



NURTURING CHILD, THE AYURVEDIC WAY

# STANDARD OPERATING PROCEDURE FOR

## SWARNAPRASHAN



Government of Lumbini Province  
Ministry of Health  
Health Directorate  
Provincial Ayurveda Hospital  
Bijauri, Dang

[www.pahdang.P5.gov.np](http://www.pahdang.P5.gov.np)



स्वास्थ्य मन्त्रालय लुम्बिनी प्रदेश अन्तर्गतका आयुर्वेद चिकित्सालय र स्वास्थ्य केन्द्र स्वास्थ्य निकाय तथा स्थानीय तहबाट सञ्चालन हुने बालबालिकाहरूको स्वास्थ्य प्रवर्द्धन, बौद्धिक विकास तथा रोग प्रतिरोधात्मक क्षमता अभिवृद्धिका लागि सञ्चालन गरिने 'स्वर्णप्राशन कार्यक्रम' सँग सम्बन्धित गतिविधिहरूको सुरक्षित, गुणस्तरीय, प्रभावकारी र व्यवस्थित सञ्चालन र सहजीकरणका लागि यो 'स्वर्णप्राशन मानक सञ्चालन प्रक्रिया (SOP)' तयार गरिएको छ ।



लुम्बिनी प्रदेश सरकार  
स्वास्थ्य मन्त्रालय  
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विजौर, दाङ्ग

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प.सं.: २०८२।८३

च.न.:

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**स्वास्थ्य मन्त्रालय**  
राप्ती उपत्यका (पैठुवा), नेपाल



मा. खेम बहादुर सारु  
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Message from Health minister of Lumbini Province



It gives me immense pride and honour to launch the Swarnabindu Prashan program across all districts of Lumbini Province. This ancient Ayurvedic tradition, rooted in the wisdom of our culture, offers a natural and holistic approach to nurturing our children's overall health. By enhancing immunity, intellect, and strength through carefully prepared herbomineral formulations, this program promises to safeguard the future generation with the best of our indigenous knowledge.

This SOP is the product of diligent effort and collaboration among Ayurveda paediatricians, pharmacy specialists, and health experts. Their commitment to blending time-tested Ayurvedic principles with modern standards of safety and quality ensures effective and hygienic implementation of the Swarnabindu Prashan in our Ayurvedic hospitals and health centres. With their expertise, we are confident that the program will be carried out with professionalism and care across Lumbini province.

I convey my heartfelt wishes to all the Ayurvedic doctors, health workers, and institutions who will spearhead this program, bringing hope and wellness to children throughout the province. I urge all families to embrace this initiative with trust and active participation to help strengthen their children's physical and mental health. Together, we can create a healthier, more resilient generation grounded in our rich Ayurvedic heritage.

The government of Lumbini Province remains committed to promoting integrative health approaches that unite traditional wisdom and modern healthcare advancements. May this noble endeavour inspire collective responsibility, pride, and sustained effort toward safeguarding the wellness of our children and community at large for years to come.

Khem Bahadur Saru  
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Ministry Of Health  
Lumbini Province, Nepal  
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Lumbini Province Government  
**Ministry of Health**  
Rapti Valley (Deukhuri), Nepal



**Message from Health Secretary**



It is a moment of great pride for Lumbini Province to launch the Swarnabindu Prashan program, an ancient Ayurvedic practice aimed to boost the immunity, intelligence, and overall health of children. This program, implemented through our Ayurvedic hospitals and health centres in all districts, reflects our commitment to integrating traditional knowledge with modern public health goals to promote holistic child development.

All Ayurveda centres are urged to strictly adhere to the guidelines on preparation, dosing, and administration as laid out in this document. Adherence to these protocols will promote the safety, efficacy, and uniformity of the program across the province. We extend our heartfelt gratitude to the dedicated Ayurveda specialists who have meticulously developed these guidelines to maintain the highest standards.

The success of the Swarnabindu Prashan program relies greatly on the active participation and cooperation of the community. We warmly invite all families, caregivers, local leaders, and community members to engage with this initiative, share their experiences, and provide feedback as the program rolls out across Lumbini Province. Your insights and suggestions are invaluable in helping us refine and improve the delivery of Swarnabindu prashan to ensure it meets the needs of every child. Together, through open dialogue and collaboration, we can build a healthier future grounded in tradition and trust with modern standard and research.

Finally, we offer our best wishes for the success of the Swarnabindu Prashan program. The Ministry of Health is committed to further strengthening Ayurveda and alternative system of medicine through on-going support, capacity building, and expansion of such preventive health programs.

.....  
Durga Laxmi Shrestha

(Province Secretary)

**Health Secretary**





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**Speech from Health director of lumbini province**



Swarna Bindu Prashan is not merely a traditional ritual; it is a strategic intervention aimed at enhancing the long-term health indicators of Lumbini Province by boosting the innate immunity and cognitive resilience of our youngest citizens. By integrating this time-honoured Ayurvedic practice into Maternal and Child Health (MCH) objectives, we are effectively bridging the profound clinical wisdom of the *Kashyapa Samhita* with the administrative rigor of modern healthcare management.

This initiative, which brings the synergistic benefits of *Swarna Bhasma* and *Medhya* herbal essences to fortify paediatric immunity and cognitive vitality, is now being operationalized across all twelve districts to ensure universal access.

Health Directorate emphasizes that the success of this mission is rooted in "One Health" excellence, requiring all Ayurvedic hospitals and health centres to maintain the highest degree of pharmaceutical integrity and dosing precision. We are moving beyond a purely curative model of medicine to foster a proactive, preventive health culture that protects the next generation from common ailments before they arise.

Through standardized protocols, continuous training, and evidence-based implementation, we are committed to making Swarna Bindu Prashan a cornerstone of our health system. This unified effort reflects our vision for a resilient Lumbini Province, where the integration of traditional wisdom and modern policy creates a foundation of lifelong wellness for our children.

Mr. Roshan Lal Chaudhary  
Health Director  
Health directorate, Lumbini Province



## PREFACE

The Government of Lumbini Province, through the Ministry of Health and Health Directorate, is committed to strengthening public healthcare by integrating evidence-based traditional medicine . This Standard Operating Procedure (S.O.P.) establishes a unified and mandatory protocol for Swarnabindu Prashan, standardizing pediatric Ayurvedic care across all Provincial and District Ayurveda Hospitals and health centres.

Rooted in classical texts like the *Kashyapa Samhita*, Swarnaprashana is a vital public health intervention aimed at enhancing pediatric immunity, cognitive development, and metabolic function . To ensure the absolute safety and efficacy of this practice, this manual provides comprehensive, end-to-end guidelines. It strictly governs the entire operational lifecycle—from the rigorous sourcing of *Swarna Bhasma*, pure honey, and *Brahmi Ghrita* to quality control, Good Manufacturing Practices (GMP), and clinical administration .

Crucially, this S.O.P. pioneers the integration of modern pharmacovigilance and public health ethics into traditional practice. It institutionalizes a robust framework for informed consent and Adverse Drug Reaction (ADR) recording, ensuring strict compliance with the Nepal Health Research Council (NHRC) and Department of Drug Administration (DDA) guidelines .

We extend our profound appreciation to the Ayurvedic Medical Officers, pharmacists, and administrative leadership at the Provincial Ayurveda Hospital, Bijauri, Dang, for their technical diligence in developing this authoritative guide . Through this S.O.P., our Ayurvedic health institutions are fully equipped to deliver safe, standardized, and effective preventative care, safeguarding the health of the next generation.



**LIST OF ABBREVIATIONS**

<b>ADR</b>	Adverse Drug Reaction
<b>AI</b>	Artificial Intelligence
<b>AMO</b>	Ayurvedic Medical Officer
<b>API</b>	Ayurvedic Pharmacopoeia of India
<b>ASU&amp;H</b>	Ayurveda, Siddha, Unani, and Homoeopathy
<b>BBB</b>	Blood-Brain Barrier
<b>CDSCO</b>	Central Drugs Standard Control Organisation
<b>CFU</b>	Colony-Forming Unit
<b>DDA</b>	Department of Drug Administration
<b>DoAA</b>	Department of Ayurveda and Alternative Medicine
<b>EDX</b>	Energy Dispersive X-ray (spectroscopy)
<b>EMA</b>	European Medicines Agency
<b>ERB</b>	Ethical Review Board
<b>GMP</b>	Good Manufacturing Practices
<b>HCP</b>	Healthcare Professional
<b>HEPA</b>	High-Efficiency Particulate Air
<b>HPLC</b>	High-Performance Liquid Chromatography
<b>ICP-MS</b>	Inductively Coupled Plasma Mass Spectrometry
<b>IPC</b>	Indian Pharmacopoeia Commission
<b>ISO</b>	International Organization for Standardization
<b>KAP</b>	Knowledge-Attitude-Practices
<b>MoHP</b>	Ministry of Health and Population
<b>NHRC</b>	Nepal Health Research Council
<b>PASS</b>	Post-Authorization Safety Studies
<b>PV</b>	Pharmacovigilance
<b>PvPI</b>	Pharmacovigilance Programme of India
<b>QC</b>	Quality Control
<b>RCT</b>	Randomized Controlled Trial
<b>RMP</b>	Risk Management Plan
<b>RPC</b>	Regional Pharmacovigilance Center
<b>RWE</b>	Real-World Evidence
<b>SAE</b>	Serious Adverse Event
<b>SEM</b>	Scanning Electron Microscope
<b>S.O.P.</b>	Standard Operating Procedure
<b>TEM</b>	Transmission Electron Microscopy
<b>UMC</b>	Uppsala Monitoring Centre
<b>USP</b>	United States Pharmacopeia
<b>WHO</b>	World Health Organization
<b>XRD</b>	X-ray Diffraction



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## STANDARD OPERATING PROCEDURE FOR SWARNAPRASHANA ADMINISTRATION IN PROVINCIAL AND DISTRICT AYURVEDA HOSPITALS



### **1.1. Purpose**

This Standard Operating Procedure (S.O.P.) establishes a unified protocol for the preparation, administration, and quality control of Swarnabindu Prashan within Lumbini Province. It standardizes practices across Ayurveda hospitals, health centres, and manufacturers to ensure the intervention is safe, effective, and consistent with classical Ayurvedic principles. The S.O.P. defines the required composition (Swarna Bhasma, honey, Brahmi ghrita), clarifies staff responsibilities, and sets minimum standards for its pediatric use in enhancing immunity and cognitive development.

### **1.2. Scope**

This S.O.P. applies to all public institutions and approved partners in the Swarnabindu Prashan programme in Lumbini Province, including Ayurveda hospitals, health centres, licensed pharmaceutical manufacturers, and regulatory bodies. The scope governs the entire operational lifecycle—from raw material sourcing and formulation to clinical administration, documentation, and adverse event reporting—ensuring full compliance with classical texts and the policies of the Ministry of Health.

### **1.3. Background & Historical Context**

The utilization of metals and minerals for therapeutic purposes is a cornerstone of Ayurveda, dating back thousands of years. Among these, Gold (*Swarna*) holds a preeminent position, revered not only as a precious metal but as a potent therapeutic agent. In ancient Vedic literature, gold is referred to as *Hiranya*, symbolizing purity, vitality, and longevity.

The roots of *Swarnaprashana* can be traced to ancient rites of passage known as *Samskaras*. The *Manusmriti* and Ayurvedic texts describe the *Jatakarma Samskara* (birth ritual), where a newborn is administered a mixture of gold, honey, and ghee. This practice was designed to initiate the child's physiological functions, specifically *Medha* (intellect) and *Ayu* (longevity). Over centuries, this ritual evolved into a specialized pediatric intervention known as *Swarnaprashana*, aimed at fostering holistic growth and bolstering immunity in children.

### **1.4. Introduction**

Swarnaprashana (Sanskrit: *Swarna* = Gold; *Prashana* = Ingestion) is a unique Ayurvedic preventive and promotive health measure for children. It involves the oral administration of processed gold (*Swarna Bhasma*) mixed with honey (*Madhu*) and cow's ghee (*Ghrita*), often fortified with *Medhya* (nootropic) herbs like *Vacha* (*Acorus calamus*), *Brahmi* (*Bacopa monnieri*), and *Shankhapushpi* (*Convolvulus pluricaulis*).

This practice is not merely a cultural ritual but a calculated therapeutic intervention categorized under *Kaumarabhritya* (Ayurvedic Pediatrics). It serves as an immunomodulator (*Rasayana*) and a cognitive enhancer (*Medhya*). While traditionally administered on the auspicious day of *Pushya Nakshatra*, its benefits are cumulative, supporting the child's physical, mental, and immunological development from infancy through adolescence (0–16 years).

