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MINISTRY OF HEALTH - ETHIOPIA
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NATIONAL GUIDELINE FOR COMPOUNDING OF DERMATOLOGICAL PREPARATIONS

1st edition

July 2020

Addis Ababa, Ethiopia

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Preface

Compounding of dermatological preparations at the health facility level has tremendous importance. It improves the healthcare services by ensuring the accessibility of essential dermatological preparations. Quick assessment conducted by the ministry of health in few hospitals indicates that the availability of essential compounded dermatological preparations is too low with various causing factors. Among the causes, absence of standard operating procedures, guidelines, and other supporting materials, which can be used by both compounders and prescribers, is the major one. Nonetheless, national guideline for compounding of dermatological preparations is not available in Ethiopia.

As a result, the development and implementation of national guideline for compounding of dermatological preparations is crucial to improve the access to basic dermatological services which is currently associated with poor availability of pharmaceutical grade and inadequate compounding practice within hospitals. Besides, it used to revitalize the compounding service within health facilities; ensure good compounding practice of non-sterile preparations; and promote evidence-based management of problems and preparation of dermatological products in hospitals.

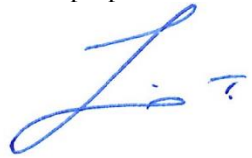
This National Guideline for Compounding of Dermatological Preparations is a publication of the Federal Democratic Republic of Ethiopia, Ministry of Health which is mainly used by pharmacy professionals and physicians working in healthcare facilities. Thus, they invariably pursue prescribing, compounding and dispensing of dermatological preparations. Additionally, this first edition addresses the country's need with respect to guideline preparation on non-sterile dermatological products, antiseptics, disinfectant and other chemical that are commonly required to deliver patient care services.

This guideline contains three chapters. General introduction present in the first chapter. The second chapter describes good compounding practice. The third chapter is about Extemporaneous Preparation Formulary.

The formulation, preparation procedures, and other relevant information included in this document were extracted from standard references and in some cases, experts' opinion were also included.

This guideline can serve as a reference in healthcare facilities for the prescribing and compounding of non-sterile preparations of dermatological products, antiseptics, disinfectants and other chemicals.

Finally, I would like to take this opportunity to acknowledge all participants for their huge contributions in the preparation of this guideline.



Dr. Lia Tadesse, Minister
Ministry of Health

Acknowledgements

The Federal Democratic Republic of Ethiopia, Ministry of Health would like to extend its sincere gratitude to all individuals who contributed to the development of this guideline.

Heartfelt appreciation is extended to the following members of the core technical team and their organization, whose support was central to the development and finalization of the entire guideline:

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Special thanks are also extended to the following contributors and their organizations, which have been providing crucial technical support in the preparation of the guideline:

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How to use the guideline

National Guideline for Compounding of Dermatological Preparations brings practical and background information for compounding, dispensing, and use of dermatological preparation, antiseptics, disinfectants and other chemicals in healthcare facilities of the country.

This guideline aims to provide sufficient information to select and compound dermatological preparation i.e. what to prepare, for which indication, how to prepare and additional information on the products. This guideline encompasses background, good compounding practice, and extemporaneous preparation formulary for non-sterile preparations.

The information can be used by healthcare providers mainly, pharmacy professionals and physicians in prescribing, compounding, dispensing and appropriate use of dermatological preparations, antiseptics, disinfectant and other chemicals.

Officials can use this guideline for preparing facilities for compounding, training healthcare professionals, and planning and purchasing raw materials required for the compounding of non-sterile preparations included. Furthermore, it can be used as a reference for teaching and learning of extemporaneous preparation of dermatological preparations, antiseptics, disinfectants, and other chemicals.

Chapter one gives background information on the compounding and dosage forms of commonly compounded preparations. It also contains objectives, scopes, and regulatory framework of guideline.

Chapter two introduces the concept of good compounding practices. It explains good compounding practice principle and requirement with respect to personnel, premises, equipment, materials, sanitation & hygiene, documentation, packaging, labeling and storage. It also describes the quality assurance system, quality control practices, and beyond-use date and dating methods.

Chapter three describes on common dermatological diseases and formulary for dermatological preparations, antiseptics, disinfectants, and other chemicals. It also covers information on dosage, instructions for use, precautions, general side effects, and risks during pregnancy and breastfeeding for each of the non-sterile preparations.

The guideline contains an annex with a list of raw materials and equipment, compounding recording template, master formula record, and standard operating procedures.

