chebula, Aegle marmelos, Desmodium gangeticum, Tribulus terrestis,* among others.
- Pharmacological actions:
- Its shows Expectorant and Mucolytic effects by facilitating mucus clearance in respiratory ailments.
- It also has anti-inflammatory and antioxidant actions. It reduces inflammation and oxidative damage.
- Evidence:
- It is traditionally prescribed for asthma, chronic cough and bronchitis proposed as supportive therapy in COVID-19 related respiratory weakness
- (Srivastava N. &., 2020)

e. CHYAWANPRASH

- System: Ayurveda
- Composition: Amla as a primary ingredient, along with that it contains 40 other herbs like Ashwagandha, long pepper and giloy. The base consists of ghee, honey and sesame oil.
- Pharmacological actions:
- It acts as a rejuvenator that enhances immunity, vitality and respiratory resilience.
- Composition is antioxidant rich and reduces oxidative stress.
- Evidence:
- Clinical trials in healthcare workers reported safety, and possible protective effect against respiratory infections
- No adverse effects were reported
- (Ahmad, 2021)

II. UNANI FORMULATIONS

a. Arq-e-Ajeeb

- Composition: Camphor, Menthol, Thymol
- Actions: Antimicrobial, Anti-Inflammatory
- Uses: Inhalant/Topical for respiratory complaints
- (Ahmad, 2021)

b. Asgandh Safoof (Withinia sonifera)

- Actions: Adaptogen, stress-reliever, immune booster.
- (Ahmad, 2021)

c. Habb-e-Bukhar

- **Composition:** *Cinchona officinale, Tinospora cordifolia, Bambusa bambos, Acacia arabica.*
- **Actions:** Antipyretic, supports immunity in febrile illness
- (Ahmad, 2021)

d. Habb-e-Hindi Zeeqi

- **Composition:** *Aconitum chasmanthum, Calotropis procera, Zingiber officinale*
- **Actions:** Respiratory tonic, anti-inflammatory
- (Ahmad, 2021)

e. Habb-e-Mubarak:

- **Composition:** *Myrica esculenta, Caesalpinia bonduc*
- **Actions:** Immune-supportive, respiratory protective.
- (Ahmad, 2021)

III. SIDHA FORMULATIONS

a. Kabasura Kudineer

- Composition: 15 herbs including *Andrographis paniculata, Zingiber officinale, Piper nigrum*
- Actions: Antiviral, antipyretic, expectorant, supports respiratory health
- Evidence: Trials showed faster recovery from mild COVID-19
- (Ahmad, 2021)

b. Nilavembu Kudineer

- Actions: Antiviral, antipyretic, also used in treatment for dengue, chikungunya and viral fevers.
- (Ahmad, 2021)

c. Amukkara Chooranam

- Action: Adaptogenic, stress-reducing, immune enhancing
- (Ahmad, 2021)

d. Brahmananda Bairavam Mathirai

- Actions: Antipyrectic, respiratory tonic, immune-supportive(Ahmad, 2021)

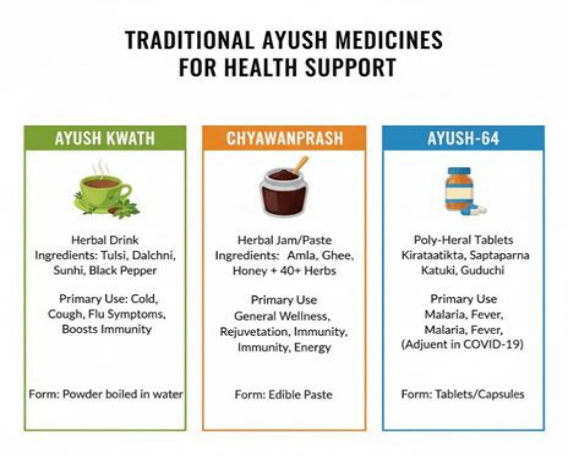


Fig 6: Commonly used Ayush medicines for health suport

V. IMMUNITY BOOSTING CLAIMS- TYPES AND EXAMPLES

During the COVID-19 pandemic Ministry of AYUSH has promoted several formulas and self-care measure as Immune-supportive. This information reached the public through various platforms like advisories, state distributors, packaged products and media campaigns. It's very important to know the wording used by the brands, because words like "supports immunity", "prevents", or "clinically used have different meaning in scientific and regulatory perspective. So, the ministry's advisories and the research activity conducted during pandemic led to the creation of data det of policy, practice and early clinical evidence. ()

TYPES OF CLAIMS:

1. FUNCTIONAL/ STRUCTURE AND FUNCTION CLAIMS

If the product helps a normal body function without saying it prevents, treats, or cures a specific disease then it is known as Structure and function claim. These claims are about supporting homeostasis or normal physiological function.

For instance, Ayush kwath is promoted as an herbal decoction made from Tulsi, Dalchini, Sunthi, and Krishna Marich that supports immune function and may help in maintaining respiratory health. If we observe the label it doesn't claim to treat any disease.

Even though the ingredients in Ayush Kwath have immunomodulatory, antioxidant and anti-inflammatory properties there were no high-quality randomized trials to prove the properties. Policy documents emphasize traditional use and experiential evidence while calling for clinical validation.

2. PREVENTIVE / PROPHYLACTIC CLAIMS

If the product claims to reduce the risk of illness, then it is known as preventive claim. This claim is stronger than functional claim and edges toward a public health claim. For this type of claim regulatory authority requires stronger evidence to support the risk-reduction statements.

For example, Ayush advisories and state programs recommended various prophylactic measures and kits. Example, the AYURAKSHA immunity kit was distributed to frontline workers and was advertised among communities for prophylactic use and it was evaluated in non-randomised intervention among Delhi police personnel. (Nesari, 2022). The messaging often used words like, "may help reduce risk" or "for prophylactic use" instead of "cures".

Non-randomised trial of AYURAKSHA reported lower IgG positivity or favourable signals, but this doesn't give authentic information as randomised trial.

3. SYMPTOM-SUPPORT/ RECOVERY CLAIMS

If the product claims to relieve symptoms and helps in recovery then it is known as recovery claim. These claims are about the symptomatic relief or convalescence rather than prevention.

Example, AYUSH-64 was repurposed and promoted as an adjunct to standard care for asymptomatic and mild COVID-19 to help in recovery and symptomatic relief. There were several published trials showing AYUSH-64 as safe and gives faster clinical recovery when used with standard of care. Studies described that AYUSH-64 can be used as adjuvant rather than a replacement for medical therapy. (Singh H, 2022)

4. TRADITIONAL USE / CULTURAL CLAIMS

If the product claim cites centuries of use in classical texts and relies on historical/traditional authority rather than modern clinical trials. This is commonly used to justify recommending an intervention in public health advisories.

Many AYUSH advisories explicitly reference classical formulations (Chyawanprash, Guduchi) and classical texts when recommending daily selfcare measures and herbal decoctions. Traditional use supports efficacy and safety for long used remedies, but modern clinical endpoints like infection rates, hospitalization, viral clearance require properly controlled trials to move beyond probability. Several AYUSH prompted trials

attended to provide that evidence, with mixed but sometimes promising results.

5. IN-SILICO / MECHANISTIC OR "SCIENTIFIC RATIONALE" CLAIMS

Producers or advocates shows lab, in-silico, or small mechanistic studies to support a claim. These are preclinical pieces of evidence that support hypotheses but do not substitute human clinical trials.

For example, for both Kabasura kudineer and several herbs in Ayush Kwath, there is a vast information on in-silico and in-vitro studies during early pandemic as mechanistic justification for trials and advisories. These findings were used to explain why the herbs could possibily be helpful.

Fig 7: Types of claims

VI. REGULATORY GUIDELINES- FSSAI & AYUSH

FSSAI GUIDELINES:

The Food Safety and Standards Authority of India (FSSAI) has made clear rules to make sure that products like health supplements, nutraceuticals, special dietary foods and foods with probiotics and prebiotics are safe, truthful, and beneficial.

01. Who and What these rules apply to

These rules cover:

- Health supplements: are the products which are meant to add nutrients to your regular diet, for people over 5 years of age.
- Nutraceuticals: are the foods that provide extra health benefits beyond basic nutrition.
- Food for special dietary use: are the foods made for people with special health or physiological needs (e.g., diabetics, pregnant women, sports persons).
- Food for special medical purposes: are the foods designed for patients who need a specific diet for medical conditions.
- Foods with probiotics/prebiotics: are the products containing beneficial bacteria or ingredients that support them.
- Plant/botanical-based specialty foods: are foods using safe herbs/plants with a history of safe use.
- Novel foods: are new or innovative food products with no traditional consumption history.

02. General rules for all products

- Must meet Indian Pharmacopoeia or other recognized quality standards.
- Nutrient levels cannot exceed the Recommended Dietary Allowances (RDA) set by ICMR or Codex standards.
- Labels must clearly state purpose, usage, warnings, and target audience.
- Claims must be backed by scientific evidence and approved by FSSAI if needed.
- No hormones, steroids, or psychotropic substances allowed.
- No misleading claims about curing diseases.
- For new or unusual ingredients, prior approval from FSSAI is mandatory.

03. Claims and Advertisements:

- Allowed claims: should mention nutrient function, enhanced function, health maintenance, immunity support, anti-aging (*with evidence*).
- Not allowed: should not give disease cure claims or drug-like promises
- All healthy claims should have a valid scientific proof- from human studies, traditional literature, or epidemiological data.
- If the evidence is weak or the ingredient is novel, FSSAI approval is required for marketing the product.

04. Labelling must include

- Product type ("HEALTH SUPPELEMENT" or "NEUTRACEUTICAL")
- Nutrient content and % of RDA
- Usage instructions and duration
- Warnings or Cautions ("not for medicinal use," "keep out of reach of children")
- Specific cautions for certain groups (ex, not for pregnant women unless advised by a doctor)

05. Special provisions

- Sportsperson products: Must be labelled "FOR SPORTSPERSON ONLY," given only under medical advice, and free from WADA- prohibited substances.

- Infant foods: These rules do not apply to foods for infant under 24 months, separate infant nutrition regulations apply.
- Botanical ingredients: Must come from an approved list, other require safety proof and FSSAI approval.
- Probiotics: Only approved strains allowed, with minimum effective amounts per serving.
- Prebiotics: Must not exceed safe daily limits.

06. Penalties and Enforcement

- Products that are not following the rules can be banned, recalled, or fined.
- Misleading claims or unsafe ingredients can lead to the licence suspension.

AYUSH/ CCRAS GUIDELINES

01. Evidence- based Validation

- Any claim that a product boosts immunity must be scientifically validated through,
  - Clinical studies on humans showing improvement in immune parameters
  - Pharmacological studies demonstrating immunomodulatory activity.
  - Evidence from traditional medicine texts and modern research data.

02. Use of traditional literature

- Immunity claims can be supported by classical Ayurveda, Siddha, or Unani references if the formulation is based on traditional recipe.
- Such claims should still be verified by modern scientific methods wherever possible.

03. Permissible language for claims

- Claims should be given in supportive terms like "supports immune function," or "helps maintain body's defence system," rather than absolute disease-prevention or cure statements.
- Avoid exaggerated or guaranteed outcomes.

04. Safety requirements

- Safety evaluation must include
  - Toxicity studies (acute, sub-acute, chronic) if the formulation is new or uses new route of administration / dose.
  - Long term safety data should be provided for chronic use.
- The product should be free from harmful contaminants or substances (heavy metals, pesticides, microbial toxins)

05. Target population considerations

- Immunity claims should specify the intended group (target group) (e.g., general adults, elderly, children) and provide supporting evidence for that demographic.

06. Labelling for immunity claims

- Must state:
  - Active ingredient(s) responsible for the immune benefit.
  - Dosage form and recommended dosage
  - Duration of use
  - Any cautions (e.g., pregnancy lactation, concurrent medical conditions).

07. Prohibited claims

- AYUSH products cannot make disease-specific prevention or cure claims for infectious disease unless it is approved after rigorous clinical validation.
- No COVID-19, flu, or similar infectious disease prevention claims unless tested and approved under formal trials.

08. Regulatory submission

- For new formulations making immunity claims, dossiers should include
  - Literature review
  - Preclinical and clinical data
  - Standardization parameters
  - Justification for dosage and route of administration.