### **1.5. Review of Classical Ayurvedic Texts**

The theoretical foundation of Swarnaprashana is firmly established in authoritative Ayurvedic compendia:

### **1.5.1. Kashyapa Samhita (The Pediatric Authority):**

Acharya Kashyapa provides the most explicit reference in the *Lehana Adhyaya*. He elucidates the multifaceted benefits of Swarnaprashana with the verse:

*"Suvarnaprashanam hyetat medhagnibalavardhanam..."*

According to this text, the practice enhances:

- Medha (Intellect): Improves memory, retention, and cognitive agility.
- Agni (Digestive Fire): Optimizes metabolism and digestion, crucial for growth.
- Bala (Strength/Immunity): Bolsters physical strength and resistance to disease.
- Varna (Complexion): Improves skin tone and luster.
- Grahapaha: Protects against idiopathic syndromes and microbial infections (historically termed as *Graha*).

### **1.5.2. Kashyapa further quantifies the efficacy based on duration:**

- One Month: The child becomes "param-medhavi" (highly intelligent) and is protected from common ailments.
- Six Months: The child becomes "Shrutadhara" (one who retains whatever is heard), indicating exceptional memory and cognitive capacity.

### **1.5.3. Sushruta Samhita & Charaka Samhita:**

While the specific term "Swarnaprashana" appears less frequently, the principles are ubiquitous.

- Sushruta classifies gold as a *Rasayana* that promotes longevity and arrests aging (*Vayahsthapana*). He recommends gold with honey and ghee for newborns to establish vitality.
- Charaka advocates the use of gold in *Jatamatra Chikitsa* (neonatal care) to enhance life force and intellect.

## **1.6. Conceptual Review of Swarna (Gold) & Processing**

In Ayurveda, raw gold is never used therapeutically due to potential toxicity and lack of bioavailability. It undergoes a rigorous pharmaceutical process to transform it into a safe, bio-assimilable form.

- Shodhana (Purification): Gold foils are heated red-hot and quenched strictly in specific liquid media (like buttermilk, decoction of *Dolichos biflorus*, etc.) to eliminate physical and chemical impurities.
- Marana (Incineration/Calcination): The purified gold is triturated with herbal extracts and subjected to prolonged heat cycles (*Putapaka*) to produce Swarna Bhasma.
- Scientific Characterization: Properly prepared *Swarna Bhasma* comprises biologically synthesized nanoparticles (typically 50–100 nm). These nanoparticles possess unique physicochemical properties that allow them to be absorbed at the cellular level without

causing heavy metal toxicity. They are biologically compatible, non-toxic, and therapeutically active in micro-doses.

### **1.7. Scientific Rationale & Mechanism of Action**

The pharmacological action of Swarnaprashana can be understood through the synergy of its components, bridging traditional wisdom with modern scientific understanding:

- **Immunomodulation (Vyadhikshamatva):** Gold nanoparticles stimulate the reticuloendothelial system. Research indicates they enhance macrophage activity and modulate the response of T-cells and B-cells, leading to improved antibody production. This "non-specific immunity" acts similarly to an oral vaccine, priming the body's defense mechanisms against bacterial and viral pathogens.
- **Nootropic & Neuroprotective Effects (Medhya):** The vehicle (*Anupana*) plays a critical role. Ghee is lipid-soluble and capable of crossing the Blood-Brain Barrier (BBB). It acts as a carrier (*Yogavahi*) for the gold nanoparticles and herbal extracts (like *Brahmi*). Once in the central nervous system, these components exhibit antioxidant activity, reduce oxidative stress in neural tissue, and modulate neurotransmitter function (e.g., Acetylcholine), thereby enhancing memory, attention span, and learning ability.
- **Antioxidant Activity:** *Swarna Bhasma* has demonstrated significant free-radical scavenging activity. By reducing oxidative stress, it protects developing cells and tissues from damage, supporting overall growth and metabolic stability.
- **Synergy of Honey and Ghee:** In Ayurveda, honey and ghee are considered *Amrita* (nectar). Honey facilitates absorption through mucosal linings, while ghee enhances bioavailability and nourishment of the nervous system. Together, they potentiate the action of the gold.

### **1.8. Safety Profile**

Safety is a paramount concern when administering metallic preparations to children. However, distinguishing between raw heavy metals and processed Ayurvedic *Bhasmas* is crucial.

- **Non-Toxicity:** Chronic toxicity studies in animal models have shown that standard *Swarna Bhasma* is non-toxic to the liver and kidneys at therapeutic doses.
- **Biocompatibility:** The incineration process renders the gold chemically inert and biologically assimilable.
- **Standardization:** When prepared following Good Manufacturing Practices (GMP) and standardized for particle size and purity, Swarnaprashana is safe for long-term pediatric use.

### **1.9. Public Health Relevance**

In the context of developing nations like Nepal, Swarnaprashana offers a strategic public health intervention.

- **Preventive Healthcare:** It serves as a cost-effective prophylactic measure against recurrent respiratory and gastrointestinal infections, reducing the burden on primary healthcare facilities.

- Addressing Malnutrition: By improving *Agni* (digestion/metabolism), it aids in better absorption of nutrients, combating malnutrition and stunting.
- Cognitive Capital: Enhancing the cognitive potential of the pediatric population contributes to long-term societal productivity.

### **1.10. Responsibilities**

- Ayurvedic Medical Officer (AMO): Oversees the preparation, administration, and monitoring of Swarnaprashana.
- Pharmacist (Ayurvedic): Prepares and verifies the Swarnaprashana formulation.
- Quality Control (QC) Officer: Ensures raw material quality and conducts basic testing.
- Nursing Staff: Assists in administration and patient counseling.
- Hospital Administrator: Ensures availability of resources and compliance with regulatory standards.

### **1.11. Materials and Equipments**

#### **1.11.1. Raw Materials**

1. Swarna Bhasma (Gold Calx): Purified and incinerated gold nanoparticles, prepared as per Ayurvedic texts.
2. Honey (Madhu): Pure, unadulterated, preferably aged honey.
3. Brahmi Ghrita: Ghee processed with herbs such as Brahmi (*Bacopa monnieri*), Vacha (*Acorus calamus*), Shankhapushpi (*Convolvulus pluricaulis*), and Guduchi (*Tinospora cordifolia*).
4. Herbal Powders (Optional): Medhya herbs (e.g., Brahmi, Vacha, Shankhapushpi, Yashtimadhu) for enhanced efficacy.

#### **1.11.2. Equipments**

- Stainless steel vessels for mixing and heating
- Mortar and pestle (iron or stone) for trituration
- Analytical balance (precision: 0.1 mg)
- Sterile wooden spoons for mixing
- Amber glass bottles or food-grade plastic sachets for storage
- pH meter and basic microbial testing kits (if available)
- Cleanroom or sterile area for preparation
- Refrigerator (for temporary storage of Brahmi Ghrita, if required)

### **1.12. Procedure**

#### **1.12.1. Raw Material Sourcing and Verification**

##### **1.12.1.1. Swarna Bhasma:**

- Procure from certified suppliers with documented Shodhana (purification) and Marana (incineration) processes.
- Verify quality using traditional Bhasma Pariksha tests:
  - Varitara: Bhasma floats on water.
  - Rekhapurnata: Bhasma enters finger ridges when rubbed.
  - Nischandratva: No metallic luster under light.
  - Amla Pariksha: No color change with curd or lemon juice.

- If laboratory facilities are available, confirm absence of heavy metals (e.g., lead, arsenic) via local approved labs.

#### **1.12.1.2. Honey:**

- Source pure, unadulterated honey from certified suppliers or local beekeepers with quality certification.
- Check for moisture content (<20%) and absence of microbial contamination (visual and smell test; lab testing if feasible).
- Ensure no artificial additives or preservatives.

#### **1.12.1.3. Brahmi Ghrita:**

- Prepare in-house or procure from certified manufacturers.
- For in-house preparation:
  - Use 50 ml ghee with 200 ml herbal decoction (e.g., Guduchi, Brahmi, Vacha, Shankhapushpi, 2 g each) and process on low flame until water evaporates.
  - Filter and store in airtight containers.
- Test for rancidity (no foul odor) and microbial contamination (if testing kits are available).
- Verify shelf life (typically 6 months).

### **1.12.2. Preparation of Swarnaprashana**

#### **1.12.2.1. Ratio and Composition:**

- Swarna Bhasma: 3 mg (e.g., 30 mg per 30 ml of final product)
- Honey: 1 ml (e.g., 10 ml per 30 ml of final product).
- Brahmi Ghrita: 2 ml (e.g., 20 ml per 30 ml of final product).

#### **1.12.2.2. Mixing Process:**

- In a sterile area, weigh Swarna Bhasma using an analytical balance in a stainless steel vessel.
- Add measured honey and mix thoroughly with a sterile wooden spoon for 10–15 minutes to form a uniform suspension.
- Gradually incorporate Brahmi Ghrita, triturating for 3 hours to ensure homogeneity.
- Maintain mixture at 35–40°C using a warm water bath to ensure consistency.

#### **1.12.2.3. Dosage Standardization:**

- Prepare single-dose units (5 ml or 10 ml) for pediatric administration.
- Recommended dosage:
  - Infants (6 months–1 year): 1 drop
  - Children (1-2 years): 2 drops
  - Children (3-5 years): 4 drops
- Adjust dosage based on AMO's assessment of patient's age, weight, and health condition.

### **1.13. Quality Control**

#### **1.13.1. Basic Testing:**

- Verify homogeneity by visual inspection (no sedimentation of Swarna Bhasma).
- Check pH (4.0–6.0) using a pH meter, if available.
- Conduct sensory tests (color, odor, consistency) to ensure no spoilage.

#### **1.13.2. Microbial Safety:**

- Perform basic microbial checks (if kits are available) to ensure absence of *E. coli*, *Salmonella*, and *S. aureus*.

- If testing facilities are unavailable, send samples to approved labs.

### **1.13.3. Stability:**

- Store prepared Swarnaprashana for no longer than 3 months.
- Check for signs of spoilage (e.g., odor change, phase separation) before administration.

## **1.14. Administration Guidelines**

### **1.14.1. Timing and Method:**

- Administer Swarnaprashana early in the morning on an empty stomach for optimal absorption.
- Preferably administer on Pushya Nakshatra day for traditional significance, though daily or monthly administration is acceptable.
- Use a clean dropper or spoon to administer the dose.
- Ensure the child faces east during administration, as per Ayurvedic tradition.

### **1.14.2. Patient Counseling:**

- Inform parents about benefits (e.g., immunity, cognitive enhancement) and potential risks (e.g., rare allergic reactions).
- Advise monitoring for adverse effects (e.g., rash, digestive discomfort) and to report immediately.
- Recommend a course of at least 30 days for maximum benefits.

## **1.15. Packaging and Storage**

### **1.15.1. Packaging:**

- Use amber glass bottles or food-grade plastic sachets for single-dose (5 ml or 10 ml) or multi-dose (30 ml) units.
- Ensure airtight sealing to prevent contamination.

### **1.15.2. Labeling:**

- Include:
  - Product name: Swarnaprashana
  - Composition: Swarna Bhasma, Honey, Brahmi Ghrita
  - Dosage instructions: Age-specific dosage, e.g., Infants (6 months–1 year): 1 drop, Children (1-2 years): 2 drops and Children (3-5 years): 4 drops
  - Storage instructions: Store at 15–25°C, avoid sunlight, do not refrigerate.
  - Batch number, preparation date, and expiry date (3 months from preparation).
  - Hospital name and certification details.
  - Warning: “For use under Ayurvedic medical supervision.”

### **1.15.3. Storage:**

- Store in a cool, dry place (15–25°C) away from sunlight.
- Avoid moisture ingress to prevent microbial growth.
- Use within 3 months of preparation or as per stability data.

## **1.16. Safety Precautions**

- Use only certified Swarna Bhasma to avoid toxicity from impure gold.

- Screen patients for metal allergies or chronic conditions (e.g., liver/kidney issues) before administration.
- Discontinue use if adverse reactions (e.g., rash, nausea) are observed and consult AMO immediately.
- Ensure sterile handling during preparation to prevent contamination.

### **1.17. Record Keeping**

- Maintain records of:
  - Raw material procurement and quality certificates.
  - Preparation details (batch number, date, quantity, AMO approval).
  - Administration details (patient name, age, dosage, dates of administration).
  - Adverse event reports, if any.
- Retain records for at least 3 years or as per local health regulations.