Acronyms

AAU	Addis Ababa University
ACD	Allergic Contact Dermatitis
AD	Atopic Dermatitis
ALERT	All Africa leprosy Rehabilitation and Training Center
BUD	Beyond-use Date
CNS	Central Nervous System
EDVS	Ethiopian Dermatology and Venereology society
EFDA	Ethiopian Food and Drug Authority
EPA	Ethiopian Pharmaceutical Association
FBC	Freshly Boiled and Cooled
GCP	Good Compounding Practice
HU	Haramaya University
IACP	International Academy of Compounding Pharmacists
ICD	Irritant Contact Dermatitis
KOH	Potassium Hydroxide
LA	Lactic Acid
MOH	Ministry of Health
MU	Mekelle University
NSP	Non-sterile Preparation
PMED	Pharmaceutical and Medical Equipment Directorate
PRP	Pityriasis Rubra Pilaris
QA	Quality Assurance
QC	Quality Control
QS	Quantity Sufficient
SA	Salicylic Acid
SD	Standard Deviation
SOP	Standard Operating Procedures
TCA	Trichloroacetic acid
UOG	University of Gondar
USP	United States Pharmacopeia
WBC	White Blood Cell

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Chapter one

Introduction

1.1. Background

Compounding is an integral part of pharmacy practice and is essential for provision of healthcare services. It is an art and science of preparing, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner–patient–pharmacist/compounder relationship in the course of professional practice. It is the timely preparation of a drug product according to a physician's prescription, a drug formula, or a recipe in which calculated amounts of ingredients are made into a homogenous (uniform) mixture.

Compounding practice can be as simple as the addition of a liquid to a manufactured drug powder or as complex as the preparation of a multi component parenteral nutrition solution. In general, compounding differs from manufacturing, that compounding involves a specific practitioner–patient–pharmacist relationship (i.e., specific prescription orders) and the preparation of a relatively small quantity of medications.

Compounding may include the following:

- Preparation of drug in different dosage forms for human use
- Preparation of drugs in anticipation of prescription drug orders, on the basis of routine and regularly observed prescribing patterns,
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients, and
- Preparation of drugs or devices for the purposes of research (clinical or academic), teaching, or chemical analysis

Compounding is done when a certain medical needs of individual patient cannot be addressed by the use of an approved commercial drug product. It is needed to compound when;

- Desired dosage forms, strengths and routes of registered products are not available commercially
- Dilution of adult doses of medications to Pediatric/Geriatric strengths is mandatory
- Unpleasant tastes of medicines are difficult to take for children

- Combination of different topical dermatological products are not readily available in the market
- Inactive ingredients of commercial products, which may cause allergic reactions in individuals, is needed to be replaced or excluded
- Preparing certain pharmaceuticals from raw materials (topical preparations, antiseptics, disinfectants, etc…)

Compounded non-sterile preparations (NSPs) include, but are not limited to the following types of dosage forms:

- **A Solution** is a homogeneous liquid preparation that contains one or more dissolved medicaments.
  - ***Tincture*** *is* alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances. Depending on the preparation, tinctures contain alcohol in amounts ranging from approximately 15% to 80%.
  - ***Elixir*** is a clear, sweetened hydroalcoholic solution intended for oral use and is usually flavored to enhance palatability.
  - ***Spirits*** are alcoholic or hydroalcoholic solutions of volatile substances. Generally, the alcoholic concentration of spirits is rather high, usually over 60%.
  - ***Collodion*** is a clear or slightly opalescent viscous liquid prepared by dissolving pyroxylin (4% w/v) in a 3:1 mixture of ether and alcohol.
  - ***Liniments*** are alcoholic or oleaginous solutions or emulsions of various medicinal substances intended to be rubbed on the skin.
  - ***Sprays*** may be defined as aqueous or oleaginous solutions in the form of coarse droplets or as finely divided solids to be applied topically, most usually to the nasopharyngeal tract or to the skin.
- **Suspension** is a heterogeneous preparation in which insoluble active ingredient (s) is suspended throughout the vehicle.
- **Emulsion** is a mixture of two or more liquids that are normally immiscible.