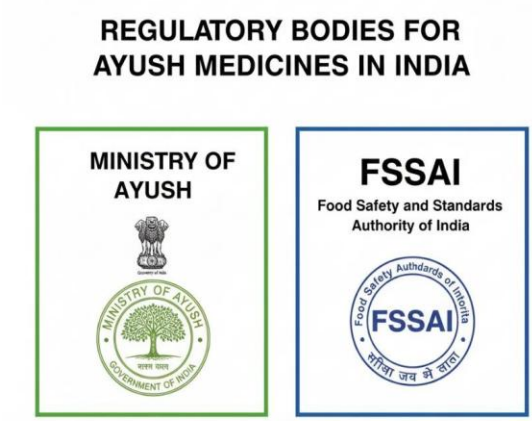


Fig 8: Logos of regulatory bodies

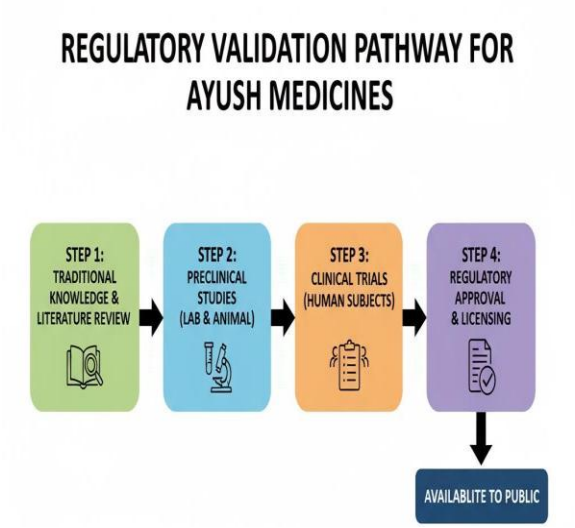


Fig 9: Regulatory validation pathway

VII.. AYURVEDIC PRINCIPLES BEHIND IMMUNITY FORMULATIONS

In Ayurveda, immunity is understood through the concept of Vyadhikshamatva -is the ability of the body to resist, recover from, and prevent diseases. This is achieved by maintaining harmony between mind, body, and spirit, ensuring strong Ojas (vital essence), balanced Tridoshas (vata, pitta, kapha), and robust Agni (digestive fire) (Patil SS, 2024) (Dr. Priyanka Inaniyan, 2021)

Ayurvedic immunity formulations, particularly Rasayana therapies, combine herbal, dietary, and lifestyle interventions for long term resilience.

01. CORE AYURVEDIC CONCEPTS OF IMMUNITY

Ojas – Vital Essence

- It is the subtle essence of all bodily tissues (dhatus)
- It maintains vitality, disease resistance, mental stability, and emotional balance.
- Built from well-digested food and healthy metabolism.
- Depletion leads to fatigue, susceptibility to infections, and poor recovery (Dr. Priyanka Inaniyan, 2021) (Patil SS, 2024)

Agni – Digestive fire

- It governs digestion, nutrient assimilation, and metabolism
- Strong Agni prevents *Ama* (toxin) formation. It is the root cause of many diseases.
- Healthy Agni directly supports Ojas and immune strength. (Dr. Priyanka Inaniyan, 2021) (Patil SS, 2024).

Tridosha balance

- Vata: it is related to movement and nervous system
- Pitta: it is related to metabolism and transformation of body
- Kapha (sleshma): it is related to structure, lubrication, stability of body; it functions like Ojas when balanced. (Dr. Priyanka Inaniyan, 2021)

Types of Bala (Strength/ immunity)

- *Sahaja Bala:* it is meant by inborn, genetic immunity
- *Kalaja Bala:* it is meant by seasonal and age dependent immunity
- *Yuktikrita Bala:* can be acquired through diet, herbs, and lifestyle (Dr. Priyanka Inaniyan, 2021) (Patil SS, 2024)

02. Rasayana therapy & Immunomodulators

Rasayana- it is rejuvenation therapy that promotes longevity, vitality, and disease resistance (Patil SS, 2024) (Govindarajan Raghavan et.al., 2022)

Key Rasayana herbs with immunomodulatory activity are mentioned in the table below

HERB	ACTIONS
Amla (*Emblica officinalis)*	Rich in vitamin C; Antioxidants; enhances Ojas; reduces oxidative stress (Patil SS, 2024) (Govindarajan Raghavan et.al., 2022)
Ashwagandha (*Withania somnifera)*	Adaptogen; improves resilience to stress; supports immune cell function (Patil SS, 2024) (Govindarajan Raghavan et.al., 2022)
Guduchi (*Tinospora cordifolia*)	Immunomodulatory, anti-inflammatory, supports detoxification (Patil SS, 2024) (Susmita Roy et.al., 2022)
Shatavari (*Asparagus racemosus)*	Nourishes Ojas; supports female reproductive health and immunity (Patil SS, 2024)
Tulsi (*Ocimum sanctum)*	Antimicrobial, adaptogenenic; enhances stress resistance (Patil SS, 2024) (Susmita Roy et.al., 2022)
Turmeric (*Curcuma longa)*	Anti-inflammatory, antioxidant, improves immune signaling (Patil SS, 2024) (Susmita Roy et.al., 2022)

03. CLASSICAL FORMULATION EXAMPLE CHYAWANPRASH

- Contains Amla and 30+ herbs such as Guduchi, Shatavari, Pippali, Ashwagandha (Govindarajan Raghavan et.al., 2022)
- Research proves that it,
  - Increases in B-cell count
  - Increases in Ig-G and IgM antibodies
  - Decreases in inflammatory cytokines (IL-6, TNF-α)
  - 99.79% viral RNA load reduction in preclinical model (Govindarajan Raghavan et.al., 2022)
- Functions as Rasayana, supporting respiratory health, tissue rejuvenation, and immune resilience.

04. LIFESTYLE & DIET IN IMMUNE SUPPORT

Dinacharya (Daily Routine) (Patil SS, 2024)

Activities that should be followed daily for better immunity are mentioned below

- Early rising in sync with natural rhythms.
- Jivhanirlekhana (tongue scraping) & oil pulling for oral detox.
- Abhyanga (oil massage) for circulation and tissue nourishment.
- Yoga, pranayama, and medication for mental balance.

Rithucharya (Seasonal Regimen) (Patil SS, 2024) (Dr. Priyanka Inaniyan, 2021)

Activities that should be done according to seasonal changes are given below

- Adjusting diet and lifestyle to seasonal dosha changes
  - E.g., Vata season- warm, unctuous, grounding foods

Sathvic Diet (Dr. Priyanka Inaniyan, 2021) (Patil SS, 2024)

Sathvic diet is also known as vegetarian diet, most important foods that should be included in diet are given below

- Fresh grains, fruits, vegetables, dairy, ghee
- Digestive spices- ginger, cumin, turmeric
- Avoid processed, stale, and incompatible foods (*Viruddha Ahara*)

05. MODERN SCIENTIFIC CORRELATION

- Gut-immune Axis- Ayurveda's Agni concept parallels the finding that 70% of immune cells reside in the gut. (Patil SS, 2024)
- Phytochemical Action-Polyphenols, flavonoids, and antioxidants in rasayana herbs modulate immunity. (Govindarajan Raghavan et.al., 2022) (Susmita Roy et.al., 2022)
- Evidence based formulations- Studies confirm that ayurvedic formulations enhance immune markers, reduce inflammation and offer viral protection.

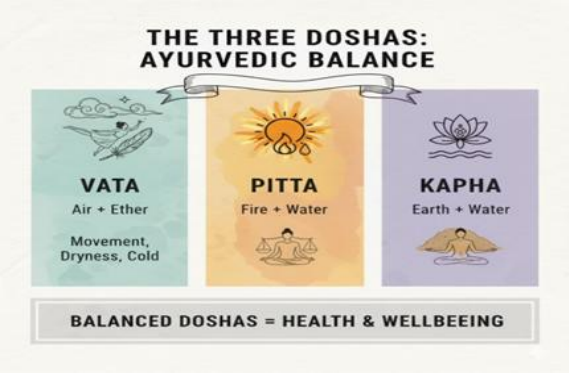


fig 10: Tridoshas

fig 11: Immunity chain

VIII.. PHYTOCHEMICAL PROFILE OF AYUSH KWATH AND OTHER FORMULATIONS

01. PHYTOCHEMICAL PROFILE OF AYUSH KWATH:

This part explores the phytochemical composition of the four herbs in AYUSH kwath they are, Tulsi, Dalchini, Sunthi, and Krishna marich. For each plant we look into the key chemical classes, notable compounds, biosynthetic origin within the plant, and physiological functions relevant to immunity and health.

TULSI (*Ocimum sanctum/ O. tenuiflorum)*

Tulsi is a rich source of Phenylpropanoids (i.e., eugenol, rosmarinic acid), flavonoids (apigenin, luteolin), and triterpenoids (ursolic acid) that orginate in the phenylpropanoid biosynthetic pathway and mevalonate pathway. Essential oils like linalool and 1,8-cineole are produced in glandular trichomes. These compounds exhibit strong antimicrobial, antioxidant, and immunomodulatory activities, supporting the role of Tulsi in respiratory and systemic immunity.

DALCHINI (*Cinnamomun verum/ C.zeylanicum)*

The bark of Dalchini contains high levels of (E)-cinnamaldehyde synthesized via the shikimate and phenylpropanoid pathways. Other phenylpropanoids (cinnamic acid, eugenol) and terpenes (linalool, β-caryophyllene) contribute to its antimicrobial, antifungal, and anti-inflammatory profile. The aromatic aldehydesare largely responsible for its flavor and preservative properties.

SUNTHI (*Zingiber officinale, dried)*

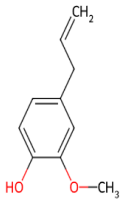
Drying fresh ginger converts gingerols inti shagoals, enhancing pungency and altering bioactivity. Both compound groups originate from the phenylpropanoid-polyketide pathway. Volatile sesquiterpenes such as zingiberene are stored in oil cells and provide antimicrobial and anti-inflammatory properties. Phenolics like 6-gingerol and 6-shagaol are particularly active against oxidative stress and inflammation.

KRISHNA MARICH (*Piper nigrum)*

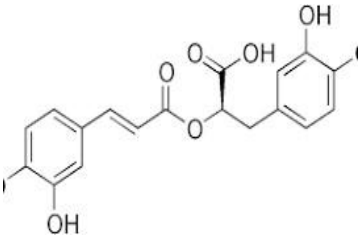
The alkaloid piperene is produced via the piperidine biosynthetic route, it is responsible for pungency and has a well-documented role as bioenhancer by inhibiting drug-metabolizing enzymes. Essential oils containing β-caryophyllene and sabinene are synthesized via the mevalonate (MVA) and methylerythritol phosphate (MEP) pathways, offering antimicrobial and antioxidant activity.

PHYTOCHEMICAL DETAILS

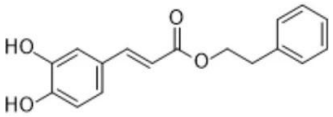
Ingredient	Major chemical classes & key constituents	Biosynthetic origin in plant	Functional role
Tulsi (*Ocimum sanctum)/ (O. tenuiflorum*	Phenylpropanoids, eugenol, rosmanic acid, caffeic acid, Flavonoids, apigenin, luteolin, triterpenoids, ursolic acid, Essential oils, linalool, 1,8-cineole, β-caryophyllene	Phenylpropanoid and flavonoids from phenylpropanoid pathway in leave; terpenes in glandular trichomes	Antimicrobial, antioxidant, anti-inflammatory, immunomodulatory.
Dalchini (*Cinnamomum verum)/ (C. zeylanicum)*	Aromatic aldehyde; (E)-cinnamaldehyde; Esters/acids: cinnamyl acetate, cinnamic acid, phenylpropanoid: eugenol; Minor terpenes: linolool, β-caryophyllene	Phenylpropanoids via shikimate & phenylpropanoid pathways in bark; terpenes in oil cells	Antimicrobial, antifungal, anti-inflammatory, flavoring
Sunthi *(Zingiber officinale, dried rhizome)*	Phenolics: [6]-, [8]-,[10]- gigerol; Shogoals: [6]-, [8]-,[10]-shogoal; Zingerone, paradols, gingerenone-A; Volatile terpenes: zingiberene, β-bisabolene, β-sesquiphellandrene	Phenolic ketones via phenylpropanoid-polyketide pathway in rhizomes; volatiles in oil cells	Anti-inflammatory, antioxidant, digestive stimulant, antimicrobial.
Krishna marich (*Piperene nigrum)*	Alkaloids: piperine, chavicine, piperettine; Volatile terpenes: β- caryophyllene, sabinene, limonene, α/β-pinene	Piperidine alkaloids via piperidine biosynthesis in pericarp cell; terpenes from MVA & MEP pathways	Bioavailability enhancer, digestive stimulant, antimicrobial.