### **1.18. Regulatory Compliance**

- Adhere to Ministry of Health and Populations and/or Department of Ayurveda and Alternative Medicine guidelines for Ayurvedic medicines.
- Ensure preparation aligns with Kashyapa Samhita and other classical texts.
- Submit periodic reports to local health authorities, if required.
- Train staff on S.O.P. and Ayurvedic principles annually.

### **1.19. Monitoring and Follow-Up**

- Monitor patients for efficacy (e.g., improved immunity, cognitive development) through follow-up visits.
- Record any adverse events and report to the AMO and local health authorities.
- Conduct periodic audits of preparation and administration processes.





# 02

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प्रादेशिक तथा जिल्ला आयुर्वेद  
अस्पतालहरूमा स्वर्णप्राशन प्रयोगका  
लागि मानक सञ्चालन कार्यविधि



## 2.1. उद्देश्य

यस मानक सञ्चालन कार्यविधि (S.O.P.) को मुख्य उद्देश्य लुम्बिनी प्रदेशभित्र स्वर्णबिन्दु प्राशनको तयारी, प्रशासन, र गुणस्तर नियन्त्रणका लागि एक एकीकृत र मानकीकृत प्रोटोकल स्थापित गर्नु हो। यसले विशेष गरी निम्न कुराहरू सुनिश्चित गर्दछ:

मानकीकरण: सबै प्रादेशिक तथा जिल्ला आयुर्वेद अस्पताल/स्वास्थ्य केन्द्रहरूमा स्वर्णप्राशनको तयारी र प्रयोगमा एकरूपता कायम गर्ने।

सुरक्षा र गुणस्तर: स्वर्ण भस्म, मह र ब्राह्मी घृतको तोकिएको अनुपातको अनिवार्य पालना गराउने र असल उत्पादन अभ्यास (GMP) सुनिश्चित गर्ने।

नियमन र अनुगमन: स्वास्थ्य मन्त्रालय र औषधि व्यवस्था विभाग (DDA) का मापदण्ड अनुरूप औषधि निगरानी (Pharmacovigilance) र प्रतिकूल घटनाहरूको अभिलेख राख्ने।

## 2.2. कार्यक्षेत्र

यो S.O.P. लुम्बिनी प्रदेश सरकार, स्वास्थ्य मन्त्रालय मातहत सञ्चालित वा सम्बन्धन प्राप्त निम्न निकायहरूमा लागू हुनेछ:

१. प्रादेशिक तथा जिल्ला आयुर्वेद अस्पताल र स्वास्थ्य केन्द्रहरू।
२. स्वर्णप्राशन उत्पादन तथा वितरण गर्ने इजाजतप्राप्त औषधि निर्माण कम्पनीहरू।
३. सम्बन्धित नियमनकारी तथा अनुगमन निकायहरू।

यसको कार्यक्षेत्रले कच्चा पदार्थको खरिद र प्रमाणीकरणदेखि फर्मुलेसन तयारी, क्लिनिकल प्रशासन, अभिलेख व्यवस्थापन, र प्रतिकूल औषधि प्रतिक्रिया (ADR) प्रतिवेदनसम्मको सम्पूर्ण सञ्चालन चक्रलाई समेट्छ।

## 2.3. पृष्ठभूमि तथा ऐतिहासिक सन्दर्भ

उपचारात्मक प्रयोजनका लागि धातु तथा खनिजहरूको प्रयोग आयुर्वेद चिकित्सा पद्धतिको एक आधारस्तम्भ हो, जसको इतिहास हजारौं वर्ष पुरानो छ। यीमध्ये, सुन (स्वर्ण) ले केवल एक बहुमूल्य धातुको रूपमा मात्र नभई एक शक्तिशाली उपचारात्मक साधनको रूपमा सर्वोच्च स्थान ओगटेको छ। प्राचीन वैदिक साहित्यमा सुनलाई 'हिरण्य' भनिएको छ, जसले शुद्धता, ओज र दीर्घायुको प्रतीकलाई जनाउँछ।

मनुस्मृति र अन्य प्राचिन ग्रन्थहरूले 'जातकर्म संस्कार' (जन्म अनुष्ठान) को स्पष्ट व्याख्या गरेका छन्, जसमा नवजात शिशुलाई सुन, मह र घ्यूको मिश्रण चटाउने विधि उल्लेख गरिएको छ। यो अभ्यास बालबालिकाको शारीरिक कार्यहरू, विशेष गरी 'मेधा' (बौद्धिक क्षमता) र 'आयु' (दीर्घायु) लाई आरम्भ गर्न र सुधार गर्न निश्चित उपचारात्मक उद्देश्यका साथ प्रतिपादन गरिएको थियो। शताब्दीयौंको निरन्तर परिष्करणपछि, यो अभ्यास 'स्वर्णप्राशन' नामक एक विशिष्ट बाल चिकित्सा वधिका रूपमा विकसित भयो, जसको मुख्य उद्देश्य बालबालिकाको समग्र विकासलाई बढावा दिनु र उनीहरूको नैसर्गिक रोग प्रतिरोधात्मक क्षमतालाई सुदृढ पार्नु हो।

## 2.4. परिचय

स्वर्णप्राशन (संस्कृत: स्वर्ण = सुन; प्राशन = चटाउनु/खुवाउनु) बालबालिकाहरूका लागि प्रतिपादन गरिएको एक विशिष्ट रोग निवारक र स्वास्थ्य प्रवर्द्धक उपाय हो। यसमा प्रशोधित सुन (स्वर्ण भस्म) लाई असमान मात्रामा शुद्ध मह (मधु) र गाईको घ्यू (घृत) सँग मिश्रण गरी सेवन गराइन्छ। यसलाई थप प्रभावकारी बनाउन प्रायः मेध्य (मस्तिष्क शक्तिवर्धक) जडीबुटीहरू जस्तै वचा (*Acorus calamus*), ब्राह्मी (*Bacopa monnieri*), र शङ्खपुष्पी (*Convolvulus pluricaulis*) मिसाइन्छ।

यो अभ्यास केवल एक सांस्कृतिक वा परम्परागत विधि मात्र नभएर, बाल स्वास्थ्य प्रवर्द्धन र उपचारका लागि समर्पित आयुर्वेदको विशिष्ट शाखा 'कौमारभृत्य' अन्तर्गत वर्गीकृत एक चिकित्सकीय विधि हो।

यद्यपि शास्त्रीय रूपमा यसलाई 'पुष्य नक्षत्र' को शुभ दिनमा सेवन गराउन सिफारिस गरिएको छ, यसका फाइदाहरू सञ्चयी हुन्छन्, जसले बालबालिकाको शैशवावस्थादेखि किशोरावस्थासम्म (०-१६ वर्ष) शारीरिक, मानसिक र प्रतिरोधात्मक विकासलाई टेवा पुऱ्याउँछन्।

## 2.5. शास्त्रीय ग्रन्थहरूको समीक्षा

स्वर्णप्राशनको सैद्धान्तिक आधार आधिकारिक आयुर्वेद ग्रन्थहरूमा स्थापित छ:

### 2.5.1. कश्यपसंहिता (बाल चिकित्साको आधिकारिक ग्रन्थ):

आचार्य कश्यपले 'लेहन अध्याय' मा यसको सबैभन्दा स्पष्ट सन्दर्भ प्रदान गरेका छन्। उनले स्वर्णप्राशनका बहुआयामिक लाभहरूलाई निम्न श्लोक मार्फत स्पष्ट पारेका छन्: "सुवर्णप्राशनं ह्येतत् मेधाग्निबलवर्धनम्..."

यस ग्रन्थका अनुसार, यो अभ्यासले निम्न कुराहरूमा सुधार ल्याउँछ:

- मेधा (बौद्धिक क्षमता): स्मरण शक्ति र संज्ञानात्मक सुधार गर्छ।
- अग्नि (पाचन शक्ति): पाचन र मेटाबोलिसम लाई अनुकूलन गर्छ, जुन विकासका लागि महत्त्वपूर्ण छ।

- बल (शक्ति/प्रतिरक्षा): शारीरिक शक्ति र रोग प्रतिरोधात्मक क्षमता बढाउँछ।
- वर्ण (कान्ति): छालाको रङ र चमकमा सुधार ल्याउँछ।
- ग्रहापहः अज्ञात रोगहरू र माइक्रोबियल सङ्क्रमणहरूबाट बचाउँछ (ऐतिहासिक रूपमा 'ग्रह भनिने)।

### 2.5.2. सेवन अवधिको आधारमा प्रभावकारिता:

एक महिना: बच्चा 'परं-मेधावी' (अत्यधिक बुद्धिमान) बन्छ र सामान्य रोगहरूबाट सुरक्षित रहन्छ।

छ महिना: बच्चा 'श्रुतधर' (सुनेको कुरा सम्झने) बन्छ, जसले असाधारण स्मरण शक्ति र संज्ञानात्मक क्षमतालाई सङ्केत गर्दछ।

### 2.5.3. सुश्रुत संहिता र चरक संहिता:

सुश्रुतले सुनलाई एक 'रसायन' को रूपमा वर्गीकृत गरेका छन् जसले दीर्घायुलाई बढावा दिन्छ र उमेरजन्य हासलाई रोक्छ (वयःस्थापन)। उनले नवजात शिशुहरूको जीवन शक्ति स्थापना गर्न मह र घ्यूसँग सुनको मिश्रण सिफारिस गरेका छन्।

चरकले जीवन शक्ति र बौद्धिक क्षमता बढाउन 'जातमात्र चिकित्सा' (नवजात शिशुको हेरचाह) मा सुनको प्रयोगको वकालत गरेका छन्।

## 2.6. स्वर्ण (सुन) को अवधारणा र प्रशोधन विधि

आयुर्वेदमा, कच्चा सुनलाई सम्भावित विषाक्तता र न्यून जैविक उपलब्धता (bioavailability) का कारण कहिल्यै पनि उपचारात्मक उद्देश्यका लागि प्रयोग गरिदैन। प्रयोग गर्नु अघी यसलाई औषधि निर्माण प्रक्रियाबाट गुज्रनुपर्छ।

- शोधन (शुद्धीकरण): सुनका पातला पत्रहरूलाई रातो हुने गरी तताइन्छ र भौतिक तथा रासायनिक अशुद्धताहरू हटाउन विशेष तरल माध्यमहरू (जस्तै मोही, गहतको काँडा) मा चोबलिन्छ।
- मारण (भस्मिकरण): शुद्ध गरिएको सुनलाई जडीबुटीहरूको रससँग लामो समयसम्म घोटिन्छ (मर्दन) र 'पुटपाक' विधिद्वारा उच्च तापक्रममा पकाइन्छ, जसबाट 'स्वर्ण भस्म' तयार हुन्छ।
- वैज्ञानिक विशेषता: सही तरिकाले तयार पारिएको स्वर्ण भस्ममा जैविक रूपमा संश्लेषित न्यानो-पार्टिकल्स (सामान्यतया ५०-१०० एनएम) हुन्छन्। यी कणहरूले कोशिकीय स्तरमा अवशोषित हुन सक्ने क्षमता राख्छन् र जैविक रूपमा अनुकूल, विषाक्तता रहित, तथा सूक्ष्म-मात्रामा उपचारात्मक रूपमा सक्रिय हुन्छन्।

## 2.7. वैज्ञानिक आधार तथा कार्य गर्ने संयन्त्र

स्वर्णप्राशनको औषधीय कार्यलाई यसका अवयवहरू बीचको समन्वयात्मक अन्तरक्रिया (synergy) मार्फत बुझ्न सकिन्छ, जसले परम्परागत ज्ञानलाई आधुनिक विज्ञानसँग जोड्दछ:

- **इम्युनोमोड्युलेसन (व्याधिक्षमत्व):** सुनका न्यानो-पार्टिकल्सले रेटिकुलोएन्डोथेलियल प्रणाली (reticuloendothelial system) लाई उत्तेजित गर्छन्। अनुसन्धानले देखाएको छ कि यसले म्याक्रोफेज (macrophage) गतिविधि बढाउँछ र T-cells तथा B-cells को प्रतिक्रियालाई सुधार गरी एन्टिबडी उत्पादनमा सुधार ल्याउँछ। यो "गैर-विशिष्ट प्रतिरक्षा" (non-specific immunity) एक मौखिक खोप जस्तै काम गर्दछ।
- **न्यूट्रोपिक र न्यूरोप्रोटेक्टिभ प्रभाव (मेध्य):** यसको माध्यम (अनुपान) ले महत्त्वपूर्ण भूमिका खेल्छ। घ्यू लिपिड-घुलनशील भएकोले रगत-मस्तिष्क अवरोध (BBB) पार गर्न सक्छ। यो सुनका कणहरू र ब्राह्मी जस्ता जडीबुटीहरूका लागि वाहक (योगवाही) को रूपमा काम गर्दछ। मस्तिष्कमा पुगेपछि, यी तत्वहरूले एन्टिअक्सिडेन्ट गतिविधि देखाउँछन्, न्यूरल तन्तुमा अक्सिडेतिभ तनाव कम गर्छन्, र एसिटाइलकोलिन (Acetylcholine) जस्ता न्यूरोट्रान्समिटरहरूको कार्यमा सुधार ल्याई स्मरण शक्ति, ध्यान र सिक्ने क्षमता बढाउँछन्।
- **एन्टिअक्सिडेन्ट गतिविधि:** स्वर्ण भस्मले उल्लेखनीय फ्री-र्याडिकल स्क्वाभेन्जिङ गतिविधि देखाएको छ। अक्सिडेतिभ तनाव कम गरेर, यसले विकासशील कोष र तन्तुहरूलाई क्षतिबाट बचाउँछ।
- **मह र घ्यूको समन्वयात्मक प्रभाव:** आयुर्वेदमा, असमान मात्रामा मह र घ्यूको मिश्रणलाई 'अमृत' मानिन्छ। महले श्लेष्म झिल्ली (mucosal linings) मार्फत अवशोषणलाई सहज बनाउँछ भने घ्यूले जैविक उपलब्धता (bioavailability) र स्नायु प्रणालीको पोषण बढाउँछ। सँगै, यिनीहरूले सुनको कार्यलाई बलियो बनाउँछन्।

## 2.8. सुरक्षा अवस्था

बालबालिकामा धातुजन्य औषधिहरू प्रयोग गर्दा सुरक्षा एक प्रमुख चिन्ताको विषय हो। तथापि, कच्चा भारी धातुहरू र प्रशोधित आयुर्वेद 'भस्म' हरू बीचको भिन्नता बुझ्नु महत्त्वपूर्ण छ।

- **विषाक्तता रहित:** जनावरहरूमा गरिएका दीर्घकालीन विषाक्तता अध्ययनहरूले देखाएका छन् कि मानक स्वर्ण भस्म उपचारात्मक मात्रामा प्रयोग गर्दा कलेजो वा मिर्गौलामा कुनै विषाक्तता हुँदैन।

- **जैविक अनुकूलता (Biocompatibility):** भस्मिकरण प्रक्रियाले सुनलाई रासायनिक रूपमा निष्क्रिय र जैविक रूपमा शरीरमा मिल्ने बनाउँछ।
- **मानकीकरण:** जब स्वर्ण भस्मलाई असल उत्पादन अभ्यास (GMP) को पालना गरी कण आकार र शुद्धतामा मानकीकृत गरिन्छ, तब स्वर्णप्राशन बालबालिकामा दीर्घकालीन प्रयोगका लागि सुरक्षित हुन्छ।

## 2.9. जनस्वास्थ्यमा यसको औचित्य

नेपाल जस्ता विकासशील राष्ट्रहरूको सन्दर्भमा, स्वर्णप्राशनले एक रणनीतिक जनस्वास्थ्य प्रक्रियाका रूपमा निम्न फाइदाहरू प्रदान गर्दछ:

- **निदानात्मक स्वास्थ्य सेवा:** यो बारम्बार हुने श्वासप्रश्वास र पेटका सङ्क्रमणहरू विरुद्ध एक लागत-प्रभावी रोकथाम उपाय हो, जसले अस्पतालहरूको भार कम गर्छ।
- **कुपोषण न्यूनीकरण:** 'अग्नि' (पाचन शक्ति) मा सुधार गरेर, यसले पोषक तत्वहरूको अवशोषणमा मद्दत गर्छ, जसले कुपोषण र पुङ्कोपन (stunting) विरुद्ध लड्न सहयोग पुऱ्याउँछ।
- **संज्ञानात्मक पूँजी:** बालबालिकाको बौद्धिक क्षमता अभिवृद्धि गरेर यसले दीर्घकालीन रूपमा समाजको उत्पादकत्वमा योगदान पुऱ्याउँछ।

## 2.10. जिम्मेवारीहरू

- **आयुर्वेद चिकित्सक (Ayurvedic Medical Officer - AMO):** स्वर्णप्राशनको तयारी, प्रशासन, र अनुगमनको निरीक्षण गर्ने।
- **फार्मासिस्ट (आयुर्वेद):** स्वर्णप्राशनको फर्मुलेसन (मिश्रण) तयार गर्ने र प्रमाणीकरण गर्ने।
- **गुणस्तर नियन्त्रण (QC) अधिकृत:** कच्चा पदार्थको गुणस्तर सुनिश्चित गर्ने र आधारभूत परीक्षणहरू गर्ने।
- **नर्सिङ कर्मचारी:** प्रशासन (खुवाउने कार्य) र बिरामी परामर्शमा सहयोग गर्ने।
- **अस्पताल प्रशासक:** स्रोतसाधनको उपलब्धता र नियमनकारी मापदण्डहरूको पालना सुनिश्चित गर्ने।

## 2.11. सामग्री र उपकरणहरू

### 2.11.1. कच्चा पदार्थहरू

१. स्वर्ण भस्म (Gold Calx): आयुर्वेदिक ग्रन्थहरू अनुसार शोधन र मारण प्रक्रिया पूरा गरी तयार पारिएको शुद्ध सुनको भस्म (nanoparticles)।

२. मह (Madhu): शुद्ध, मिसावट रहित, र प्राथमिकतामा पुरानो मह।

३. ब्राह्मी घृत (Brahmi Ghrita): ब्राह्मी (*Bacopa monnieri*), वचा (*Acorus calamus*), शङ्खपुष्पी (*Convolvulus pluricaulis*), र गुडूची (*Tinospora cordifolia*) जस्ता जडीबुटीहरूबाट सिद्ध गरिएको घ्यू।

### 2.11.2. उपकरणहरू

- मिश्रण र तताउनका लागि स्टिलका भाँडाहरू
- मर्दनका लागि खरल (फलाम वा ढुङ्गाको)
- विश्लेषणात्मक तराजु (Analytical balance - ०.१ मि.ग्रा. शुद्धता भएको)
- मिश्रण चलाउनका लागि स्टेरिलाइज्ड काठका चम्चाहरू
- भण्डारणका लागि गाढा रडका सिसाका बोतलहरू (Amber glass bottles) वा फूड-ग्रेड प्लास्टिक प्याकेटहरू
- pH मिटर र आधारभूत माइक्रोबियल परीक्षण किटहरू (उपलब्ध भएमा)
- तयारीका लागि सफा कोठा (Cleanroom) वा स्टेरिलाइज्ड क्षेत्र
- फ्रिज (आवश्यकता अनुसार ब्राह्मी घृतको अस्थायी भण्डारणका लागि)

## 2.12. प्रक्रिया (Procedure)

### 2.12.1. कच्चा पदार्थको स्रोत र प्रमाणीकरण

#### 2.12.1.1. स्वर्ण भस्म:

- शोधन र मारण प्रक्रियाको अभिलेख भएका प्रमाणित आपूर्तिकर्ताहरूबाट खरिद गर्ने।
- परम्परागत भस्म परीक्षा विधिहरू प्रयोग गरी गुणस्तर प्रमाणित गर्ने:

- वारितर (Varitara): भस्म पानीमा तैरिनुपर्छ।
- रेखापूर्णता (Rekhapurnata): औँलाले माइदा भस्म औँलाको रेखाभिन्न पस्नुपर्छ।
- निश्चन्द्रत्व (Nischandratva): प्रकाशमा हेर्दा धातुको चमक देखिनु हुँदैन।
- अम्ल परीक्षा (Amla Pariksha): दही वा कागतीको रससँग मिसाउँदा रङ परिवर्तन हुनु हुँदैन।
- यदि प्रयोगशाला सुविधा उपलब्ध छ भने, स्थानीय स्वीकृत प्रयोगशालाहरू मार्फत भारी धातुहरू (जस्तै: सिसा, आर्सेनिक) को अनुपस्थिति निश्चित गर्ने।

#### 2.12.1.2. मह:

- गुणस्तर प्रमाणित आपूर्तिकर्ता वा स्थानीय मौरीपालकहरूबाट शुद्ध र मिसावटरहित मह ल्याउने।
- ओसिलोपन (Moisture content) २०% भन्दा कम भएको र कुनै माइक्रोबियल प्रदूषण नभएको (हेरेर वा सुँघेर; सम्भव भए प्रयोगशाला परीक्षण) सुनिश्चित गर्ने।
- कुनै कृत्रिम रङ वा संरक्षक (preservatives) नमिसाइएको निश्चित गर्ने।

#### 2.12.1.3. ब्राह्मी घृत:

- अस्पतालमै तयार गर्ने वा प्रमाणित उत्पादकहरूबाट खरिद गर्ने।
- इन-हाउस (अस्पतालमै) तयारीका लागि:
  - ५० मि.लि. घ्यूमा २०० मि.लि. जडीबुटीको क्वाथ (जस्तै: गुडूची, ब्राह्मी, वचा, शङ्खपुष्पी, हरेक २ ग्राम) राखी सानो आगोमा पानी बाफ बनेर नउडेसम्म पकाउने।
  - छान्ने र हावा नछिर्ने भाँडोमा भण्डारण गर्ने।
- गन्ध बिग्निएको (Rancidity) र माइक्रोबियल प्रदूषणको परीक्षण गर्ने (किट उपलब्ध भएमा)।
- सेल्फ लाइफ (Shelf life) प्रमाणित गर्ने (साधारणतया ६ महिना)।

### 2.12.2. स्वर्णप्राशनको तयारी

#### 2.12.2.1. अनुपात र संरचना:

- स्वर्ण भस्म: ३ मि.ग्रा. (उदाहरण: ३० मि.ग्रा., ३० मि.लि. स्वर्णप्राशनको लागि)।
- मह: १ मि.लि. (उदाहरण: १० मि.लि., ३० मि.लि. स्वर्णप्राशनको लागि)।

- ब्राह्मी घृत: २ मि.लि. (उदाहरण: २० मि.लि., ३० मि.लि. स्वर्णप्राशनको लागि)।

#### 2.12.2.2. मिश्रण प्रक्रिया:

- एक सफा/स्टेरिलाइज्ड क्षेत्रमा, स्टिलको भाँडोमा विश्लेषणात्मक तराजु प्रयोग गरी स्वर्ण भस्म तौलिने।
- नापिएको मह थप्ने र एकनासको घोल (suspension) नबनेसम्म १०-१५ मिनेटसम्म स्टेरिलाइज्ड काठको चम्चाले राम्ररी चलाउने।
- बिस्तारै ब्राह्मी घृत मिसाउने र एकरूपता (homogeneity) सुनिश्चित गर्न ३ घण्टा सम्म मर्दन गर्ने (घोट्ने)।
- मिश्रणको गाढापन (consistency) कायम राख तातो पानीको भाँडो (warm water bath) प्रयोग गरी ३५-४० डिग्री सेल्सियस तापक्रम कायम गर्ने।

#### 2.12.3. मात्रा (Dosage) निर्धारण:

- बालबालिकालाई खुवाउनका लागि एकल-मात्रा एकाइहरू (५ मि.लि. वा १० मि.लि.) तयार गर्ने।
- सिफारिस गरिएको मात्रा:
  - शिशुहरू (६ महिना - १ वर्ष): १ थोपा
  - बालबालिका (१ - २ वर्ष): २ थोपा
  - बालबालिका (३-५ वर्ष): ४ थोपा
- बिरामीको उमेर, तौल र स्वास्थ्य अवस्थाको आधारमा चिकित्सक (AMO) ले मात्रा समायोजन गर्न सक्नेछन्।

### 2.13. गुणस्तर नियन्त्रण (Quality Control)

#### 2.13.1. आधारभूत परीक्षण:

- दृश्य निरीक्षणद्वारा एकरूपता (homogeneity) जाँच गर्ने (स्वर्ण भस्म थिग्निएको हुनु हुँदैन)।
- उपलब्ध भएमा pH मिटर प्रयोग गरी pH (४.० - ६.०) जाँच गर्ने।
- कुनै खराबी नभएको सुनिश्चित गर्न रङ, गन्ध, र गाढापनको सेन्सरी परीक्षण (Sensory tests) गर्ने।