- **Lotions** are solutions, but may also be suspensions or emulsions, that are intended to be applied to the skin without friction on a carrier fabric such as lint and covered with a waterproof dressing.
- **Ointments** are semisolid preparations that are applied externally to the skin or mucous membranes, in which solids or liquids are dispersed.
- **Creams** are viscous semi-solids emulsion for external application.
- **Pastes** are semi-solid preparations that contain a high proportion of powdered ingredients.
- **Gels** are semi-solid systems consisting of dispersions of small or large molecules in aqueous liquid vehicle rendered jelly-like by the addition of jelling agent.
- **Bulk powders** are dry, free-flowing preparations consisting of one or a mixture of finely powdered substances and intended for external application.

1.2. Objective/Purpose

The purpose of this guideline is

- To provide guidance for compounding of non-sterile preparations (NSPs)
- To standardize formulations of non-sterile preparations (NSPs) and compounding practice in healthcare facilities
- To recommend the minimum standards and requirements for compounding of non-sterile preparations (NSPs)

1.3. Scope of the guideline

This guideline is applicable in health facilities, where dermatological preparations, antiseptics, disinfectants, and laboratory reagents will be prepared for purpose of diagnosis, prevention, and treatment.

1.4. Regulatory framework

At national and regional level there are rule and regulations enacted by the federal and regional regulatory bodies regarding the compounding of NSPs. This guideline is prepared complying with these rules and regulations. Thus, health facilities and pharmacy professionals are expected to act upon the regulatory bodies' rules and regulation and this guideline.

Chapter two

Good Compounding Practice

Good Compounding Practice (GCP) is a system for ensuring that products are consistently produced and controlled according to quality standards.

2.1. General compounding principles

- Personnel are appropriately trained and qualified to perform their assigned duties.
- Compounding raw materials of appropriate identity, purity, and quality should be used, properly stored and labeled according to manufacturer recommendations.
- All equipment used in compounding should be cleaned, status labeled, properly handled, and used appropriately.
- Compounding environment should be clean and suitable for its intended purpose.
- System must be in place to reduce any risk of contamination and cross-contamination.
- Quality control (QC) and assurance system must be in place.
- All aspects of compounding must be appropriately documented.

2.2. General Steps in the Compounding Process

The steps to be followed before, during, and after compounding shall be grouped into five categories

Preparatory

Designated pharmacist or pharmaceutical technician shall

- Judge the suitability of the prescription in terms of its safety and intended use and the dose for the patient.
- Wear the proper attire and washing hands according to the respective written procedures.
- Clean the compounding area and the equipment if necessary.
- Perform the calculations to determine the quantities of the ingredients needed.
- Select the proper equipment and making sure it is clean.
- Assemble all the necessary materials and ingredients to compound and pack the preparation.

Compounding

- Compound the prescription according to the formulary record or the prescription using techniques according to the art and science of pharmacy, strictly observing GCP procedures.
- Proper compounding record should be maintained.

Final Check

- Check and ensure adequacy of mixing, clarity, odor, color, consistency, and/or pH.
- Register the information in the compounding log and documented.
- Pack the compounded product in suitable container appropriately; check weight variation; and label it.

Sign-Off

- Sign and date the prescription, affirming that all of the indicated procedures were carried out to ensure uniformity, identity, strength, quantity, and purity.

Cleanup

- Cleaning and storing all equipment.
- Cleaning the compounding area.

2.3. Personnel

In order to ensure GCP, sufficient and qualified personnel (pharmacy professionals and supporting staffs) are required. Besides, individual responsibilities should be clearly defined and understood by the persons concerned and recorded as written descriptions.

Key Personnel

There should be an adequate number of personnel having knowledge, skill and capabilities relevant to their assigned function, in good health, and capable of handling their duties properly. They should have the attitudes for achieving the goals of GCP. Key personnel include pharmacy director, compounding unit coordinator, compounding pharmacist, and pharmacy technicians.

Roles and responsibilities

Pharmacy director or pharmacy department head

- The pharmacy manager or pharmacy department head is responsible for developing, organizing, and supervising over all activities related to pharmacy compounding of preparations.
- This person may share or assign these responsibilities to a pharmacist, who will be designated as compounding supervisor.
- He/she is also responsible for deploying required number of staffs for the compounding unit.

Compounding unit coordinator

The compounding unit coordinator shall have the following minimum responsibilities:

- Confirm all raw materials used for compounding are with desired quality and from reliable source.
- Ensure all compounding preparations are of acceptable strength and quality.
- Ensure all compounding processes are conducted appropriately.
- Ensure compounding environment is always clean and tidy.
- Ensure that all personnel involved in compounding activities possess the relevant training and proficiency necessary to properly and safely perform compounding duties.
- Ensure the compounded preparation is supplied with appropriate packaging and labeling.
- Ensure all compounding processes have been documented accordingly.
- Ensure appropriate safety procedures and requirements; incident reporting; and follow-up are in place.