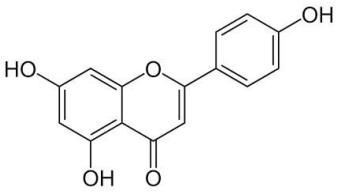
12a, Eugenol



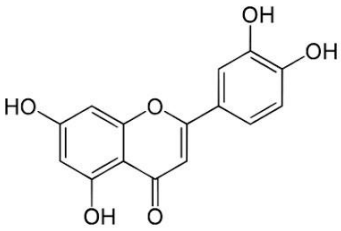
12b, Rosmanic acid



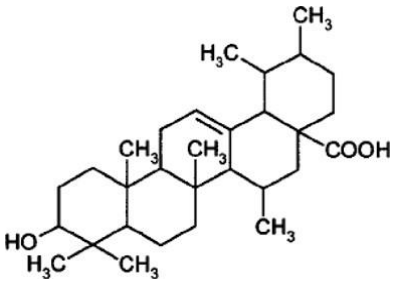
12c, Caffeic acid



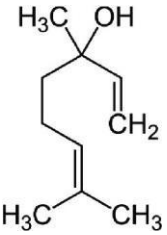
12d, Apigenin



12e, Luteolin

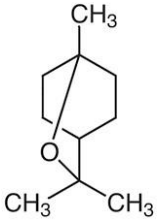


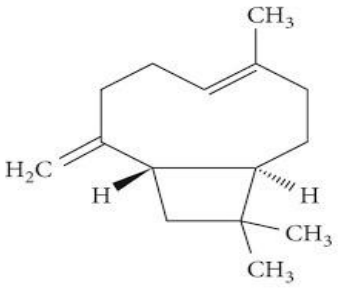
12f, Ursolic acid



12g, Linolool

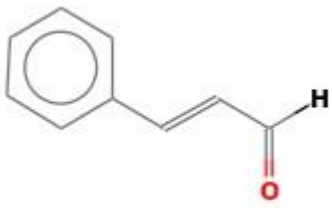
12h, 1,8- Cineole



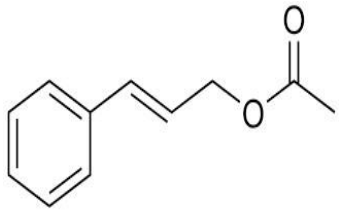


12i, β- Caryophyllene

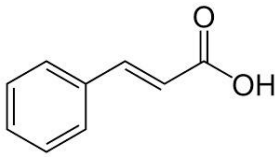
Fig 12: Chemical constituents of Tulsi



13a, (E) Cinnamaldehyde

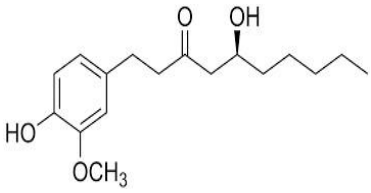


13b, Cinnamyl acetate

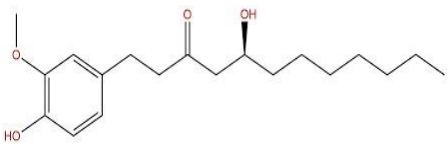


13c, Cinnamic acid

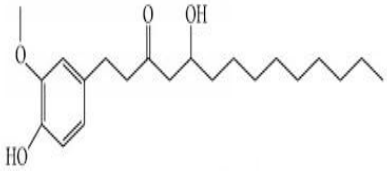
Fig 13: Chemical constituents of Cinnamon



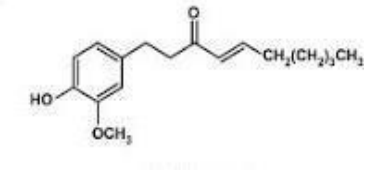
14 a, 6- Gingerol



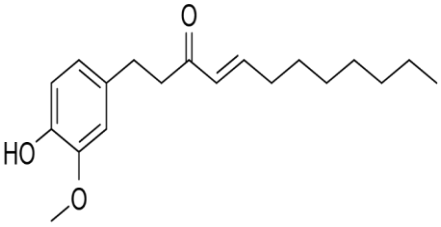
14 b, 8- Gingerol



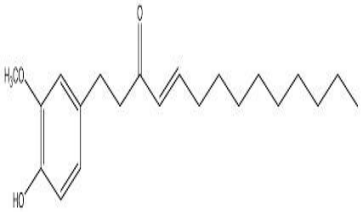
14c, 10-gingerol



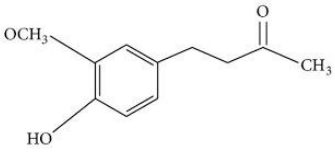
14d, 6-Shogoal



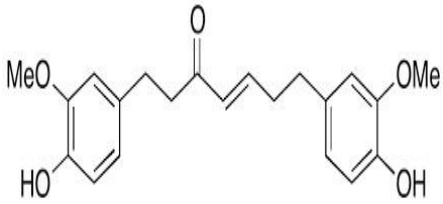
14e, 8-Shogoal



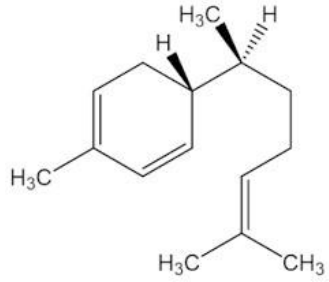
14f, 10-Shogoal



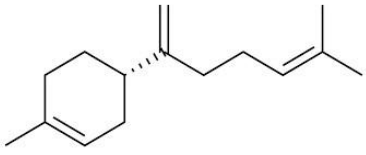
14g, Zingerone



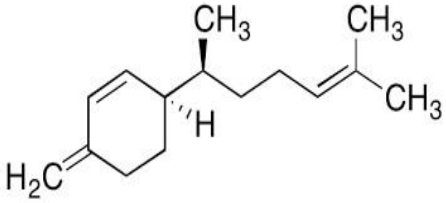
14h, Gingerenone-A



14i, Zingeberene

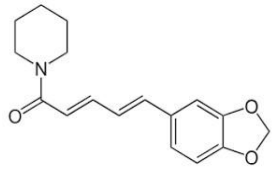


14j, β-bisabolene

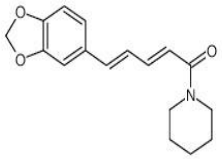


14k, β-sesquiphellandrene

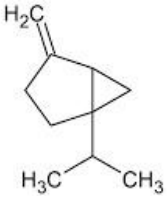
Fig 14: Chemical constituents of Ginger



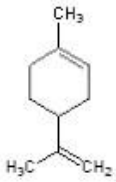
15a, piperine



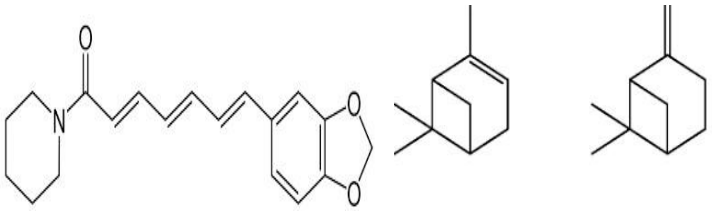
15b, Chavicine



15c, Sabinine



15d, Limonene



15e, Piperttine

15f, α-pinene 15g, β-pinene

Fig 15, Chemical constituents of pepper

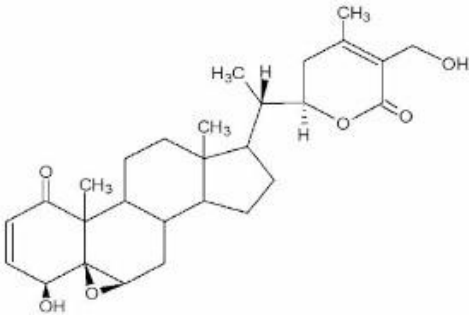
PHYTOCHEMICAL PROFILE OF CHYAWANPRASH

- Chyawanprash is not one fixed recipe: classical texts describe that it contains 35-50 herbs however, commercial brands vary. In simple way chyawanprash is an amla-centric polyphenolic base layered with adaptogenic roots like ashwagandha, guduchi, satavari and also have aromatic spices whose essential oils add antimicrobial/ antioxidant power.
- Chemistry matrix is dependent. Heating amla with ghee/honey/sesame oil creates a lipid-rich, sugar-rich environment that can protect phenolics and carry fat-soluble actives like withanolides essential-oil terpenes. Vehicle composition that is oil: ghee: honey matters for stability and accessibility.
- Signature "maker" compounds to track in analysis are emblicanin A/B (amla), withaferin A/withanolide A (ashwagandha), piperine (pippali), tinosporaside (guduchi), 1,8-cineole & α- terpinyl acetate (cardamom), cinnamaldehyde (cimmamom), eugenol (clove), sesamolin/sesamolin (sesame oil). Labs ofter qnatify these compounds in chyawanprash related QC work.
- Evidence tiering: For most constituents; mechanistic and preclinical data are stronger than human trial data. Whole product clinical data is available but are limited and heterogenoeus.

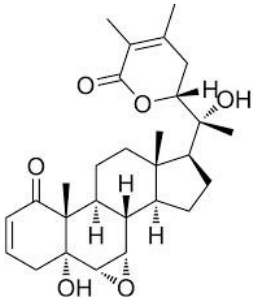
CORE BOTANICALS IN CHYAWANPRASH

INGREDIENT	KEY PHYTOCHEMICAL	MAJOR CLASSES	WHAT THEY ARE STUDIED FOR
Amla (*Phyllanthus emblica*)	Emblicanin A&B, gallic acid, ellagic acid	Hydrolyzable tannins, phenolic acids	Potent antioxidant, supports anti-inflammatory and cytorotective effects in vitro/ in vivo
Guduchi (*Tinospora cordifolia)*	Tinosporide, cordifolioside A,	Diterpenoids, Alkaloids, polysaccharides	Immunomodulatory, antioxidant, antipyretic

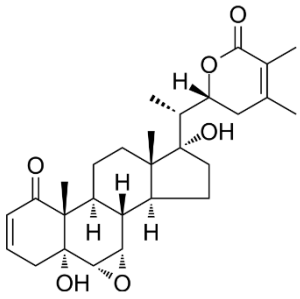
	magnofloeine(alkaloid), diterpenoid lactones		signals repeatedly in preclinical work
Ashwagandha (*Withania somnifera)*	Withaferin A, withanolide A, withanone	Steroidal lactones (withanolides)	Adaptogenic/ anti-stress claims map to withanolides; assorted anti-inflammatory and neuroendocrine effects studied.
Pippali (*Piper longum)*	Piperine, piperlongumine	Amide alkaloids	Bioavailability enhancement(piperine), wide-ranging anti-inflammatory/ anticancer signals (esp. piperlongumine)
Vidarikand (*Pueraria tuberosa)*	Puerarin, daidzin/ daidzein (isoflavanoids)	Isoflavones, saponins	Tonic/ demulcent uses; preclinical cardiometabolic and antioxidant effects reported
Shatavari (*Asparagus racemosus)*	Shatavarins (I-IV), racemoside	Steroidal saponins	Traditional “rasayana”; experimental GI, reproductive, and immune effects linked to saponins
Bala (*S. cardifolia*)	(varies by species) ephedrine- like alkaloids reported in some *sida* spp.; flavonoids	Alkaloids, flavonoids	Traditional tonic; literature notes variability and safety considerations-species identification matters.
Gokshura (*Tribulus terrestris)*	Protodioscin, tribulosin	Steroidal saponins	Urogenital/tonic claims; mixed clinical data, mostly preclinical mechanistic work
Dashamula (ten-root group)	(Composite) polyphenols, lignans, saponins depending on species mix	Mixed	Used as functional decoction; phytochemistry varies with exact species composition
Agar/ Aquilaria	Agarwood sesquiterpernes (agarospirol, etc.)	Seaquiterpenes	Aromatic, carminative roles; limited direct data in Chyawanprash context