### 2.13.2. माइक्रोबियल सुरक्षा:

- *E. coli*, *Salmonella*, र *S. aureus* को अनुपस्थिति सुनिश्चित गर्न आधारभूत माइक्रोबियल जाँच गर्ने (किट उपलब्ध भएमा)।
- यदि परीक्षण सुविधाहरू उपलब्ध छैनन् भने, नमुनाहरू स्वीकृत प्रयोगशालामा पठाउने।

### 2.13.3. स्थायित्व (Stability):

- तयार गरिएको स्वर्णप्राशन ३ महिनाभन्दा बढी भण्डारण नगर्ने।
- प्रयोग गर्नु अघि विग्रिएको सङ्केत (जस्तै: गन्ध परिवर्तन, पदार्थ छुट्टिनु/phase separation) जाँच गर्ने।

## 2.14. स्वर्णविन्दु खुवाउने विधि

### 2.14.1. समय र विधि:

- राम्रो शोषण (absorption) का लागि बिहान खाली पेटमा स्वर्णप्राशन खुवाउने।
- परम्परागत महत्त्वका लागि पुष्य नक्षत्रको दिनमा खुवाउनु उत्तम हुन्छ, यद्यपि दैनिक वा मासिक रूपमा पनि खुवाउन सकिन्छ।
- मात्रा खुवाउन सफा ड्रपर वा चम्चा प्रयोग गर्ने।
- आयुर्वेदिक परम्परा अनुसार खुवाउँदा बच्चालाई पूर्व तर्फ फर्काउने।

### 2.14.2. बिरामी/अभिभावक परामर्श:

- अभिभावकहरूलाई यसका फाइदाहरू (जस्तै: रोग प्रतिरोधात्मक क्षमता, बौद्धिक विकास) र सम्भावित जोखिमहरू (जस्तै: दुर्लभ एलर्जी प्रतिक्रियाहरू) बारे जानकारी गराउने।
- कुनै पनि प्रतिकूल असरहरू (जस्तै: डाबर आउनु/rash, पाचनमा असजिलोपन) देखिएमा तुरुन्त खबर गर्न सल्लाह दिने।
- चिकित्सकको सल्लाह अनुसार अधिकतम फाइदाका लागि कम्तिमा ३० दिनको कोर्स पूरा गर्न सिफारिस गर्ने।

## 2.15. प्याकेजिङ र भण्डारण

### 2.15.1. प्याकेजिङ:

- एकल-मात्रा (५ मि.लि. वा १० मि.लि.) वा बहु-मात्रा (३० मि.लि.) एकाइहरूका लागि गाढा रडका सिसाका बोतलहरू वा फूड-ग्रेड प्लास्टिक प्याकेटहरू प्रयोग गर्ने।
- प्रदूषण रोक्न हावा नछिर्ने गरी सिलबन्दी (airtight sealing) सुनिश्चित गर्ने।

### 2.15.2. लेबलिङ (Labeling):

- निम्न कुराहरू समावेश गर्ने:
  - उत्पादनको नाम: स्वर्णप्राशन
  - घटक: स्वर्ण भस्म, मह, ब्राह्मी घृत
  - मात्रा निर्देशन: उमेर अनुसारको मात्रा, जस्तै: शिशुहरू (६ महिना - १ वर्ष): १ थोपा, बालबालिका (१ - २ वर्ष): २ थोपा र बालबालिका (३-५ वर्ष): ४ थोपा
  - भण्डारण निर्देशन: १५-२५ डिग्री सेल्सियसमा भण्डारण गर्ने, सूर्यको किरणबाट बचाउने, फ्रिजमा नराख्ने।
  - ब्याच नम्बर, तयारी मिति, र म्याद सकिने मिति (तयारीको ३ महिना)।
  - अस्पतालको नाम र प्रमाणीकरण विवरण।
  - चेतावनी: "आयुर्वेदिक चिकित्सकको निगरानीमा मात्र प्रयोग गर्नुपर्ने।"

### 2.15.3. भण्डारण:

- सूर्यको किरणबाट टाढा, चिसो र सुख्खा ठाउँमा (१५-२५ डिग्री सेल्सियस) राख्ने।
- माइक्रोबियल वृद्धि रोक्न ओसिलो पस्नबाट बचाउने।
- तयारीको ३ महिनाभित्र वा स्थायित्व तथ्याङ्क (stability data) अनुसार प्रयोग गरिसक्ने।

### 2.16. सुरक्षा सावधानीहरू

- अशुद्ध सुनबाट हुने विषाक्तताबाट बच्न केवल प्रमाणित स्वर्ण भस्म मात्र प्रयोग गर्ने।
- प्रयोग गर्नु अघि बिरामीलाई धातुको एलर्जी वा दीर्घकालीन अवस्थाहरू (जस्तै: कलेजो/मिर्गौला समस्या) भए/नभएको जाँच गर्ने।
- यदि प्रतिकूल प्रतिक्रियाहरू (जस्तै: डाबर, वाकवाकी) देखिएमा प्रयोग बन्द गर्ने र तुरुन्त चिकित्सक (AMO) सँग परामर्श गर्ने।

- प्रदूषण रोक्न तयारीको समयमा पूर्ण सफाइ (sterile handling) सुनिश्चित गर्ने।

## 2.17. अभिलेख व्यवस्थापन (Record Keeping)

- निम्न कुराहरूको अभिलेख राख्ने:
  - कच्चा पदार्थ खरिद र गुणस्तर प्रमाणपत्रहरू।
  - तयारी विवरण (ब्याच नम्बर, मिति, परिमाण, चिकित्सकको स्वीकृति)।
  - प्रशासन/वितरण विवरण (बिरामीको नाम, उमेर, मात्रा, खुवाइएको मिति)।
  - प्रतिकूल घटना रिपोर्टहरू, यदि भएमा।
- स्थानीय स्वास्थ्य नियमहरू अनुसार वा कम्तीमा ३ वर्षसम्म अभिलेख सुरक्षित राख्ने।

## 2.18. नियमनकारी अनुपालन (Regulatory Compliance)

- स्वास्थ्य तथा जनसङ्ख्या मन्त्रालय र/वा आयुर्वेद तथा वैकल्पिक चिकित्सा विभागका आयुर्वेदिक औषधि सम्बन्धी निर्देशिकाहरूको पालना गर्ने।
- काश्यप संहिता र अन्य शास्त्रीय ग्रन्थहरूसँग तयारी विधि मेल खाएको सुनिश्चित गर्ने।
- आवश्यक भएमा स्थानीय स्वास्थ्य अधिकारीहरूलाई आवधिक प्रतिवेदन बुझाउने।
- कर्मचारीहरूलाई वार्षिक रूपमा S.O.P. र आयुर्वेदिक सिद्धान्तहरूबारे तालिम दिने।

## 2.19. अनुगमन र फलो-अप (Monitoring and Follow-Up)

- फलो-अप भ्रमणहरू मार्फत प्रभावकारिता (जस्तै: रोग प्रतिरोधात्मक क्षमतामा सुधार, बौद्धिक विकास) को अनुगमन गर्ने।
- कुनै पनि प्रतिकूल घटनाहरू रेकर्ड गर्ने र चिकित्सक (AMO) तथा स्थानीय स्वास्थ्य अधिकारीहरूलाई रिपोर्ट गर्ने।
- तयारी र प्रशासन प्रक्रियाहरूको आवधिक लेखापरीक्षण (audit) गर्ने।





# 03

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STANDARD OPERATING PROCEDURE  
(S.O.P.) FOR PREPARATION AND QUALITY  
CONTROL OF SWARNAPRASHANA DROPS  
FOR PHARMACEUTICAL COMPANIES



### **3.1. Purpose**

To provide a standardized procedure for the preparation, quality control, packaging, and distribution of Swarnaprashana in drop form, an Ayurvedic formulation for pediatric use to enhance immunity and cognitive development. This S.O.P. ensures the composition of Swarna Bhasma, Honey, and Brahmi Ghrita, formulated for precise drop administration, and compliance with Ayurvedic and modern pharmaceutical standards.

### **3.2. Scope**

This S.O.P. applies to pharmaceutical companies manufacturing Swarnaprashana drops for commercial distribution. It covers raw material sourcing, formulation, quality testing, packaging in dropper bottles, and storage, ensuring safety, efficacy, and regulatory compliance.

### **3.3. Responsibilities**

- Production Manager: Supervises the manufacturing process and ensures adherence to S.O.P..
- Quality Control (QC) Team: Tests raw materials and finished products for compliance.
- Ayurvedic Pharmacist: Verifies formulation accuracy per Ayurvedic texts.
- Regulatory Affairs Team: Ensures compliance with GMP, and international standards.
- Packaging Team: Handles filling, sealing, and labeling of dropper bottles.

### **3.4. Materials and Equipment**

#### **3.4.1. Raw Materials**

1. Swarna Bhasma (Gold Calx): Purified and incinerated gold nanoparticles, prepared as per Ayurvedic texts.
2. Honey (Madhu): Pure, unadulterated, preferably aged honey.
3. Brahmi Ghrita: Ghee processed with herbs such as Brahmi (*Bacopa monnieri*), Vacha (*Acorus calamus*), Shankhapushpi (*Convolvulus pluricaulis*), and Guduchi (*Tinospora cordifolia*).
4. Herbal Powders (Optional): Medhya herbs (e.g., Brahmi, Vacha, Shankhapushpi, Yashtimadhu) for enhanced efficacy.

#### **3.4.2. Equipment**

- Stainless steel mixing vessels (GMP-compliant)
- Mortar and pestle (iron or stone) for trituration
- Analytical balance (precision: 0.01 mg)
- Particle size analyzer (e.g., for Swarna Bhasma nanoparticle verification)
- X-ray diffraction (XRD) and Scanning Electron Microscope (SEM) for quality control
- Sterile wooden or stainless steel spatulas for mixing
- Cleanroom facility (Class 100 for Swarna Bhasma handling)
- pH meter, moisture analyzer, and microbial testing equipment
- Automated dropper bottle filling and sealing machine
- Amber glass dropper bottles (5 ml, 10 ml, or 15 ml) with calibrated droppers
- High-efficiency particulate air (HEPA) filtration system for sterile packaging

### **3.5. Procedure**

#### **3.5.1. Raw Material Sourcing and Verification**

##### **3.5.1.1. Swarna Bhasma:**

- Source from certified suppliers with documentation of Shodhana (purification) and Marana (incineration) processes.
- Verify particle size (28–35 nm) using SEM and XRD to confirm nanoscale gold particles.
- Test for purity (>94% gold content) and absence of heavy metals (e.g., lead, mercury, arsenic) using Energy Dispersive X-ray (EDX) spectroscopy.
- Perform traditional Bhasma Pariksha tests:
  - Varitara: Bhasma floats on water.
  - Rekhapurnata: Bhasma enters finger ridges when rubbed.
  - Nischandratva: No metallic luster under light.
  - Amla Pariksha: No color change with curd or lemon juice.

##### **3.5.1.2. Honey:**

- Procure pure, unadulterated honey from certified suppliers.
- Test for moisture content (<20%), pH (3.4–6.1), and microbial load (conforming to USP standards).
- Confirm absence of artificial sweeteners or preservatives using high-performance liquid chromatography (HPLC), if available.

##### **3.5.1.3. Brahmi Ghrita:**

- Prepare as per Ayurvedic texts (e.g., Charaka Samhita, Kashyapa Samhita) or source from certified manufacturers.
- For in-house preparation:
  - Process 50 ml ghee with 200 ml herbal decoction (e.g., 2 g each of Brahmi, Vacha, Shankhapushpi, Guduchi, Yashtimadhu, Pippali, Maricha) on low flame until water evaporates as per Ghrita preparation method mentioned in classical texts.
  - Filter through muslin cloth and store in airtight containers.
- Test for rancidity (peroxide value <10 meq/kg), microbial contamination, and shelf life (6 months).

#### **3.5.2. Preparation of Swarnaprashana Drops**

##### **3.5.2.1. Ratio and Composition:**

- Swarna Bhasma: 3 mg (e.g., 30 mg per 30 ml of final product)
- Honey: 1 ml (e.g., 10 ml per 30 ml of final product).
- Brahmi Ghrita: 2 ml (e.g., 20 ml per 30 ml of final product).

##### **3.5.2.2. Mixing Process:**

- In a Class 100 cleanroom, weigh Swarna Bhasma using an analytical balance in a stainless steel vessel.
- Add measured honey and mix thoroughly using a sterile spatula for 15–20 minutes to form a uniform suspension.
- Gradually incorporate Brahmi Ghrita, triturating for 3 hours to ensure homogeneity and prevent sedimentation.

- Maintain mixture at 35–40°C using a controlled water bath to ensure flowability suitable for drop administration.
- Filter the mixture through a 100-micron sterile mesh to remove any particulate matter, ensuring suitability for dropper dispensing.

#### **3.5.2.3. Dosage Standardization:**

- Formulate for drop administration (1 drop  $\approx$  0.05 ml, containing  $\sim$ 0.05 mg Swarna Bhasma).
- Recommended dosage:
- Recommended dosage:
  - Infants (6 months–1 year): 1 drop
  - Children (1-2 years): 2 drops
  - Children (3-5 years): 4 drops
- Ensure each 10 ml bottle contains  $\sim$ 200 drops, with Swarna Bhasma content of 10 mg for consistent dosing.

### **3.6. Quality Control and Testing**

#### **3.6.1. Physical and Chemical Tests:**

- Verify homogeneity using visual inspection and particle size analysis (no sedimentation after 24 hours).
- Test pH (4.0–6.0) to ensure stability and compatibility.
- Confirm gold content and absence of contaminants using EDX spectroscopy.
- Measure viscosity (suitable for dropper flow,  $\sim$ 10–20 cP at 25°C) using a viscometer.

#### **3.6.2. Microbial Testing:**

- Test for microbial load (total aerobic count  $<10^3$  CFU/g, yeast/mold  $<10^2$  CFU/g, absence of *E. coli*, *Salmonella*, *S. aureus*) per USP standards.
- Conduct preservative efficacy testing if preservatives are used (not recommended for Ayurvedic purity).

#### **3.6.3. Stability Testing:**

- Perform accelerated stability studies at 40°C  $\pm$  2°C and 75%  $\pm$  5% relative humidity for 6 months.
- Check for sedimentation, phase separation, or changes in viscosity, pH, and microbial load.
- Establish shelf life (typically 6–12 months for drops in amber glass bottles).

#### **3.6.4. Safety and Toxicity:**

- Conduct in vitro cytotoxicity tests (e.g., Caco-2 cell lines) to confirm non-cytotoxicity.
- Verify blood compatibility (no hemolysis, no platelet activation) per ISO 10993 standards.
- Review clinical data to ensure no adverse effects (e.g., allergies, digestive issues).

### **3.7. Packaging and Labeling**

#### **3.7.1. Packaging:**

- Use amber glass dropper bottles (5 ml, 10 ml, or 15 ml) with calibrated droppers (0.05 ml per drop).
- Sterilize bottles and droppers before filling using autoclaving or UV sterilization.

- Fill bottles in a cleanroom using an automated filling machine to ensure precision and sterility.
- Seal with tamper-evident caps to ensure product integrity.

### **3.7.2. Labeling:**

- Include the following on the label:
  - Product name: Swarnaprashana Drops
  - Composition: Swarna Bhasma, Honey, Brahmi Ghrita
  - Dosage instructions: Age-specific
  - Storage instructions: Store at 15–25°C, avoid direct sunlight, do not refrigerate.
  - Batch number, manufacturing date, and expiry date (6–12 months from manufacturing).
  - Manufacturer’s name, address, and GMP certification.
  - Warning: “Consult an Ayurvedic practitioner before use. Shake well before use.”
  - Net volume (e.g., 10 ml ≈ 200 drops).

### **3.8. Storage and Handling**

- Store Swarnaprashana drops at 15–25°C in a cool, dry place away from direct sunlight.
- Ensure bottles are stored upright to prevent leakage.
- Handle Swarna Bhasma in a cleanroom to avoid contamination during preparation.
- Maintain inventory records and implement first-expired, first-out (FEFO) stock rotation.

### **3.9. Regulatory Compliance**

- Comply with Ministry of Health and Populations and/or Department of Ayurveda and Alternative Medicine guidelines for Ayurvedic formulations and Good Manufacturing Practices (GMP).
- Obtain necessary licenses from state and central drug authorities.
- Submit samples for periodic testing to approved laboratories.
- Maintain documentation of raw material certificates, batch records, QC reports, and stability data for at least 5 years.

### **3.10. Administration Guidelines**

- Shake the bottle well before use to ensure uniform dispersion of Swarna Bhasma.
- Administer drops early in the morning on an empty stomach for optimal absorption.
- Optionally administer on Pushya Nakshatra day for traditional significance, though daily use for 30–180 days is recommended for maximum benefits.
- Use the calibrated dropper to dispense the exact number of drops directly into the child’s mouth or mix with a small amount of warm water, if preferred.
- Ensure the child faces east during administration, as per Ayurvedic tradition.

### **3.11. Safety Precautions**

- Use only certified Swarna Bhasma to avoid toxicity from impure gold.
- Monitor for rare allergic reactions or digestive discomfort; discontinue use if observed and consult a practitioner.
- Avoid use in children with known metal sensitivities or chronic liver/kidney conditions without medical supervision.
- Ensure sterile handling during preparation and packaging to prevent contamination.

### **3.12. Record Keeping**

- Maintain detailed records of:
  - Raw material procurement and testing certificates.
  - Batch-wise production details (weights, mixing conditions, filtration).
  - QC test results (physical, chemical, microbial, stability).
  - Packaging and distribution logs.
- Retain records for a minimum of 5 years or as per regulatory requirements.





04

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ETHICAL ISSUES AND  
PHARMACOVIGILANCE IN  
SWARNAPRASHANA



## **4.1. Introduction**

Swarnaprashana, an Ayurvedic practice involving the administration of processed gold (Swarna Bhasma) with honey, ghee, and sometimes herbal extracts to children, is rooted in traditional texts like the Kashyapa Samhita. It is believed to enhance immunity, cognitive function, and overall health. However, as a traditional medicine involving a heavy metal, Swarnaprashana raises significant ethical and pharmacovigilance concerns. These include ensuring informed consent, addressing safety risks, managing underreporting of adverse drug reactions (ADRs), and integrating traditional practices into modern pharmacovigilance systems. This document provides a detailed exploration of these issues and proposes solutions to ensure ethical and safe use of Swarnaprashana, drawing on principles of pharmacovigilance and public health ethics.

## **4.2. Ethical Issues in Swarnaprashana**

The ethical challenges associated with Swarnaprashana primarily revolve around beneficence (promoting well-being), non-maleficence (avoiding harm), autonomy (respecting individual choice), and justice (ensuring equitable access and treatment). These issues are particularly pronounced in pediatric populations, where consent and safety considerations are critical.

### **4.2.1. Informed Consent and Autonomy**

- Issue: Swarnaprashana is typically administered to children from infancy to adolescence, raising concerns about informed consent. Parents or guardians provide consent on behalf of minors, but they may not be fully aware of the risks, benefits, or scientific evidence due to the traditional and cultural context of the practice. Studies indicate that participants in clinical trials or traditional medicine use in India may not fully understand their rights, particularly regarding serious adverse events (SAEs).
- Ethical Concern: The principle of autonomy requires that parents receive comprehensive, transparent information about Swarnaprashana's potential benefits (e.g., improved immunity, cognitive enhancement) and risks (e.g., heavy metal toxicity, allergic reactions). Lack of standardized information or reliance on anecdotal claims can undermine informed decision-making.
- Solutions:
  - Develop Standardized Consent Protocols: Create detailed, parent-friendly information sheets explaining the composition of Swarnaprashana, its traditional claims, current scientific evidence, and potential risks. These should be available in local languages and use simplified medical terminology.
  - Audio-Visual Consent Processes: Implement audio-visual recording of the consent process, as explored in clinical trial settings in India, to ensure clarity and documentation. This approach enhances transparency but must address privacy concerns, ensuring anonymity and confidentiality.
  - Educational Campaigns: Conduct awareness programs for parents, emphasizing their right to ask questions, withdraw from treatment, and report adverse effects. These campaigns should involve Ayurvedic practitioners, pediatricians, and community health workers.

### **4.2.2. Safety and Non-Maleficence**

- Issue: Swarna Bhasma, the processed gold used in Swarnaprashana, is a heavy metal preparation. Improper preparation (e.g., inadequate incineration) may lead to toxicity,

including heavy metal accumulation in tissues, which poses risks to children's developing organs. Limited long-term safety data exacerbates this concern.

- Ethical Concern: The principle of non-maleficence obligates practitioners to avoid harm. The lack of rigorous safety studies and standardized preparation protocols for Swarna Bhasma raises the risk of adverse events, particularly in vulnerable pediatric populations.
- Solutions:
  - Long-Term Safety Studies: Conduct longitudinal studies to monitor the safety of Swarnaprashana over extended periods (e.g., 5–10 years), focusing on potential heavy metal accumulation and organ toxicity. Biomarkers for gold levels in blood, urine, or tissues should be developed.
  - Standardized Preparation Guidelines: Establish strict protocols for Swarna Bhasma production, including purification, incineration, and nanoparticle size control, using advanced analytical techniques like Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Transmission Electron Microscopy (TEM).
  - Regulatory Oversight: Collaborate with the DoAA and DDA to enforce quality control standards for Swarnaprashana products, preventing contamination or adulteration.

#### **4.2.3. Equity and Justice**

- Issue: Access to Swarnaprashana is often limited to specific communities or regions where Ayurvedic practices are prevalent, potentially excluding marginalized or rural populations. Additionally, the cost of high-quality Swarna Bhasma may create disparities in access.
- Ethical Concern: The principle of justice requires equitable access to healthcare interventions. Uneven distribution of Swarnaprashana programs, such as those run by institutions like Sri Dharmasthala Manjunatheshwara College of Ayurveda, may disproportionately benefit urban or affluent populations.
- Solutions:
  - Public Health Programs: Expand community-based Swarnaprashana initiatives, like those funded by the Ministry of Health and Population, to rural and underserved areas. Subsidize costs to ensure affordability for low-income families.
  - Training Local Practitioners: Train community health workers and local Ayurvedic practitioners to administer Swarnaprashana safely, increasing accessibility in remote regions.
  - Cultural Sensitivity: Adapt Swarnaprashana formulations and administration protocols to align with local dietary and cultural preferences, ensuring broader acceptance and equitable access.

#### **4.2.4. Public Health Ethics vs. Individual Rights**

- Issue: Public health ethics emphasizes the health of populations over individual rights, which may conflict with individual autonomy in the context of Swarnaprashana. For example, promoting Swarnaprashana as a public health intervention to boost immunity may lead to pressure on parents to participate, even if they are skeptical or uninformed.
- Ethical Concern: Balancing public health goals with individual autonomy requires careful consideration of when paternalistic interventions are justified. Without robust evidence, promoting Swarnaprashana broadly could undermine trust in healthcare systems.
- Solutions:

- Evidence-Based Advocacy: Promote Swarnaprashana only with supporting clinical evidence from randomized controlled trials (RCTs) and safety studies, avoiding overgeneralization of traditional claims.
- Transparent Communication: Public health campaigns should clearly distinguish between traditional beliefs and scientifically validated benefits, ensuring parents make informed choices without undue pressure.
- Ethical Review Boards: Establish independent ethics committees to review Swarnaprashana programs, ensuring they align with public health ethics principles while respecting individual rights.

### **4.3. Pharmacovigilance Challenges and Solutions**

Pharmacovigilance (PV) involves the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems. For Swarnaprashana, PV is critical due to its use of a heavy metal and its application in pediatric populations. India's Pharmacovigilance Programme (PvPI), under the Indian Pharmacopoeia Commission (IPC), includes traditional medicines like Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) in its scope, but challenges remain.

#### **4.3.1. Underreporting of Adverse Drug Reactions (ADRs)**

- Challenge: Underreporting of ADRs is a significant issue in India, with PV rates below 1% compared to the global average of 5%. Community pharmacists and healthcare providers often lack awareness or training in reporting ADRs for traditional medicines like Swarnaprashana.
- Solutions:
  - Training Programs: Integrate PV training into the curricula of Ayurvedic and allopathic medical, pharmacy, and nursing colleges. Focus on recognizing and reporting ADRs specific to Swarna Bhasma, such as allergic reactions, gastrointestinal issues, or neurological symptoms.
  - Simplified Reporting Systems: Develop user-friendly, language-appropriate ADR reporting forms for Swarnaprashana, as recommended for traditional medicines. Mobile apps like VigiMobile, piloted by the WHO and Uppsala Monitoring Centre, can facilitate real-time reporting.
  - Incentives for Reporting: Introduce incentives, such as recognition or financial rewards, for healthcare providers who report ADRs, as demonstrated in a Spanish study that increased ADR reporting through educational and financial interventions.