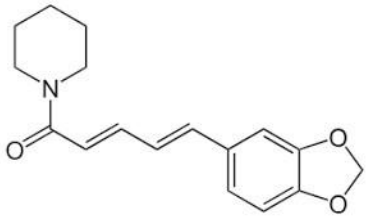
16a, Withaferin A



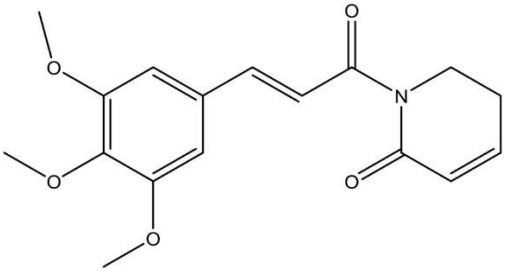
16b, Withanolide A



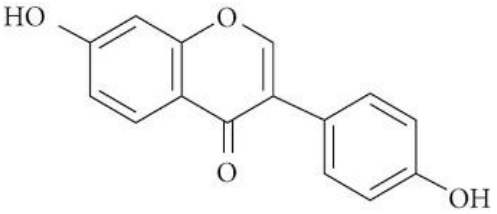
16c, Withanone



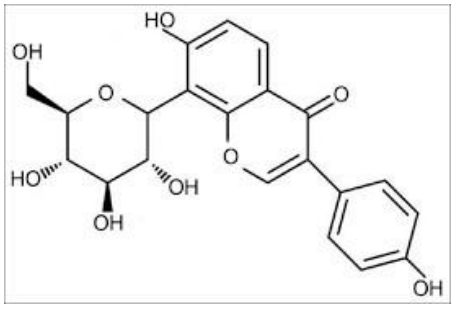
16d, Piperine



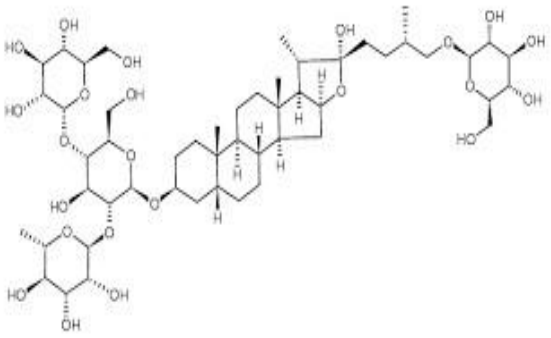
16e, Piperlongumine



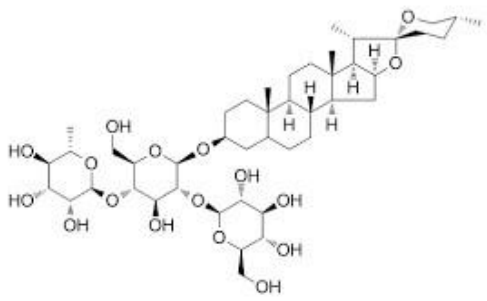
16f, Diadzene



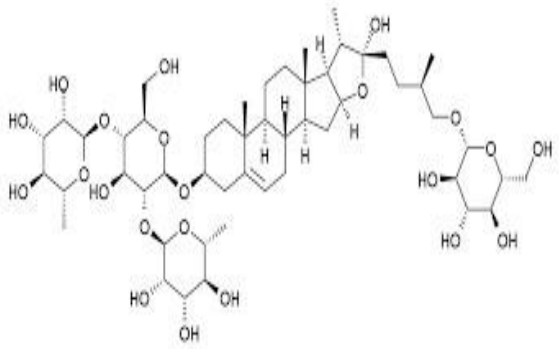
16g, Puerarin



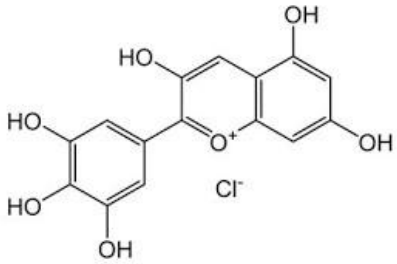
16h, Shatavarin I



16i, Shatavarin IV

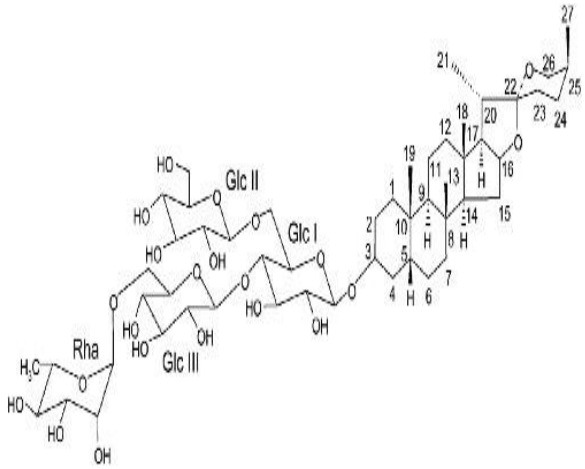


16j, Protodiosin



16k, Turbulosin

16l, Agarospirol

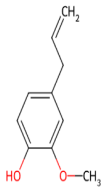


16m, Racemoside A

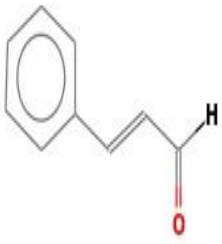
Fig 16, Chemical constituents of Core botanicals of Chyawanprash

SPICE/ ARMONIZING INGRDIENTS COMMONLY PRESENT

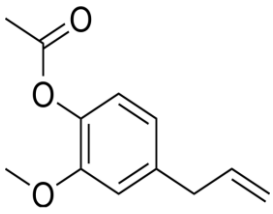
INGREDIENT	DOMINANT COMPOUNDS	MAJOR CLASSES	NOTES
Dalchini (*Cinnamomum* spp.)	Trans-cinnamaldehyde; eugenol (esp, *C.verum*	Phenylpropanoids	Strong antimicrobial/ antioxidant essential-oil profile; cinnamaldehyde is often the top constituent.
Tejpat (*Cinnamomum tamala)*	(Varies) cinnamaldehyde, eugenol	Phenylpropanoids	Used as aromatic, carminative, composition overlaps with cinnamon leaves.
Lavanga (*Syzygium aromaticum*)	Eugenol, eugenyl acetate, β-caryophyllene	Phenylpropanoids, sesquiterpenes	Very high eugenol content drives antioxidant and antimicrobial activity
Ela (*Elettaria cardamomum)*	1,8-cineole, α-terpinyl acetate	Monoterpenes (oxygenated)	Signature aroma; oils typically dominated by these two constituents (percentages vary by origin).
Nagakesar (*Mesua ferrea)*	Xanthones/flavonoids; mesuol	Xanthones, phenolics	Aromatic stamens used; antioxidant/ anti-inflammatory signals in preclinical literature



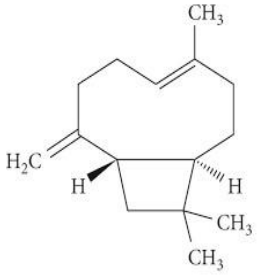
17a, Eugenol



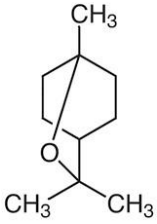
17b, Cinnamaldehyde



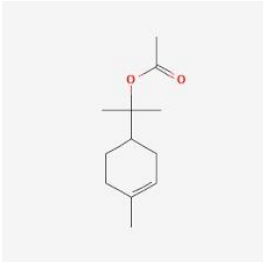
17c, Eugenyl acetate



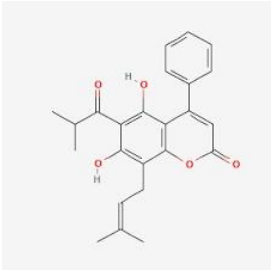
17d, β-Caryophyllene



17e, 1,8- Cineole



17f, α- Tripenyl acetate

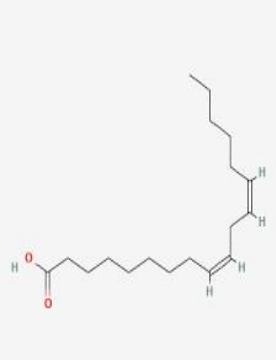


17g, Mesuol

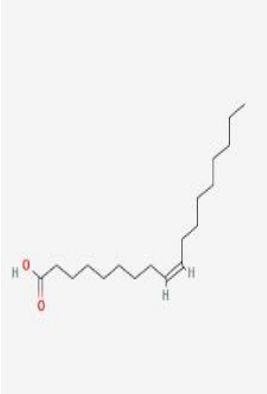
Fig 17- Chemical constituents of S pice ingredients of Chyawanprash

VEHICLE/ BASE INGREDIENTS TO SHAPE MATRIX

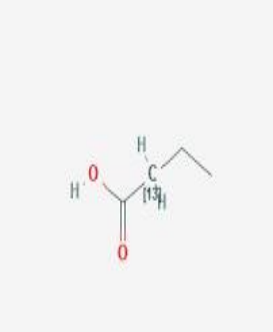
INGREDIENT	WHAT'S INSIDE	WHY IT MATTERS
Sesame oil	High in oleic + linoleic acids; lignans (sesamin, sesamolin), ϒ-tocopherol	Lipid carrier improves solubility/ dispersion of lipothilic actives; oil itself supplies antioxidant lignans and Vitamin E homologs
Ghee	Saturated and short-chain fatty acids including butyric acid, phospholipids; fat-soluble vitamins A, D, E, K (Variable by source)	Enhances mouthfeel, acts as lipid vehicle; adds fat-soluble vitamins
Honey	Approx.- 80- 85% sugars (fructose/glucose), approx.- 15-17% water; enzymes; phenolic compounds	Sweetener, preservative; contributes its own phenolics/ enzymes to antioxidant pool



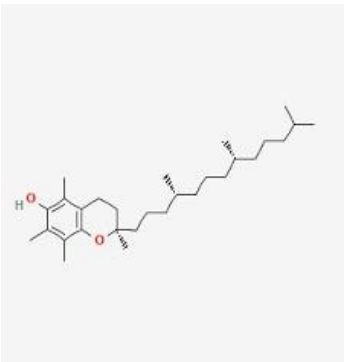
18a, Lineolic acid



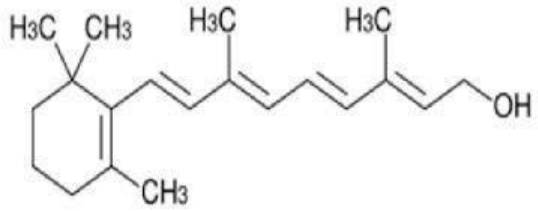
18b, Oleic acid



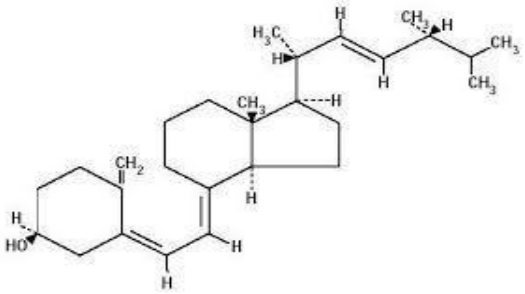
18c, Butyric Acid



18d, Vitamin E



18e, Vitamin A



18F, Vitamin D

Fig 18- Chemical constituents of Base ingredients of Chyawanprash

PHYTOCHEMICAL PROFILE OF AYUSH-64

AYUSH-64 is a polyherbal formulation developed by CCRAS that contains *Alstonia scholaris* (Saptaparna) bark extract, *Picrorhiza kurroa* (Katuki) root/rhizome extract, *Swetia chirata* (Kiratatika) whole plant extract and *Caesalpinia crista* (Kuberaksha) seed powder. The formulation is rich in diverse phytochemicals such as alkaloids, iridoid glycosides, secoiridoids, xanthones, diterpenes, triterpenes, and phenolics, which together are believed to contribute to its therapeutic actions in infectious and inflammatory conditions.

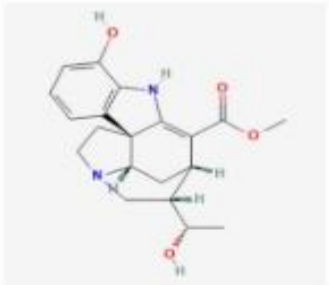
INGREDIENT-WISE PHYTOCHEMICALS

- *Alstonia scholaris* (Saptaparna- bark): *Alstonia scholaris* is an alkaloid-rich medicinal tree widely used in ayurveda. The bark contains plenty indole alkaloids such as echitamine, scholaicine, alstonine, and picrinine, that are considered the main bioactive markers. These alkaloids are associated with antimicrobial, antimalarial and immunomodulatory activities. Its overall phytochemical complexity dominated by indole alkaloids along with phenolic antioxidants explains why it is included in multi herbal formulation such as AYUSH-64.
- *Picrorhiza kurroa* (Katuki) root/rhizome extract: It is a well-known medicinal herb of the Scrophulariaceae family, widely known for its hepatoprotective and immunomodulatory actions. The root and rhizome are the important medicinal parts, rich in iridoid glycosides, which serve as its chemical markers. Major constituents include picroside-I, picrocide-II, kutkoside, and apocynin, that collectively are sometimes referred to as the "kutkin" fraction. In addition, studies also show the presence of cucurbitacins, phenolic acids, flavonoids, sterols (β- sitosterol), and vanillic acid derivatives, contributing to antioxidant, anti-inflammatory, and antimicrobial properties. The picrosides (I&II) are the most abundant and are widely used for HPLC/HPTLC quantification as quality-control standards. The chemical richness

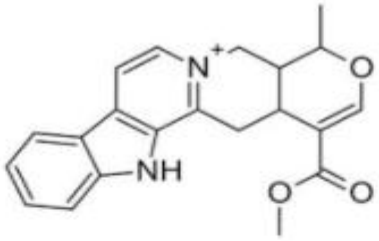
of Katuki is the reason for its therapeutic applications in liver protection, digestive health, and immune enhancement.

- *Swetia chirata* (Kiratatika) whole plant extract: is a highly valued Himalayan herb, that contains a wide variety of natural plant chemicals that give it both its strong bitterness and medicinal power. Researchers have found that the whole plant is rich in especially bitter glycosides such as amarogentin, swertiamarin, amaroswerin, gentiopicroside, and chiratin, which are the main reasin it has been used for centuries in traditional healing. Alongwith these, the plant also carries a wide range of xanthones (like swerchirin, bellidifolin, and mangiferin), flavonoids (such as swertisin and luteolin), and alkaloids like gentianin. It additionally provides plant sterols and triterpenes (including β-sitosterol, oleanolic acid, and ursolic acid), as well as phenolic compounds, coumarins, terpenoids, and quinones. Together, these compounds make *S. chirata* a natural powerhouse with strong antioxidant, antimicrobial, antidiabetic, liver-protective, anti-inflammatory, and anticancer properties. This is the reason why it is used widely in Ayurveda, Siddha, Unani and Tibetan medicine for treating fevers, digestive issues, liver problems, diabetes and infections. The abundance of its phytochemical profile highlights its potential in traditional remedies as well as making it a promising source for development modern medicines.
- *Caesalpinia crista* (Kuberaksha) seed powder: also known as Fever nut or Latakaranja, is an important Ayurvedic plant, whose seed powder is rich in diverse bioactive compounds. Phytochemical studies have reported the presence of glycosides especially bonducin, which is linked to antitumor, analgesic, and anti-inflammatory effects. Seeds also contain fixed oils rich in fatty acids, along with alkaloids, saponins, tannins, flavonoids, sterols, and triterpenoids, which contribute to its medicinal value. These phytoconstituents are associated with wide range of pharmacological actions such as Antipyretic, antidiabetic, blood-purifying, wound healing, antimicrobial, hepatoprotective and immunomodulatory properties.