#### **4.3.2. Lack of Standardized PV Protocols for Traditional Medicines**

- Challenge: The PvPI has made progress in monitoring ASU&H drugs, but specific protocols for Swarnaprashana are lacking. The variability in Swarna Bhasma preparation and administration complicates ADR detection and causality assessment.
- Solutions:
  - Dedicated PV Framework for ASU&H: Expand the PV program to include specific guidelines for Swarnaprashana, addressing its unique composition and pediatric use. This should include standardized case report forms and signal detection methods tailored to heavy metal-based formulations.

- Data Integration: Establish a national database for Swarnaprashana-related ADRs, integrating data from Ayurvedic clinics, hospitals, and community programs. Collaborate with the WHO's Uppsala Monitoring Centre to share data globally.
- Pharmacoepidemiological Studies: Conduct studies to characterize Swarnaprashana's safety profile, using methods like the WHO PV indicators checklist to benchmark performance against other traditional medicines.

#### **4.3.3. Monitoring Herbal and Heavy Metal Interactions**

- Challenge: Swarnaprashana often includes herbal components (e.g., Brahmi, Ashwagandha), which may interact with Swarna Bhasma or other medications, as seen in a study where the Ayurvedic preparation Shankhapushpi reduced phenytoin's antiepileptic activity.
- Solutions:
  - Interaction Studies: Conduct in vitro and in vivo studies to identify potential interactions between Swarna Bhasma and common herbal additives or allopathic drugs, focusing on pharmacokinetics and pharmacodynamics.
  - Labeling Requirements: Mandate clear labeling of Swarnaprashana products, listing all ingredients, potential interactions, and instructions for use under medical supervision.
  - Surveillance of Polypharmacy: Monitor children receiving Swarnaprashana alongside other medications, using electronic health records to detect adverse interactions.

#### **4.3.4. Post-Marketing Surveillance**

- Challenge: Post-marketing surveillance for Swarnaprashana is limited, as most studies focus on pre-administration safety. The PvPI emphasizes post-marketing surveillance for ASU&H drugs, but implementation is inconsistent.
- Solutions:
  - Active Surveillance Systems: Implement active surveillance, such as cohort studies or sentinel site monitoring, to track Swarnaprashana's long-term effects in real-world settings. This can leverage digital tools like QR codes for prompt ADR reporting.
  - Collaboration with Stakeholders: Engage Ayurvedic practitioners, pediatricians, and parents in PV activities through workshops and symposiums, as done by the NCC-PvPI in 2017 for herbal medicines.
  - Real-World Evidence (RWE): Use RWE from community programs (e.g., Swarnamritaprashana camps) to evaluate safety and efficacy, supporting post-authorization safety studies (PASS).

#### **4.4. Integration with Modern PV Systems**

To address ethical and PV challenges, Swarnaprashana must be integrated into Nepal's broader PV framework, aligning with global standards like those of the WHO and the European Medicines Agency (EMA).

#### **4.4.1. Regulatory Alignment**

- Solution: Strengthen collaboration between the Department of Ayurveda and Alternative Medicine and CDSCO to align Swarnaprashana PV with Schedule Y of the Drugs and Cosmetics Act 1945, which governs clinical trial and post-marketing safety requirements.
- Implementation: Develop a risk management plan (RMP) for Swarnaprashana, as piloted by the WHO PVG in 2025, to guide ADR reporting and risk minimization.

#### **4.4.2. Technology and Data Analytics**

- Solution: Use artificial intelligence (AI) and machine learning to enhance PV for Swarnaprashana, as suggested for modern PV systems. AI can automate ADR case processing, identify clusters of adverse events, and predict risks using real-world data.
- Implementation: Pilot AI-based tools in PvPI centers to analyze Swarnaprashana ADR reports, focusing on signal detection and causality assessment.

#### **4.4.3. Global Collaboration**

- Solution: Leverage India's role as a WHO Collaborating Centre for PV to share Swarnaprashana safety data globally, enhancing its credibility and informing international PV practices for traditional medicines.
- Implementation: Participate in global PV initiatives like the WHO's Programme for International Drug Monitoring, ensuring Swarnaprashana's safety profile is evaluated in diverse populations.

#### **4.5. Public Health and Ethical Communication**

- Solution: Develop a communication strategy to address public concerns about Swarnaprashana's safety and efficacy, balancing cultural reverence with scientific rigor. This should involve transparent reporting of PV findings and ethical considerations to build trust.
- Implementation:
  - Publish PV data in accessible formats, such as public health advisories or online portals, to inform parents and practitioners.
  - Engage patient advocacy groups and healthcare professionals in dialogues about Swarnaprashana's risks and benefits, fostering a multi-stakeholder approach.

#### **4.6. Conclusion**

Addressing the ethical and pharmacovigilance challenges of Swarnaprashana requires a multifaceted approach that integrates traditional practices with modern scientific and ethical standards. By ensuring informed consent, standardizing safety protocols, enhancing ADR reporting, and leveraging technology, Swarnaprashana can be safely and equitably administered. Collaboration between Ayurvedic and allopathic systems, supported by robust PV frameworks, will ensure that this ancient practice meets contemporary ethical and safety requirements, benefiting children while respecting individual and public health rights.

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05

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SWARNAPRASHANA ADVERSE  
DRUG REACTION (ADR)  
RECORDING



## 5.1. Introduction

Swarnaprashana, an Ayurvedic practice involving the administration of processed gold (Swarna Bhasma) combined with honey, ghee, and sometimes herbal extracts, is used to promote immunity, cognitive function, and overall health in children. While popular in India, its use in Nepal, a country with a shared Ayurvedic heritage, is less documented. Given the involvement of a heavy metal (gold), monitoring adverse drug reactions (ADRs) is critical to ensure safety, particularly in pediatric populations. The Nepal Health Research Council (NHRC), as the apical body for health research regulation in Nepal, provides ethical and scientific guidelines for research and pharmacovigilance (PV) activities. This document outlines the framework for ADR recording for Swarnaprashana in Nepal, aligned with NHRC guidelines and the national pharmacovigilance system managed by the Department of Drug Administration (DDA).

## 5.2. Nepal's Pharmacovigilance Framework

Nepal joined the World Health Organization's (WHO) Programme for International Drug Monitoring in July 2006, with the DDA designated as the National Pharmacovigilance Center. The country has established 15 regional pharmacovigilance centers (RPCs) to monitor ADRs, including those from traditional medicines like Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H). The NHRC oversees ethical health research, including PV studies, ensuring compliance with national and international standards, such as the WHO's definition of an ADR: "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man."

Key Features of Nepal's PV System

- **Voluntary Reporting:** ADR reporting in Nepal is voluntary, involving healthcare professionals (HCPs) such as doctors, pharmacists, nurses, and health assistants.
- **Regional Centers:** Twelve RPCs, including those at institutions like KIST Medical College and Manipal Teaching Hospital, collect and forward ADR reports to the DDA.
- **Underreporting:** Underreporting is a significant challenge, with only 831 ADR reports recorded by the DDA as of recent data, attributed to limited awareness and training among HCPs.
- **Consumer Involvement:** There is growing recognition of the need for consumer pharmacovigilance to address underreporting, though this is still in its infancy.

## 5.3. Swarnaprashana and ADR Concerns

Swarnaprashana's use of Swarna Bhasma, a heavy metal preparation, raises specific safety concerns, including:

- **Potential Toxicity:** Improperly processed Swarna Bhasma may contain unreacted gold or contaminants, potentially leading to heavy metal accumulation or organ toxicity.
- **Herbal Interactions:** Formulations including herbs like Brahmi or Ashwagandha may cause drug-herb interactions, as seen in cases where Ayurvedic preparations altered the efficacy of allopathic drugs (e.g., Shankhapushpi reducing phenytoin's antiepileptic activity).
- **Pediatric Vulnerability:** Children are more susceptible to ADRs due to their developing physiology, necessitating rigorous monitoring. No specific studies on Swarnaprashana ADRs in Nepal were identified in the available literature, but the general principles of PV for ASU&H drugs apply.

#### 5.4. NHRC Guidelines for ADR Recording

The NHRC’s “National Ethical Guidelines for Health Research in Nepal” (2022) and its oversight of evidence-based health practices provide a framework for ADR recording. While these guidelines do not explicitly address Swarnaprashana, they apply to all health interventions, including traditional medicines. Key NHRC requirements relevant to Swarnaprashana ADR recording include:

- Ethical Approval: Research or PV activities involving Swarnaprashana must receive approval from the NHRC’s Ethical Review Board (ERB) to ensure participant safety and data integrity.
- Informed Consent: Parents or guardians of children receiving Swarnaprashana must provide informed consent, with clear information on potential risks (e.g., toxicity, allergic reactions) and benefits (e.g., immunity enhancement).
- Data Collection Standards: ADR data must be systematically collected, documented, and reported using standardized formats, ensuring confidentiality and anonymity.
- Community Engagement: Research involving traditional practices like Swarnaprashana should involve community stakeholders to align with cultural and ethical norms.

#### 5.5. ADR Recording Process for Swarnaprashana

Based on Nepal’s PV framework and NHRC guidelines, the following process is proposed for recording ADRs associated with Swarnaprashana:

##### 5.5.1. Identification of ADRs

- Sources: ADRs can be reported by HCPs (doctors, pharmacists, nurses), community pharmacists, or parents/consumers. Community pharmacies in Nepal, though often run by non-pharmacist professionals with limited training, are integral to ADR reporting.
- Common ADRs: Based on general PV data, ADRs may include maculopapular rash, diarrhea, vomiting, or rare cases of neurological or hepatic effects. Specific ADRs for Swarnaprashana (e.g., gold-related toxicity) require further study.
- Causality Assessment: Use tools like the WHO-UMC causality assessment system or Naranjo scale to determine the likelihood that Swarnaprashana caused the ADR.

##### 5.5.2. Reporting Mechanisms

- Standardized Forms: Use the DDA’s ADR reporting form, available through RPCs, to document details such as patient demographics, Swarnaprashana formulation, dose, administration schedule (e.g., daily or on Pushya Nakshatra), and ADR description.
- Digital Tools: Leverage mobile apps like VigiMobile, piloted by the WHO, for real-time ADR reporting by HCPs and consumers.
- Community Pharmacist Involvement: Train community pharmacists, as demonstrated in a Pokhara valley study, to recognize and report ADRs using validated Knowledge-Attitude-Practices (KAP) questionnaires.

##### 5.5.3. Submission to RPCs and DDA

- Regional Centers: Reports should be submitted to one of the 15 RPCs, such as those at KIST Medical College or Nepal Cancer Hospital, which forward data to the DDA.
- National Database: The DDA integrates ADR reports into a national database, contributing to the WHO’s Uppsala Monitoring Centre (UMC) for global PV monitoring.

- Consumer Reporting: Encourage parents to report ADRs directly to RPCs or through community pharmacists, addressing the infancy of consumer PV in Nepal.

#### **5.5.4. Analysis and Follow-Up**

- Severity and Preventability: Assess ADR severity using scales like the Hartwig scale and preventability using the Schumock and Thornton criteria. For Swarnaprashana, focus on preventable ADRs due to improper preparation or dosing.
- Signal Detection: Use statistical methods to identify potential safety signals, such as clusters of gold-related toxicity or allergic reactions.
- Feedback Loop: Provide feedback to HCPs and parents on ADR outcomes to improve reporting compliance and trust in the PV system.

### **5.6. Challenges in ADR Recording for Swarnaprashana**

- Lack of Specific Data: No studies specifically address Swarnaprashana ADRs in Nepal, limiting baseline knowledge. General PV studies indicate underreporting and low awareness among HCPs.
- Cultural and Traditional Context: Swarnaprashana's cultural significance may lead to underreporting, as parents or practitioners may attribute adverse effects to other causes or hesitate to report due to faith in Ayurveda.
- Limited HCP Training: Only 16.3% of community pharmacies in Nepal are run by pharmacists with bachelor's degrees, and many lack PV training.
- Regulatory Gaps: ADR reporting is not mandatory in Nepal, reducing compliance.
- Genetic Variability: Nepal's multiethnic population may exhibit pharmacodynamic and pharmacokinetic variations, increasing ADR risks.

### **5.7. Solutions to Enhance ADR Recording**

#### **5.7.1. Training and Awareness**

- HCP Training: Integrate PV training into medical, pharmacy, and nursing curricula, focusing on traditional medicines like Swarnaprashana. A 2018 study showed improved ADR reporting after educational interventions in a Nepal cancer hospital.
- Community Pharmacist Engagement: Conduct workshops, as done in Pokhara valley, to improve KAP among community pharmacists.
- Public Awareness: Educate parents about ADR reporting through community health programs, leveraging NHRC's emphasis on community engagement.

#### **5.7.2. Standardized Protocols**

- Swarnaprashana-Specific Guidelines: Develop PV guidelines for Swarnaprashana, addressing its unique composition (gold, herbs) and pediatric use, under NHRC and/or DDA oversight.
- Quality Control: Enforce standards for Swarna Bhasma preparation using analytical techniques (e.g., ICP-MS, TEM) to minimize toxicity risks.
- Formulation Disclosure: Mandate labeling of Swarnaprashana products with ingredient lists, potential ADRs, and reporting instructions.

### 5.7.3. Technology Integration

- Digital Reporting: Expand access to digital tools like VigiMobile for HCPs and consumers, ensuring language-appropriate interfaces for Nepal's diverse population.
- AI and Data Analytics: Use AI to automate ADR case processing and signal detection, as suggested for modern PV systems, to handle Swarnaprashana data efficiently.

### 5.7.4. Consumer Pharmacovigilance

- Consumer Reporting Systems: Establish consumer-friendly reporting channels, such as hotlines or online portals, as proposed in a 2014 study on consumer PV in Nepal.
- Community-Based Programs: Integrate Swarnaprashana ADR reporting into community health initiatives, similar to those for chronic diseases, to increase accessibility.

### 5.7.5. Collaboration and Research

- NHRC-Led Studies: Fund NHRC-led research on Swarnaprashana ADRs, focusing on incidence, types, and long-term effects, as recommended for ASU&H drugs.
- Regional Collaboration: Partner with India's Pharmacovigilance Programme of India (PvPI), which includes ASU&H drugs, to share data and best practices for Swarnaprashana PV.

## 5.8. Proposed Framework for Swarnaprashana ADR Recording

1. Ethical Approval: Obtain NHRC ERB approval for Swarnaprashana PV studies or programs.
2. Training: Train HCPs and community pharmacists on Swarnaprashana-specific ADR recognition and reporting.
3. Informed Consent: Provide parents with clear, multilingual information on risks and benefits.
4. Reporting: Use standardized DDA forms or digital tools for ADR reporting to RPCs.
5. Analysis: Conduct causality, severity, and preventability assessments, integrating data into the DDA's national database.
6. Feedback: Disseminate findings to HCPs, parents, and policymakers to improve safety and compliance.
7. Continuous Monitoring: Implement active surveillance, such as cohort studies, to track long-term ADRs in Swarnaprashana users.

## 5.9. Summary

Recording ADRs for Swarnaprashana in Nepal, under the NHRC's ethical and scientific oversight, requires aligning with the national PV framework managed by the DDA. Key strategies include enhancing HCP and consumer awareness, standardizing protocols, leveraging technology, and fostering research to address the lack of specific data. By integrating Swarnaprashana into Nepal's PV system, the safety of this traditional practice can be ensured, protecting pediatric populations while respecting cultural practices. Collaboration between the NHRC, DDA, and regional stakeholders, alongside consumer engagement, will strengthen ADR recording and promote evidence-based use of Swarnaprashana.



06

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ANNEX



**ANNEX 01: Swarnaprashana Administration Record Form**

LUMBINI PROVINCIAL GOVERNMENT  
 MINISTRY OF HEALTH  
 HEALTH DIRECTORATE  
 PROVINCIAL AYURVEDA HOSPITAL, BIJAURI, DANG  
**SWARNAPRASHANA ADMINISTRATION RECORD**

Child Registration ID: \_\_\_\_\_

Date: \_\_\_\_\_

**1. Child Information**

- Name of Child: \_\_\_\_\_
- Date of Birth: \_\_\_\_\_
- Age: \_\_\_\_\_ months / years
- Sex:  Male  Female
- Parent/Guardian Name: \_\_\_\_\_
- Contact Number: \_\_\_\_\_
- Address: \_\_\_\_\_

**2. Health Background (Optional but Recommended)**

Field	Details
Known Allergies	
Past Medical History	
Current Medications	
Immunization Status	

**3. Preparation Details**

- Type of Gold Used:  *Swarna Bhasma*
- Combined with:  Honey  Ghee
- Dosage: \_\_\_\_\_ mg/ml
- Route of Administration: Oral / Sublingual / Licking
- Nakshatra:  Pushya Nakshatra

**4. Monthly Administration and Monitoring Record**

Month	Date Administered	Administered By (Name & Sign)	Immediate Reaction (Y/N)	Parent Feedback	Weight (kg)	Height (cm)	Next Due Date
1st			<input type="checkbox"/> Yes <input type="checkbox"/> No				
2nd			<input type="checkbox"/> Yes <input type="checkbox"/> No				
3rd			<input type="checkbox"/> Yes <input type="checkbox"/> No				
4th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
5th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
6th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
7th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
8th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
9th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
10th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
11th			<input type="checkbox"/> Yes <input type="checkbox"/> No				
12th			<input type="checkbox"/> Yes <input type="checkbox"/> No				

**5. Adverse Effects Monitoring (Monthly)**

Month	Vomiting	Diarrhea	Skin Rash	Fever	Allergy	Others (specify)	Action Taken
1 <sup>st</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2 <sup>nd</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3 <sup>rd</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12 <sup>th</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

### 6. Final Review (After 12 Months)

- Overall Improvement Observed in Child:
  - Immunity
  - Digestion
  - Physical Strength
  - Mental Alertness
  - Speech & Cognition
  - Sleep Pattern
  - General Well-being
- Overall Satisfaction:
  - Very Satisfied  Satisfied  Neutral  Dissatisfied  Very Dissatisfied
- Remarks / Suggestions by Parent:

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### 7. Consent

I, the undersigned parent/guardian of the child named above, give my full consent for the regular administration of Swarnaprashana as per Ayurvedic guidelines.

म, माथि नाम उल्लेख गरिएको बालक/बालिकाको अभिभावक/अभिभावक प्रतिनिधि, आयुर्वेद निर्देशिका अनुसार नियमित रूपमा स्वर्णप्राशन गराउन पूर्ण सहमति जनाउँदछु।

Signature of Parent/Guardian

अभिभावक/ संरक्षकको हस्ताक्षर

Date

मिति

Physician In-Charge: \_\_\_\_\_

Signature & Stamp: \_\_\_\_\_

**ANNEX 02: Swarnaprashana Feedback Form**

LUMBINI PROVINCIAL GOVERNMENT  
 MINISTRY OF HEALTH  
 HEALTH DIRECTORATE  
 PROVINCIAL AYURVEDA HOSPITAL, BIJAURI, DANG  
**SWARNAPRASHANA FEEDBACK FORM**

Child Registration ID: \_\_\_\_\_ Date of First Dose: \_\_\_ / \_\_\_ /

**1. Child Details**

- Name of Child: \_\_\_\_\_
- Age: \_\_\_\_\_ months / years
- Sex:  Male  Female
- Parent/Guardian Name: \_\_\_\_\_
- Contact Number: \_\_\_\_\_
- Address: \_\_\_\_\_

**2. Monthly Observation**

Month	Date of Dose	Immunity (Infections Reduced?)	Appetite	Digestion	Sleep	Energy Level	Behavior / Cognition	Illness (If Any)	Remarks
1st		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
2nd		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
3rd		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
4th		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
5th		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		

<b>6th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
<b>7th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
<b>8th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
<b>9th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
<b>10th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
<b>11th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		
<b>12th</b>		<input type="checkbox"/> Improved <input type="checkbox"/> No Change	<input type="checkbox"/> ↑ <input type="checkbox"/> ↓ <input type="checkbox"/> N	<input type="checkbox"/> Normal <input type="checkbox"/> Irregular	<input type="checkbox"/> Normal <input type="checkbox"/> Disturbed	<input type="checkbox"/> Good <input type="checkbox"/> Low	<input type="checkbox"/> Improved <input type="checkbox"/> No Change		

\*N: No change

**3. Adverse Effects**

Month	Vomiting	Diarrhea	Rash	Fever	Allergy	Others (specify)	Action Taken
1st	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2nd	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3rd	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12th	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

**4. Final Summary (After 12 Months)**

- Overall Observed Benefits:
  - Reduced frequency of illness
  - Better appetite and digestion
  - Improved energy and growth
  - Enhanced speech and cognitive abilities
  - Better sleep pattern
  - Increased alertness and activity
- Overall Satisfaction:
  - Very Satisfied  Satisfied  Neutral  Dissatisfied  Very Dissatisfied

**5. Parent/Guardian Comments**


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Name and Signature of Parent/Guardian:

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Date: \_\_\_ / \_\_\_ / \_\_\_\_\_

Physician In-Charge: \_\_\_\_\_

Signature & Stamp: \_\_\_\_\_

### ANNEX 03: Swarnaprashana Adverse Drug Reaction (ADR) Recording Form

This form is designed for recording adverse drug reactions (ADRs) associated with Swarnaprashana, an Ayurvedic practice involving the administration of processed gold (Swarna Bhasma) with honey, ghee, and herbal extracts, in accordance with the Nepal Health Research Council (NHRC) guidelines and the Department of Drug Administration (DDA) pharmacovigilance framework. It is intended for use by healthcare professionals (HCPs), community pharmacists, and consumers (e.g., parents/guardians) in Nepal to ensure systematic and standardized ADR reporting.

#### Section 1: Reporter Information

- Name of Reporter:
- Profession/Role:
- Contact Details:
  - Phone:
  - Email:
- Institution/Location:
- Date of Report:

#### Section 2: Patient Information

- Patient Initials:
- Age:
- Sex:
- Weight:
- Ethnicity:
- Relevant Medical History:
- Concurrent Medications:

#### Section 3: Swarnaprashana Details

- Formulation:
- Dose:
- Administration Schedule:
- Duration of Use:
- Source/Manufacturer:
- Batch Number:
- Route of Administration:

#### Section 4: Adverse Drug Reaction (ADR) Details

- Description of ADR: (e.g., maculopapular rash on arms, vomiting, diarrhea)
- Date of Onset:
- Duration of ADR: (e.g., 2 days, ongoing)
- Severity:
  - (Mild/Moderate/Severe, based on Hartwig scale)
  - Mild: No treatment required, minimal discomfort
  - Moderate: Requires medical intervention, significant discomfort
  - Severe: Life-threatening, hospitalization required
- Outcome: (e.g., resolved, ongoing, required hospitalization)
- Action Taken: (e.g., Swarnaprashana discontinued, antihistamine administered)
- Suspected Cause:

#### Section 5: Causality Assessment

- WHO-UMC Causality Category: (Check one based on WHO-UMC criteria)
  - Certain: ADR follows plausible time relationship, confirmed by dechallenge/rechallenge
  - Probable/Likely: Reasonable time sequence, unlikely due to other causes
  - Possible: Could be due to other drugs/diseases
  - Unlikely: Improbable time relationship
  - Conditional/Unclassified: More data needed
  - Unassessable/Unclassifiable: Insufficient data

### Section 6: Additional Information

- Laboratory Tests (if any): (e.g., liver function tests, blood gold levels)
- Concomitant Conditions: (e.g., fever, infection at time of ADR)
- Previous ADRs to Swarnaprashana: (e.g., none, similar rash reported 1 month ago)
- Reporter's Comments: (e.g., suspected impure Swarna Bhasma, need for quality testing)

### Section 7: Submission Details

- Submission Method:
- Submission Date:
- Regional Pharmacovigilance Center (RPC):
- DDA Contact:
  - Email: [pharmacovigilance@dda.gov.np](mailto:pharmacovigilance@dda.gov.np)
  - Phone: +977-1-5355032

### Instructions for Use

1. Who Can Report: Healthcare professionals (doctors, pharmacists, nurses, health assistants) and consumers (parents/guardians) can complete this form.
2. How to Report:
  - Submit the completed form to the nearest Regional Pharmacovigilance Center (RPC) or directly to the DDA.
  - Use digital tools like VigiMobile (if available) for real-time reporting.
  - Ensure confidentiality by avoiding full patient names.
3. Ethical Compliance:
  - Obtain informed consent from parents/guardians before administering Swarnaprashana, as per NHRC guidelines.
  - Ensure ethical approval from the NHRC Ethical Review Board for any research-related ADR data collection.
4. Follow-Up:
  - RPCs will assess causality and severity, forwarding reports to the DDA for inclusion in the national database.
  - Reporters may be contacted for additional information to complete causality assessments.

### Notes

- Confidentiality: All patient and reporter information will be kept confidential as per NHRC and DDA regulations.
- Quality Control: Report any suspected issues with Swarna Bhasma quality (e.g., impurities) to the DDA for investigation.
- Consumer Reporting: Parents/guardians are encouraged to report ADRs to RPCs or community pharmacists to enhance consumer pharmacovigilance.

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