19a, Echitamine

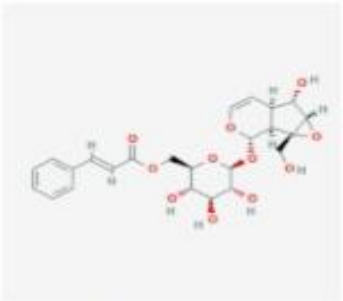


19b, Scholaicine

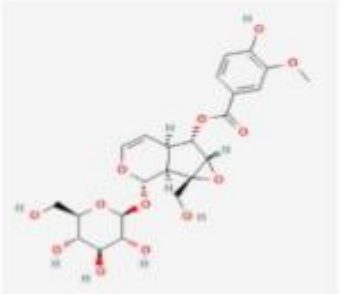


19c, Alstonine

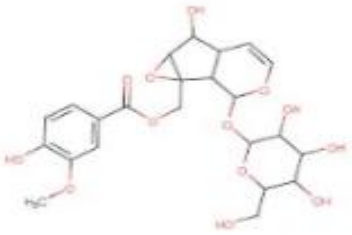
19d, Picrinine



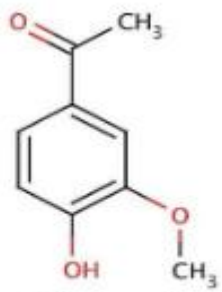
19e, Picroside I



19f, Picroside II

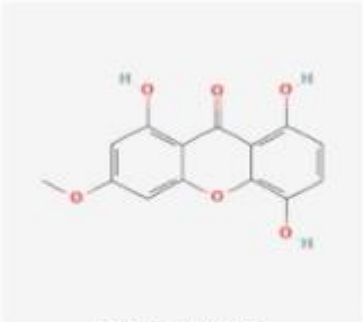


19g, Kutkoside

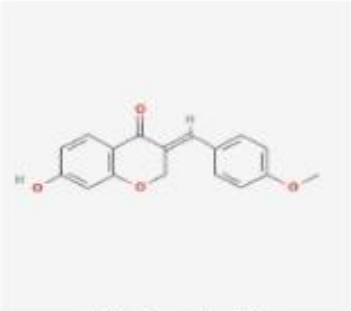


19h, Apocynin

19i, Amarogentin



19j, Bellidifolin



19k, Bonducellin

Fig 19- Chemical constituents of Ayush-64

IX. MECHANISM OF ACTIONS (MODERN SCIENTIFIC PERSPECTIVES)

MECHANISM OF ACTION OF AYUSHKWATH

From a modern scientific point of view, Ayush Kwath is a multi-herbal decoction that contains Tulsi, Dalchini, Sunthi, and Krishna marich and has health benefits like anti-inflammatory, antiviral, antioxidant, and immunomodulatory mechanisms.

1. Antiviral activity

Phytoconstituents such as flavonoids, terpenoids, and polyphenols in Tulsi and Cinnamon shows potential to interfere with viral entry by blocking the ACE2 receptor and inhibiting SARS-CoV-2 viral proteases. Gingerol and shagols grom ginger also demonstrates the ability to supress viral replication pathways.

2. Anti-inflammatory effects:

Chronic inflammation is a hallmark of COVID-19 severity. Compounds like Cinnamaldehyde from cinnamon, curcuminoids, and gingerols act by suppressing pro-inflammatory cytokines (IL-6, IL-1β, TNF-α) and downregulating COX and LOX enzymes, thereby preventing the "**cytokine storm"** associated with severe infections.

3. Immunomodulation:

Ayush kwath enhances both **innate and adaptive immunity.** Tulsi polyphenols stimulate NK cells and macrophage activity, while Piperine from black pepper modulates T-helper cell responses by balancing Th1/Th2/Th17/Treg. These actions improve the body's defence while reducing harmful hyper-inflammation.

4. Gut-immune Axis Conditioning:

The herbs support gut-associated lymphois tissue (GALT) by promoting beneficial microbiota and reducing gut inflammation. Since 70% of immune cells reside in the gut, this conditioning strengthens systemic immunity and improves immune tolerance.

5. Antioxidant protection:

The bioactive molecules act as free-radical scavengers, reducing oxidative stress and protecting lung and endothelial tissues from damage during viral infection.

6. Synergistic effect:

Piperine in krishna marich enhances the bioavailability of other phytochemicals, ensuring better systemic absorption and efficacy.

Overall, Ayush kwath works not as a direct immunobooster but it acts as an immune-modulator, harmonizing inflammatory pathways, strengthening

antiviral defences, protecting vital organs from oxidative damage, and supporting recovery. This modern understanding resonates with the Ayurvedic concept of *Rasayana,* where balance and resilience are restored rather than simply overstimulating the immune system.

MECHANISM OF ACTION OF CHYAWANPRASH

Chyawanprash is a classical rasayana formulation that shows its pharmacological effects through a combination of bioactive phytochemicals derived from its approximately 50 ingredients with Amla as a primary constituent. The mechanism of action is not attributable to a single compound, but rather to the synergistic interaction of diverse antioxidants, immunomodulators and adaptogenic herbs.

1. Antioxidant and Anti-aging pathways

Amla and other polyphenol-rich herbs in chyawanprash provide Vitamin C, tannins, flavonoids and phenolic acids that remove free radicals and reduce lipid peroxidation. This prevents oxidative damage at cellular and mitochondrial level, delays degenerative changes, and support anti-aging effects.

2. Immunomodulation

Experimental and clinical studies demonstrate that chyawanprash enhances both innate and adaptive immune responses.

- It augments macrophage phagocytic activity and stimulates natural killer cell cytotoxicity
- Increases secretion of immune mediators such as TNF-α, IL-β and MIP-1α, thereby priming host defences.
- Reduction in serum IgE levels and histamine release indicates its role in alleviating responses.

3. Anti-inflammatory action

Phytoconstituents like curcuminoids, saponins, and alkaloids modulate inflammatory signalling by downregulating **COX (cyclooxygenase) and LOX (lipoxygenase) pathways,** leading to decreased synthesis of pr**o**-inflammatory prostaglandins and leukotrienes. This mechanism is the reason for its benefits in chronic respiratory conditions and systemic inflammation.

4. Adaptogenic and Stress-modulating effects

Chyawanprash is recognised as adaptogen, helps to maintain homeostasis under stress. Herbs in chyawanprash regulate the hypothalamic-pituitary-adrenal (HPA) axis, thereby lowering cortisol levels, enhancing resilience and improving energy and vitality.

5. Neuroprotective and cognitive support

Active components present in ashwagandha, guduchi and amla support cholinergic neurotransmission, reduce neuroinflammation, and improve cerebral blood flow. Clinical trials have shown improvements in memory, attention and mood, suggesting anti-depressive and nootropic properties.

6. Metabolic and Detoxifying role

Several ingredients, including Haritaki and Guduchi, support liver detoxification, glucose regulation, and lipid metabolism. Chyawanprash has shown hypolipidemic activity and protection against metabolic syndrome by lowering LDL and improving HDL levels.

7. Synergistic “Yogavahi” effect

Traditional carriers like ghee and honey act as Yogavahi that means bioavailability enhancers, facilitating deeper tissue penetration and assimilation of active constituents, thereby amplifying the overall efficacy of the formulation.

MECHANISM OF ACTION OF AYUSH-64

It is a polyherbal product comprising 4 herbs; Alstonia scholaris, Picrorhiza kurrao, Swertia chirata and Caesapinia crista. It has antiviral, immunomodulatory, anti-Inflammatory, antioxidant and thrombolytic activity and makes it one of the best drugs for COVID-19.

Antiviral Action

- Phytoconstituents α-amyrin, amarogentin, kutkin, caesalpinins block the virus entry by preventing the interaction between SARS-CoV apikne protein and ACE-2 receptor.
- Certain compounds elevate intracellular Ph (Phi), suppress endosomal function like those used in treating malaria.
- Immunomodulation and Anti-inflammatory effects
- AYUSH-64 diminishes cytokine storm by down-regulating IL-6, TNF-α and pro- inflammatory kinases
- Herbal drugs such as Saptaparna and Katuki enhance digestion and metabolism correcting Amadosha
- Swertia chirata has antioxidant and immunosuppressive actions, correcting excessive response.

Pulmonary protection

- Phytoconstituents cure cough and dyspnea, inhibit alveolar inflammation and prevent fibrin deposition in lungs
- AYUSH-64 inhibits neutrophil extracellular traps (NETs) a major contributor to lung injury, thus preventing pulmonary dysfunction.

Anti-thrombotic and Anti-hyperinflammatory activity

- Endothelial dysfunction and platelet activation in severe COVID-19 lead to micro/macro thrombosis.
- Picrorhiza kurroa reverses thrombolytic effects, whereas AYUSH-64 decreases D-dimer levels in severe patients.
- These activities prevent prothrombotic and hyperinflammatory complications.

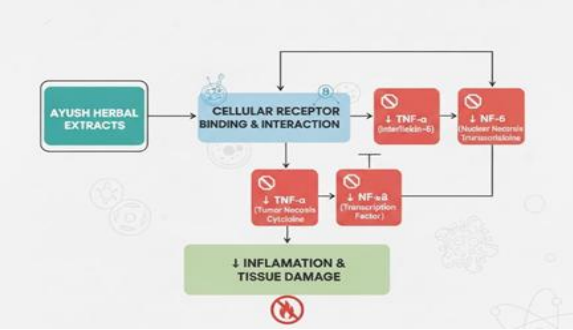


fig 20: Anti-inflammatory cytokine suppression pathway

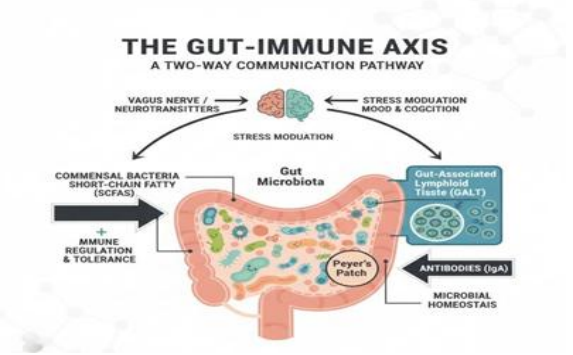


Fig 21: Gut-Immune axis

X. LABORATORY AND PRECLINICAL STUDIES

LABORATORY AND PRECLINICAL STUDIES ON AYUSH KWATH

The therapeutic rationale for Ayush Kwath, is a polyherbal formulation comprising Tulsi, Sunthi, Dalchini, and Black pepper. It has been substantiated by several laboratory and preclinical investigations carried out on its constituent herbs. Although there is limited, studies on overall formulation but there is a robust information on individual ingredients from cell-based and animal models shows the **anti-**inflammatory, immunomodulatory, antioxidant and antiviral properties of each component, providing a strong foundation for the formulation's activity.

Tulsi (*Ocimum sanctum*)

In-vitro studies conducted recently confirmed the immunomodulatory potential of Tulsi. A standardized formulation TulsiOdaat™ was tested on raw 264.7 murine macrophage cell lines and was demonstrated to significantly enhance phagocytic activity at a non-toxic concentration of 3 µg/ML. These findings indicate that Tulsi increases the innate immune response by directly stimulating the macrophage-mediated engulfment of foreign particles. Additionally, tulsi's phytochemical constituents like eugenol and ursolic acid have been reported to elevate antioxidant enzyme levels such as superoxide dismutase (SOD), catalase, and glutathione, thereby protecting cells from oxidative stress-induced damage. Collectively, these findings support immune stimulant and antioxidant agent properties at the cellular level.

Ginger (*Zingiber officinale*)

Previous researches revealed that ginger and phenol compounds, including gingerols, shogaols, paradols, and zingerone have profound impacts in vitro and animal models. In immune cell experiments they were found to reduce the pro-inflammatory cytokines IL-1β and TNF-α release by inhibiting NF- kB, COX-2, LOX, MAPK and P13K/Akt/mTOR pathways. The experimental evidence also supports that the ginger components modulate the activity of macrophages, neutrophils, T lymphocytes and dendritic cells underscoring their immunomodulatory actions. In arthritis animal model, compared to nonsteroidal anti-inflammatory drugs (NSAIDs), the ginger extract alone could remarkably inhibit joint inflammation and oxidative stress with a symptomatic improvement but not the gastric ulcerogenic action. Furthermore, ginger has also been shown to inhibit the formation of neutrophil extracellular traps in animal models of lupus and to be protective in an autoimmune setting. These in-vitro and in-vivo results support that ginger may be a strong anti-inflammatory and immune modulating agent.

Cinnamon (*Cinnamomum verum*)

This is verified in cell cultures through mediation of cinnamon anti-inflammatory. C. verum extract reduced the expression of pro-inflammatory cytokines and enzymes such as IL-1β, IL-6, COX-2 and CCL5 in PMA-differentiated THP-1 human monocytes. Mechanistically, it was found that this result was related to the inhibition of ROS production, which was mediated by NOX2, and the suppression of the PKCδ/JNK/AP-1/NF-kB signalling pathway. Recently, the main active component of cinnamon, cinnamaldehyde was found to have obvious biological activities based on preclinical studies. It has been demonstrated to have antiplatelet effect, to inhibit prostaglandins synthesis, and to pass the arachidonic acid mediated inflammatory reactions in experimental studies. Collectively, these findings suggest that cinnamon may play a regulatory role in both oxidative stress and the production of inflammatory mediators at the cellular and molecular levels.

Black pepper (*Piper nigrum, Piperine*)

Piperine is the most abundant alkaloid in black pepper, and has shown various biological effects in in-vitro and in-vivo studies. It modulates several inflammatory pathways including inhibition of NF-kB, COX-2 and iNOS, and regulation of AMPK-NLRP3 inflammasome signal, resulting in the suppression of the cytokine overproduction. In animal models, piperine diminished inflammation damage in arthritis and metabolic syndrome, and had antiviral properties. Another pharmacologic effect characteristic of PE is increased bioavailability of co-administered phytochemicals due to inhibition of cytochrome P450 enzymes and P-glycoprotein efflux transporters. This dual effect of directing immunomodulation and making synergy provides an added worth to piperine in multi-herb formulations like Ayush kwath.

Formulation-Level Evidence

The laboratory data on Ayush kwath are sparse, but the combined mechanistic understanding of its components gives robust preclinical rationale for its utility. All the ingredients of the formulation operate on overlapping inflammatory and immune regulative mechanisms like NF-Kb inhibition, ROS inhibition, modulation of cytokines, and macrophage activation. Reverse-pharmacological examination indicates that the formulation can work synergistically to boost immune defense, dampen oxidative stress, and modulate inflammatory cascades. In future, work must be directed toward in-vitro and in-vivo research on the decoction itself to verify such synergistic effects.

LABORATORY AND PRECLINICAL STUDIES ON CHYAWANPRASH

EXPERIMENTAL MODELS USED

The preclinical research of Chyawanprash has been done in in vivo and in vitro models. The zebrafish inflammation model was chosen for its similarity to those of mammals. LPS was used to induce systemic pathological changes in the zebrafish by injecting into the abdomen. Parallel in vitro assays were conducted with human THP-1 macrophages and NF-κB reporter cell lines. These dual models facilitated the monitoring of organism-level phenotypes and the cellular level molecular events.

PROPHYLACTIC ANTI-INFLAMMATORY EFFECTS

The pre-treatment with Chyawanprash in zebrafish indicated strong prophylactic protection against inflammatory stress. Zebrafish fed with diet incorporated with Chyawanprash before LPS exposure showed substantial protection against LPS-induced inflammatory symptoms including behavioral fever, hyperventilation, decreased locomotion, skin hemorrhage, and caudal fin degeneration. Inhibiting of caudal fin loss, in particular, indicated an osteoprotective potential of Chyawanprash that could be of relevance in pathologies characterised by inflammation-induced tissue and bone destruction.

MODULATION OF INFLAMMATORY BIOMARKERS

Further laboratory studies in zebrafish found that Chyawanprash modulated key indicators of inflammation. The levels of pro-inflammatory cytokines (IL-6, TNF-α, IL-1β) levels were significantly reduced in animals receiving the formulation diet. In addition, levels of C-reactive protein (CRP), a bio-indicator of inflammation, were also decreased. These results were indicative that Chyawanprash is able to not only protect trout from cutaneous inflammatory signs, but even mediate the molecular activators of such reaction.

IN-VITRO MECHANISTIC STUDIES

The protective nature ofChyawanprash was further confirmed using human THP-1 macrophages in in-vitro experiments. The untreated macrophages secreted extremely high levels of IL-6 and TNF-α upon LPS stimulation, whereas the levels of these cytokines detected in the Chyawanprash-treated cells

were significantly lower. Mechanistic studies revealed that NF-κB signaling is the major pathway modulated by Chyawanprash. Through repression of NF-κB activation, the formulation efficiently blocked transcriptional activity for the release of pro-inflammatory mediators. Cytotoxicity assays also revealed that the Chyawanprash extract at multiple concentrations ranging from 250 µg/ml to 1000 µg/ml was safe and non-toxic to cell viability.

PHYTOCHEMICAL AND COMPOSITIONAL ANALYSIS

HPTLC and HPLC were used for chemical fingerprinting of different batches of Chyawanprash. The analyses revealed the presence of different bioactive phytochemicals, of which gallic acid was found to be the predominant. Ellagic acid, eugenol, piperine, chebulagic acid, glycyrrhizin, and cinnamic acid as well as other components were also present. These phytoconstituents have been reported extensively in the literature for its antioxidant, immunomodulatory and anti-inflammatory properties. The consistency of these chemicals in the different batches verified the content of the formulation and the function of drug, to some extent.

OVERALL PRECLINICAL SIGNIFICANCE

Collectively, the preclinical data provided a rationale for the use of Chyawanprash as a safe and effective multi-component formulation of Ayurveda with remarkable anti-inflammatory and immunomodulatory potential. The capacity to regulate cytokine expression, as well as to inhibit the inflammatory process-induced pathology, and the ability to act on NF-κB signaling underline, in modern experimental terms, the original traditional claims. These data underscore Chyawanprash as a promising nutraceutical with therapeutic potential for inflammation-associated morbidities and merit further translational studies in higher animal models and human subjects.

LABORATORY AND PRECLINICAL STUDIES ON AYUSH-64

AYUSH-64 is a polyherbal formulation comprising of drugs, such as Alstonia scholaris, Picrorhiza kurroa, Swertia chirata and Caesalpinia crista. Its safety and pharmacological profile has been evaluated in several laboratory and preclinical studies.

IN-SILICO AND ANTIVIRAL ACTIVITY STUDIES

In silico screening of 36 bio-active compounds from Indian medicinal plants on AYUSH-64 against COVID-19 by molecular docking and dynamics simulation approach. Of these 35 compounds, Akuammicine N-Oxide (from Alstonia scholaris) has the best binding energy(−8.4 kcal/mol). Molecular dynamics supported the stability of it and its interactions with several crucial Mpro residues (Cys 145, His 164). These insights hint that AYUSH-64 contains putative antiviral leads that could be possibly considered for use against viral infections including though not limited to COVID-19.

Preclinical data AYUSH-64 (Chirakin) was also found to exhibit in vitro antiviral activity against Chikungunya virus in plaque reduction as well as protection assays and inhibited viral replication more effectively than ribavirin.

PHARMACOLOGICAL SAFETY AND TOXICITY STUDIES

A recent study on the oral acute and subchronic toxicity in Sprague Dawley rats has been conducted using the OECD 423 and 408 guidelines, which provide a reliable base for evaluating drug safety of AYUSH-64:

- Acute toxicity: there were no deaths, overt signs of toxicity or changes in the gross necropsy over a period of 14 days at the limit dose of 2000 mg/kg/body weight.
- In a 90 days toxicity study, rats were given the dosages of 500, 1000 and 1500 mg/kg/day. None of these doses resulted in any death cases, clinical signs of toxicity, changes in hematological parameters or biochemical assays or/and histopathology findings. The organ weight changes and effect on urine parameters were within the normal ranges only.
- This is equivalent to a NOAEL of 1500 mg/kg/day indicating that the safety margin is very high with respect to these compounds.

OTHER EXPERIMENTAL EVIDENCE

Earlier laboratory investigations have also reported:

- The antimalarial activity of the plant was tested in albino mice (250–750 mg/kg) and it reflects its traditional use in the treatment of Vishama jwara (malarial fever).
- Different herbs as the components of this drug may have immunomodulatory and anti-inflammatory effects, among which there is increased phagocytic activity, inhibition of

inflammatory mediators and the protection against oxidation.

XI. HUMAN CLINICAL TRIALS AND REAL-WORLD EVIDENCE

AYUSH KWATH

In the year 2020, AYUSH Kwath was officially recommended by the Ministry of AYUSH and it was designed to be an immunomodulatory as well as prophylactic solution for COVID-19. Ayuraksha Kit (ARK) has provided the largest real-world evidence on open-label use of AYUSH Kwath; ARK is a community-based study that employed a prospective, cluster-randomized design during October 2020–March 2021. The trial included treatment with Ayush Kwath, Chyawanprash, Samshamani Vati and Anu Taila among more than 150,000 individuals residing in several districts of India over a period of time. It showed that the COVID-19 free survival rate was slightly higher in intervention group than control group (98.9% vs. 98.1%). As well as this , among infected participants hospitalization rates were found much lower in intervention clusters (9.8% vs 12.5%). Additionally , there were subjective benefits including boosting appetite , bowel movement and quality sleep which together signify better overall health condition . However, there are several challenges that hinder the clear interpretation of these findings. AYUSH Kwath was not an independent arm intervention which makes it difficult to know if the effects are specifically resulting from this particular formulation. The open label approach, use of community surveillance and self reported outcomes all lead to bias. Also, infection rates confirmed in laboratory and biomarker based immune outcomes were not systematically evaluated. But still, public acceptance and favorable safety profile highlights the potential of AYUSH Kwath in preventive health measures. For furthering Clinical credibility more randomized, double blind placebo controlled future trials required with laboratory confirmed outcomes, dosing schedule stratification and immune-biomarker analysis. Such studies will offer clear evidence if AYUSH Kwath can work as an independently effective prophylactic measure beside other measures or directions in integrated into community approach for public health systems is required or not.

AYUSH-64

AYUSH-64 is a polyherbal preparation which was developed by the Central Council for Research in Ayurvedic Sciences (CCRAS) in 1980s for the treatment of malaria. In the light of COVID-19 pandemic this preparation was rapidly repurposed and evaluated as a therapeutic and supportive measure. A number of RCTs registered with the Clinical Trials Registry of India (CTRI) explored on benefits of AYUSH-64 alongside standard care for mild to moderate COVID-19 patients. These hospital-based studies always found that, there is faster clinical improvement, shorter time to resolution of fever, cough and fatigue and decreased hospital stay duration compared to standard care alone. Importantly, AYUSH-64 had very good safety profile showing minimal gastrointestinal or constitutional side effects and no serious drug-related adverse events were observed.

Frequently cited studies enrolled AYUSH and CCRAS qualified patients on AYUSH drugs or AYUSH prescribed AYUSH-64 in the treatment of Influenza like infections, with a sample size range between 60 to 250 conducted in multicentres under the Ministry of Health and Family Welfare, Government of India. Those studies further validated the role of Ayush-64 in management of immune modulator and adjuvant anti-viral agent. However, there are still methodological pitfalls that are clear from these trials. Sometimes it was difficult for us to conduct blinding assessment because there were no enough details provided by included trials regarding randomization and allocation concealment and their endpoints were not well defined neither. Trials lasted shortly which made it impossible to evaluate long-term recovery course, recurrences, or post-COVID complication.

To be sure, AYUSH-64 is not without shortcomings, but it remains one of the well-studied AYUSH formulation during the COVID-19 era. It has shown good results and this fact became known in many countries which then officially recommended its use under supervision. However, it utterly remains expedient to carry out large-scale, well-designed phase III RCTs that have laboratory-confirmed endpoints and an extended follow-up for further evidence. Furthermore, the future trials need to clarify whether AYUSH-64 can also prevent disease progression and what is its effect on inflammatory biomarkers/ its usefulness in post-COVID recovery.

CHYAWANPRASH

Chyawanprash, one of the classical Ayurvedic form Venkataraman and Sebastian ulation is made from more than 40 medicinal herbs with a base of gooseberry (Emblica officinalis) and is generally taken as rejuvenative and immunomodulatory tonic. Its wide popularity and good name in society regarding immunity diseases caused it to be recommended as a part of case measures in the course of the COVID-19 pandemic. In the Ayuraksha Kit (ARK) study, Chyawanprash was daily given along with AYUSH Kwath, Samshamani Vati, and Anu Taila to over 134k people. Intervention clusters have not only shown lower COVID-positive cases hospitalization rate but also subjective health measures including appetite and bowel regularity as well as sleep onset improved in those individuals who caught cold or flu. Those results support traditional healing system notion that Chyawanprash is effective for systemic resilience enhancement and vitality boosting

Also, there were several CTRI-registered multicentric trials which assessed the effect of Chyawanprash alone or in combination with other Ayurvedic formulations for prophylaxis among frontline health care workers as well as general public. Some reports indicated qualitative difference and possible reduction in infection rates though detailed published experience is lacking. The methodological quality of these studies was variable, many did not have proper controls, blinding and/or laboratory confirmation of the outcomes.

Concerns regarding the suitability of Chyawanprash was not raised, however, because there are no proper randomized controlled trials it is not possible to have a very clear perception about the efficacy of this remedy in treating and preventing COVID-19. With wide usage among the Indian population, and good safety record, it is one of the medicines suitable for further evaluation through clinical investigations. Among them there are randomized controlled trials with clinically-diagnosed COVID-19 cases as outcomes, determination of immunological biomarkers; and investigation of prophylactic effect on “long-COVID” syndrome. The data would be useful to confirm the ethno-medicinal claims of Chyawanprash and to provide a rational scientific justification to include it in modern healthcare system for prevention of diseases.

XII. SCIENTIFIC INITIATIVES BY MINISTRY OF AYUSH

The COVID-19 pandemic was a unique health crisis in the world and thus highlighted the need to implement preventive and therapeutic measures. In the Indian example, the Ministry of AYUSH (MoA) was simultaneously pursuing biomedical strategies and systematically scientifically evaluating and integrating traditional medicinal systems Ayurveda, Siddha, Unani, Homeopathy and Yoga and Naturopathy into the COVID-19 management measures. The MoA placed more emphasis on evidence-based approach by which they attempted to prove the traditional formulations through in-silico, preclinical, clinical and community-based research.

The Ministry used this to support these activities through creating an online research repository that consolidated information relating to current and completed studies, broadcasting public health instructions, and organizing multicentric clinical trials, with several leading institutions such as AIIMS, CSIR, ICMR, DBT, IITs and major Ayurvedic research councils. The general plan included immune protection, prevention, therapeutic follow-up, and after-COVID treatment.

This section gives a summary of the major formulations under AYUSH example: AYUSH Kwath, AYUSH-64, Chyawanprash, Guduchi based preparations, Kabasura Kudineer and Ashwagandha and will focus on their scientific review and role in managing COVID-19.

AYUSH KWATH (AYUSH KADHA)

AYUSH Kwath is a standardized poly herbal decoction which contains Ocimum sanctum (Tulsi), Cinnamomum zeylanicum (Dalchini), Zingiber officinale (Sunthi), and Piper nigrum (Krishna Marich). Traditionally used as a supplement-to-supplement respiratory health and immunity, this formula was largely recommended in the pandemic.

Its repurposing effectiveness has been proven by scientific research. in vitro testing in IIT-BHU and ICMR-NIN demonstrated that the active phytoconstituents of AYUSH Kwath have an inhibitory effect on SARS-CoV-2 main protease and RNA-dependent RNA polymerase. Its immunomodulatory effect, safety and tolerability were

confirmed by preclinical studies conducted at ICMR-National Institute of nutrition.

On a health awareness front, AYUSH Kwath has been added to Ayuraksha Kit which is a preventive health pack of AYUSH Kwath, Chyawanprash, Samshamani Vati, and Anu Taila. There was a significant cohort study on the Delhi Police staff which reported a decreased rate of SARS-CoV-2 and decreased age-specific mortality in comparison to the general population.

AYUSH-64

AYUSH-64 is polyherbal preparation that was initially prepared in 1980s by the Central Council of Research in Ayurvedic Sciences (CCRAS) to treat malaria. It was reused later in COVID-19 and was an active program of scientific validation that started with the pandemic.

Scientific evidence of research cuts across various cognition of science:

In-silico experiments showed that its phytocompounds have a binding affinity with high-quality SARS-CoV-2 proteases. The antiviral activity and decrease in viral load were verified in-vitro.

Clinical trials: Multicentric randomized controlled trials with AIIMS Jodhpur, KGMU Lucknow, DMIMS Wardha, and others, demonstrated faster clinical recovery, reduced hospitalization, early RT-PCR negativity and markedly improved inflammatory markers, IL 6, TNF -a, and D-dimer. Notably, AYUSH-64 proved to improve quality of life by reducing fatigue, increasing appetite, level of sleep, and diminishing anxiety.

Health implications in the society were enormous. In the second wave, a national program of mass distribution of AYUSH-64 was introduced. It was shown to be efficient in preventing the development of disease and accelerating the process of recovery with the help of the data gathered on almost 96,000 patients. It is important to note that there were no any serious adverse events reported which proved the safety of this formulation.

CHYAWANPRASH

Chyawanprash is a classical Rasayana preparation which contains Emblica officinalis (Amla) as a main constituent with over forty adjuvant herbs, honey and ghee. Historically, it was known to have rejuvenative as well as immunomodulatory effects, and was widely supported in the pandemic.

The empirical studies found out that regular use of Chyawanprash improved the immunological conditions, stamina, and the ability to resist respiratory infections. Therefore, it became part of Ayuraksha kits and recommendable in the Ministry national preventive health advisories. The interventions implemented at the community level among the frontline workers reported a decrease in the rate of infection and general well-being.

PREPARATIONS MADE FROM GUDUCHI (GUDUCHI GHAN VATI AND GUDUCHI-PIPPALI)

Tinospora cordifolia which is otherwise known as Amrita in the Ayurvedic tradition has undergone various formulations. Guduchi Ghan Vati and Guduchi-Pippali formulations were both tested in the community and the clinical setting.

Guduchi-Pippali was evaluated as an adjunctive therapy in a clinical study that was carried out at Medanta hospital, Gurugram. The outcomes showed that all the patients in the intervention group did not develop a severe disease. Symptom resolution was earlier as compared to the control cohort and there was a significant decrease in the mean length of stay. These effects supported the immunomodulatory effect of Guduchi and its use as a complementary mode of treatment.

SIDDHA FORMULATION (KABASURA KUDINEER).

Kabasura Kudineer (KSK), an established Siddha polyherbal preparation came up as a potential intervention against COVID-19.

In vitro studies showed that the phytoconstituents of the compound have strong binding affinities with the SARS-CoV-2 spike protein. Supplementary in vitro 3 immunomodulatory and thrombolytic effects, and antiviral effects were comparable to Remdesivir in some studies.

As a result, clinical trials in Tamil Nadu, Delhi and Noida demonstrated prophylactic effectiveness in high-risk groups, speed of recovery and reduction of viral load in asymptomatic and mild COVID-19 patients. Adjunctive KSK was found to be correlated with reduced mortality as compared to regular care.

ASHWAGANDHA *(Withania somnifera).*

Ashwagandha has gone through a lot of research both as a prophylactic drug and as an adjunctive one.

A randomized, controlled, multicentric, trial of healthcare workers proved Ashwagandha as non-inferior to Hydroxychloroquine in chemoprophylaxis against COVID-19 with a significantly better safety profile.

Continued trials will be used to assess its effect on the maintenance of immune responses to COVID-19 vaccination, and its early results suggest augmented immunogenicity.

Its adaptogenic characteristics and anxiolytic effects also highlight the usefulness of Ashwagandha in the prevention of stress and long-COVID.

COMPARATIVE SUMMARY OF KEY FORMULATIONS

Formulation	Composition	Type of Studies Conducted	Key Outcomes in COVID-19 Context
AYUSH Kwath	Tulsi, Dalchini, Sunthi, Krishna Marich	In-silico, pre-clinical, community studies	Blocked viral enzymes; safe and immunomodulatory; lower rates of infection in frontline workers.
AYUSH-64	*Alstonia scholaris, Picrorhiza kurroa, Swertia chirata, Caesalpinia bonduc*	In-silico, in-vitro, multicentric clinical trials, mass distribution	Faster recovery, earlier RT-PCR negativity, reduced hospitalization, better QoL; safe and no SAE
Chyawanprash	Amla base with 40+ herbs, honey, ghee	Prophylactic community studies	stimulate better immunity, increase stamina, and reduce incidence of infection; it is generally recommended as a daily dose.
Guduchi-based (Ghan Vati, Guduchi-Pippali)	Guduchi alone or combined with Pippali	Clinical studies in tertiary hospitals, community studies	Progression to severe disease prevented; better symptom resolution; reduced hospital stay
Kabasura Kudineer (Siddha)	Multi-herb Siddha decoction (15+ herbs)	In-silico, in-vitro, RCTs	Antiviral affinity; accelerated recovery; lowered viral load and mortality; and an effective prophylaxis.
Ashwagandha	*Withania somnifera* root extract	RCTs for prophylaxis, adjunct therapy, vaccine-linked studies	Similar to HCQ prophylaxis; increased vaccine immunity response; lessened stress, better long-COVID results

GENERAL SCIENTIFIC RESULTS.

The Ministry of AYUSH was able to organize 139 research work under Ayurveda (70), Homeopathy (29), Siddha (13), Unani (8) and Yoga and Naturopathy (19). The papers included prophylaxis, interventional, observational and preclinical research.

Key achievements include:

- Defining the prophylactic effectiveness of AYUSH interventions in a high-risk population, including healthcare workers and police officers.
- Prove that AYUSH formulations have a therapeutic value as adjuncts to the standard of care, which results in a decrease in hospitalization, acceleration of rehabilitation, and the quality of life.
- Published the National Clinical Management Protocol (2020) of Ayurveda and Yoga, thus establishing AYUSH interventions in national guidelines on the management of COVID-19.
- Introducing large-scale programs of distribution (e.g. AYUSH-64 and Ayuraksha Kit campaigns) that promoted prevention and home-based care.

XIII. CHALLENGES IN SCIENTIFIC VALIDATION OF TRADITIONAL REMEDIES

METHODOLOGICAL LIMITATIONS IN CLINICAL STUDIES

One of the main challenges to the validation of traditional preparations including Ayurvedic

preparations like Ayush Kwath, Ayush64, and Chyawanprash is due to the lack of methodological rigor that has been witnessed in the current clinical studies. Most of the studies conducted in the COVID -19 pandemic had small sample sizes, which reduced statistical power and limited the external validity of outcomes. As an illustration, the number of trials testing Chyawanprash as a prophylaxis was several hundred, and ones evaluating Ayush-64 were mostly single-centred and of a small scale.

No less important is the fact that placebo-controlled cohorts have often been omitted in the literature. Without comparator arms, the issue of defining the role of spontaneous remission, the effect of the psychosomatic factors, and the actual effect of the intervention on pharmacodynamics can be a problem. An example is Ayush Kwath, which was widely disseminated using community prophylactic kits; however, its results (e.g., no COVID -19 infection or improvement of perceived well-being) were reported without proper randomization or blinding. The lack of such methodological rigor is the obstacle to scientific acceptance of such otherwise promising therapies.

Further, the outcome heterogeneity also contributes to interpretation. The modern biomedical studies generally use objective, standardized endpoints, such as viral load reduction and hospitalization incidence, whereas Ayurvedic studies often report subjective ones such as perceived energy, vitality, or overall well -being. The lack of standardized outcome definitions obstructs the cross-study synthesis, and it is very difficult to validate the meta-analysis in this case.

CHALLENGES OF STANDARDIZATION, SAFETY, AND MECHANISTIC UNDERSTANDING

Polyherbal preparations are yet to be subjected to standardization that will facilitate scientific validation. As an example, Ayush Kwath that includes Tulsi, Dalchini, Sunthi, and Marich, has considerable flotation in its phytochemical profile that can be explained by differences in the plant source, processing, and preparation procedures. Similarly, Chyawanprash, a formulation containing over 40 herbal ingredients, shows a significant inter-manufacturer variance and in even the case of Ayush-64 there remains a continuing issue of pharmacognostic consistency as a preservative. In the absence of pharmacopoeial standards and strict controls and checks of batch-to-batch quality, the reproducibility of the experimental results in different trials is therefore compromised.

Another area of concern is safety assessment. Even though most of the studies indicate tolerability is acceptable, systematic reporting of the adverse events has been limited. Massive distribution research like the Ayuraksha trial, which involved frontline police force officers taking Ayush Kwath as a part of immunity program, only produced some biochemical and hematological follow-ups. This underreporting reduces the quality of evidence base and creates suspicion amongst medical professionals and regulators. Since these formulations are complex and multi-component, there is a systematic and methodologically rigorous need to scrutinize possible herb-herb and herb-drug interactions in the same manner that is done with traditional pharmaceuticals.

Explanation of mechanisms behind the same is also absent. Although the immunomodulatory effect of individual botanicals e.g., Tulsi and ginger have been reported to be effective, multi-herbal preparations have not been sufficiently studied in relation to their synergistic effect. Both in vitro and animal research suggest antiviral, antioxidant and immunomodulatory routes, but the application of these to measurable human biomarkers has not been achieved completely. As a result, there still exists a sense of disconnect between the Ayurvedic concepts of what is known as Rasayana (rejuvenation) and the modern-day biomedical validation systems.

REGULATORY AND TRANSLATIONAL BARRIERS

Lastly, Ayurvedic medicine integration in the evidence-based practice of the world is limited by regulations and translation issues. A significant proportion of the studies during the COVID era were pragmatic, open-label, or community-based interventions which were not randomized controlled trials (RCTs). Consequently, even when the signs of effectiveness are positive, the scepticism in the world scientific community remains.

As an example, the AYURAKSHA initiative, where Ayush Kwath-based kit was given to the Delhi police officers demonstrated a decreased seropositivity rate within the intervention group. Nevertheless, being a non-randomized and non-blinded design, it was not able to remove such biases like unequal exposure or other behavioural issues. In the same way, although

Ayush-64 trials proved to have a positive impact on clinical outcome in mild to moderate COVID-19 cases, the researchers themselves admitted that the studies should be larger, multi-centric, and blinded.

The regulatory frameworks also make the situation more difficult. Ayurvedic products are normally regulated like traditional medicines, usually with less stringent regulations than the modern pharmaceutical. This discrepancy poses challenges relating to harmonization of Ayurvedic evidence with the standards of international drug approvals and this restricts their usage in other parts of the globe. Harmonisation of reporting standards, compliance with Good Clinical Practice (GCP), joint research designs which avoids the violation of Ayurvedic traditions as well as biomedical research methods are badly needed to fill this gap.

XIV. ETHICAL AND COMMERCIAL FACTORS

Commercialisation of traditional medicines creates unique ethical issues because the products find themselves at the nexus of cultural heritage, market-driven forces and health issues of the people. Key issues of ethics relate to the clarity of assertions, the evidencing of security and efficiency, the safety of the vulnerable consumers, and the regulatory responsibilities of the industrial as well as state forces. These issues become more acute when it is the governments or major corporations that encourage or aggressively sell traditional formulations during the emergence of a public health crisis (see regulatory developments and government promotion below).

MISLEADING LABELS AND HEALTH CLAIMS

The false labels and advertising statements are ethical offences since they disrupt the consumer knowledge of the benefits and risks. Claims that relate to preventing or curing or treating an illness that lacks rigorous clinical evidence are against the informed consent and consumer protection principles. In Ayurvedic products, advertisements have been used and social media posts have been made of herbal formulations as immunity boosters or as protective against certain infectious diseases in the absence of adequate direct clinical evidence. The governments and watchdog organisations have continually warned the manufacturers against making unsubstantiated claims; failure to which the population has received warnings and legal prosecution in many instances.

PRACTICES IN ADVERTISING AND CORPORATE RESPONSIBILITY.

Commercial actors have an ethical duty to avoid manipulation of the anxieties of the population, as well as to provide equal information on the benefits and dangers. Advertisements that demean the rivals or assert ineffable betterment might be unethical as well as unlawful and the practice has been subject to further examination by the courts and other authorities in the Indian market. Companies need to use the industry-recognized standards regarding the substantiation of efficacy claims, disclose the specific dosage and safety, as well as disclose the known contraindications and interactions with allopathic drugs. The reputational and regulatory consequences of not maintaining them are highlighted by the high-profile litigation of large Ayurvedic brands in recent times.

REGULATORY HORIZONS AND ENFORCEMENT FAILURES.

The regulatory framework of India has certain legislations on objectionable advertisements (e.g., Rule 170 of Drugs and Cosmetics Rules, and Drugs and Magic Remedies (Objectionable Advertisements) Act). However, the enforcement has never been even. The courts have occasionally come in to provide additional supervision and other judicial orders have eased pre-approval conditions- creating a legal ambiguity both to the regulators and the industry. Enforcing it with the help of codified rules is not enough: it needs to be transparent in terms of complaint follow-ups (e.g., the dashboard), timely recalls or corrective instructions, and regular punishments once it is not enforced. Recent court action shows active policing of advertising, but also shows inconsistent results, which emphasize the need to bring a sense of institutional clarity.

THE PLACE OF GOVERNMENT MESSAGING IN PUBLIC HEALTH CAMPAIGNS.

In those instances when the state is propagating the traditional formulations, via public health campaigns, it undertakes an augmented ethical responsibility. Public endorsements have the danger of granting unproven credibility to products whose effectiveness might not be determined by randomised controlled trial. The Ministry of AYUSH promoted Ayush Kwath as brands, such as Ayush kwath, among others, during the Covid 19 pandemic as a larger immunity-supporting message. Though these principles can make cultural activities more acceptable and more

reachable, they should be supported by clear declarations concerning the evidence quality, limitations that are known, and the fact that other proven means of public-health control (e.g., vaccination, masking, supported therapeutics) remain the priority. Lack of contextualisation of such messaging drives untrue reassurance and can mask successful interventions.

AYUSH KWATH-ETHICAL AND COMMERCIAL ASPECTS.

This is the case with the AYUSH Kwath that was promoted throughout the COVID-19 pandemic, which illustrates how the ethical scandals and business exploitation collide in the sphere of traditional medicine advertising. The formulation was officially recommended by the Ministry of AYUSH in April 2020 as an immunity-enhancing drink made of tulsi, cinnamon, ginger and black pepper, to neutralize COVID-19. This state approval led to a mad rush of corporate output and advertising by herbal producers, most of whom claimed that AYUSH Kwath could prevent or treat COVID-19, had no side effects, and treated all of the symptoms of the disease.

The above claims are ethical problems in nature. One, there is no empirical evidence behind the conception of an immunity booster; physiological immune activity cannot be raised without cause beyond its natural level, and in critical cases of COVID-19, immunosuppression and not amplification may be required. The use of unproven therapeutic statements can be dangerous as it can mislead people and lead to a lack of concentration on evidence-based interventions, including masking, vaccination, and social distancing. Moreover, pharmacological studies on the component's herbs have produced scanty or inconclusive evidence on the efficacy of these constituents in humans thus casting doubt on the scientific purity of promoting their use in masses without validating clinical testing. Possible side effects, such as hepatotoxicity, hypersensitivity, changes in drug metabolism, and increased risk in comorbid patients further increases the ethical risks of upholding AYUSH Kwath as non-toxic.

In the business front, the Ministry endorsement triggered a fast market growth in the herbal sector and it took advantage of the increased popular panic amid the pandemic. Lack of proper regulatory controls allowed aggressive advertising campaigns with exaggerated statements with massive returns on the economy to the producers and shifting health hazards to the unsuspecting users. Lack of responsibility in case of any adverse events, whether due to the producers, practitioners or the endorsing governmental body brings about major regulatory/legal gaps. Therefore, the AYUSH Kwath presents a model where the goals of the community health, business interests, and ethical standards merge, and strict evidence-based regulatory norms and responsible marketing procedures regarding the use of traditional medicine preparations are most urgent.

CHYAWANPRASH ETHICAL AND COMMERCIAL ASPECTS.

Chyawanprash, which is one of the most recognizable Ayurvedic preparations in India, has been a part of the traditional health practice as well as the target of considerable commercial rivalry. The marketing techniques that the main Ayurvedic brands utilize have, in some cases, been the focus of some ethical and legal issues, specifically with regard to adverts that directly or indirectly undermine the products of the competitors. Interestingly, both Patanjali and Baidyanath have been restrained by the Delhi High Court on conducting adverts that have potential of deceiving the consumers by suggesting that Dabur Chyawanprash is an inferior brand, especially since it is a well-established and reputed brand. These instances bring to the fore the issue of competition marketing and ethical consideration in the Ayurvedic industry.

The claims which have been subject to legal scrutiny are mainly claims which overstate the benefits of the products or unfairly undermine the competitors. Courts have made it clear that though such promotional statements which focus on the features of a brand, which are sometimes known as puffery, are acceptable, unverified or even comparative statements which portray a competing product in a negative light should not be made. An example is that advertisement that indicated that Dabur Chyawanprash was ordinary or inferior to another formulation was not permitted but generalized claims made regarding a brand and its composition or quality was permitted without the advertisement having to be made as a direct comparison. Such interventions of the law bring out the moral obligation of the companies to be transparent, accurate and fair in their marketing business practices thus safeguarding consumers against misleading information.

In the business sense, these controversies demonstrate the market demand of trust and credibility in the herbal supplement market. False advertisements can lead to temporary promotional benefits at the cost of loss of reputation, legal fines, and loss of customer trust. Besides, these cases indicate the growing demand of scientific substantiation of product claims. Industry observers support promotion of Chyawanprash on evidence basis and not on a negative basis of the competitors. Finally, there is a close relation between the ethical and business aspects of the marketing of Chyawanprash, whereby ethical advertising is associated with consumer trust, and this provides a long-term commercial success, whereby the conventional Ayurvedic remedies are still being appreciated due to their genuine therapeutic and preventive qualities.

ETHICAL AND COMMERCIAL FACTORS OF AYUSH-64

Making AYUSH-64 popular in the COVID-19 pandemic provoked serious ethical issues of the most correct proportion of the promotion of traditional medicine and evidence-based healthcare. They were actively supported by the Indian government as a possible treatment modality even when there were no large-scale, peer-reviewed, clinical trials available. Scientific reports (2021) expressed criticism of this strategy by stating that the endorsement by the general population obscured the distinction between political expressions and scientific approval. In the case of a public health crisis promoting a medicinal product without strong evidence may undermine and affect transparency and accountability, which may lead to the misinformed opinion concerning the effectiveness of the product and reduce reliance on health authorities.

The initial clinical trials of AYUSH-64, as reported by The Wire Science (2021) were of small size and under-powered, with no statistically significant evidence of efficacy against COVID-19. In spite of these restrictions, the results were occasionally reported publicly in a manner that suggested therapeutic value. Ethically, this type of dissemination could misguide patients and healthcare providers, and the problem of informed consent is difficult to overcome. The cultural importance of the traditional medicine needs to be communicated with a duty to uphold strict scientific principles, especially in a world health crisis where the susceptible groups of the population may be swayed by the assertions of efficacy.

It is also interesting to note the commercial implications of promotion of AYUSH-64. The official recommendations caused an increase in demand, and the number of sales increased in both the pharmacy and online stores. Although commercial success can be positive, it is an indication of a market that is more informed by activism by the government rather than being supported by conclusive scientific findings. Early commercialization begs ethical questions, because patients possibly have trusted the AYUSH-64 more than clinically proven medications, and businesses made money on the fear of the people during a pandemic. Also, the problem of selective reporting of positive trials, which is observed in the Journal of Ayurveda and Integrative Medicine (2021), speaks of the danger of putting commercial and political interests before methodological rigor and scientific honesty.

On the whole, the AYUSH-64 case represents the larger dilemma of ethical obligations, scientific integrity, and the commercial interests in conventional medicine. Although integrating indigenous formulations in the contemporary healthcare is a legitimate objective, it should not lead to the sacrifice of patient safety and transparency. Both traditional and modern medical system may lose credibility by prematurely promoting and commercializing them. Ethical guidelines ought to prioritize in turn stringent clinical validation, open reporting and responsible communication, so that commercial interests and governmental advocacy do not take precedence to scientific and ethical requirements.

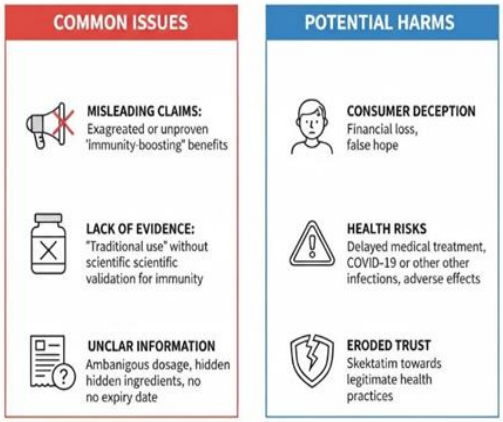


fig 22 Common issues of advertising and labelling

XV. GLOBAL PERSPECTIVES AND FUTURE DIRECTIONS

The world health fraternity, spearheaded by the World Health Organization (WHO), has come to appreciate the importance of traditional medicine as a way of boosting the health systems of the people. WHO has developed the Global Centre of Traditional Medicine (GCTM) in India in 2022 that seeks to unlock the promise of traditional knowledge systems by scientifically validating and innovating. The move emphasizes the worldwide observance of incorporating traditional ways of doing things such as Ayurveda into modern medicine in a way that would guarantee safety and effectiveness. WHO has also highlighted the necessity of effective structures of quality assurance, pharmacovigilance and evidence creation, especially of intervention suggested to boost the immune systems.

Within Ayurveda, a number of preparations have been the focus of attention during the COVID-19 pandemic, including Chyawanprash, AYUSH Kwath, and AYUSH-64. One traditional rasayana formulation, chyawanprash, has been researched in terms of immunomodulatory and antioxidant effects and initial clinical trials have shown promise regarding its use in lowering infection rates and overall, wellbeing. Likewise, another herbal decoction, AYUSH Kwath, prescribed by the Ministry of AYUSH, was popularly marketed as an immunity-enhancing home remedy, but the available efficacy evidence is sparse and needs to be strengthened through controlled trials. First designed as a malaria medication, AYUSH-64 was used during the pandemic as another therapy (as an adjunct treatment), and its study showed promising yet preliminary outcomes. These examples also demonstrate the possibilities as well as the evidence gaps that need to be bridged by future global and national research efforts.

In the future, better-designed multi-centric randomized controlled trials with sufficient sample sizes, placebo control groups, and extended follow-ups to assess efficacy as well as safety profiles of these traditional interventions should be prioritized. Formulations, quality of raw materials and lot to lot consistency are important to achieve reproducibility of results. Moreover, mechanistic research on the molecular mediators of immune regulation and anti-inflammatory effect, and possible herb-drug interactions is required to incorporate the use of traditional remedies into conventional clinical care.

On the policy-level, WHO urges nations to be integrative with traditional medicine being a supplement to conventional healthcare. In the case of India, it is a special chance to place Ayurvedic preparations such as Chyawanprash, AYUSH Kwath and AYUSH-64 in the world of evidence, assuming that the issues of scientific proof, safety surveillance and open communication are given priority. Through this, the fusion of Ayurveda to the contemporary biomedicine will serve to make the world healthier and balanced in terms of wisdom and scientific principles.

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