- Ensures the facilities and equipment used to compound preparations meet requirements and are maintained, calibrated or certified according to manufacturers' specifications or standards, whichever are more stringent.
- Should be responsible for unusable and damaged/expired compounding raw materials and finished products.
- Ensure the availability of relevant guidelines, regulations, and updated references and compliance to them and regulations.

Compounding Pharmacist

Pharmacist engaged in compounding of pharmaceutical preparation has the following duties and responsibilities;

- Inspect and approve all ingredients, containers, closures, labeling and any other material used in the compounding process.
- Perform or supervise compounding activities as per the master formulation record
- Ensure that the equipment, instruments, and space used are properly cleaned and maintained.
- Ensure the facilities and equipment used for compounding preparations meet requirements, cleaned, maintained, calibrated or certified according to manufacturers' specifications or standards, whichever are more stringent.
- Conduct daily verification of weighing balance and other measuring devices and maintain records.
- Conduct in-process and final quality checks to assure that basic requirements are met in the compounding process.
- Perform verification during the various stages of compounding and verify the final preparation.
- Enforce or ensure compliance with required rules relating to hygiene, cleanliness and safety.

- Adhere to policies and procedures related to the compounding of extemporaneous preparations, including handling of hazardous drugs and materials where applicable.
- Complete and document all records related to ongoing activities.
- Perform all required verifications and QC measures to ensure the quality of each preparation.
- Store and label the final preparation properly until delivery to the patient.
- Prior to dispensing or releasing a preparation to the patient, ensure that all standards of practice associated with dispensing the preparation have been met when the compounder is dispenser.
- Should be responsible for unusable and damaged/expired compounding raw materials and finished products.

Pharmacy technicians

- Pharmacy technicians are engaged in any compounding activities under supervision of a compounding pharmacist.

Qualification and competence

All pharmacy professionals involved in compounding must possess adequate education, training, and proficiency necessary to perform suitable, safe, and effective compounding duties at the level at which they are involved. They should be proficient in the art and science of compounding practice and maintain the expertise through updated knowledge.

Competency for compounding pharmacy professionals should cover the following:

- Proper selection and use of compounding equipment (such as balances and measuring devices);

- Required necessary compounding skill (i.e., comminution, trituration, levigation, pulverization by intervention, and geometric dilution);

- Knowledge on raw materials and finished compounded products (such as stability, solubility, and other physicochemical properties of the ingredients);
- Handling of non-hazardous and hazardous materials in the work area including protective measures for avoiding exposure and emergency procedures to follow in the event of exposure;
- Proper interpretation of chemical and pharmaceutical symbols and abbreviations in medication orders and in formulation directions; and
- Basic skill of pharmaceutical calculations.

2.4. Premises

- There should be defined and reserved room for compounding service. It should be located sufficiently away from high traffic areas.
- The design of premises must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination.
- Premises should be of a suitable construction and adequate area for different activities (such as weighing area, compounding area, QC area, and storage area).
- The compounding room's walls, floor, and ceiling should be smooth and have no cracks or holes. They should be painted and/or made of washable material.
- Any material used for work surfaces must be able to withstand repeated cleaning and disinfecting and be resistant to damage from cleaning and disinfecting products.
- The areas shall be maintained in clean, orderly and sanitary conditions with appropriate and sanitary waste disposal.
- A clean water supply with hot and cold running water must be available in the room.
- Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas.
- Electrical supply, water supply, lighting, temperature, humidity and ventilation shall be appropriate such that they do not adversely affect, directly or indirectly, either the products during their compounding and storage.

- Compounding space should be well-designed and arranged in such way to prevent contamination and cross-contamination.

- Weighing should be carried out in a reserved area with a minimum of draughts and vibration.
- QC activities should be performed in a separate designated area.
- Storage area must be large enough to store equipment, packaging and raw materials, and compounded products neatly in a clean and secure manner.

2.5. Equipment

- Equipment used for compounding should be:
  - Suitable for the intended purposes and must not present any hazard to the quality of the product.
  - Inspected, calibrated or checked on a regularly scheduled basis.
  - Kept clean, dry, and protected from contamination during storage.
- Operating, maintenance and cleaning procedures should be in the immediate vicinity of the apparatus.
- Faulty equipment should be taken out of use and labeled as such until repaired or removed.

2.6. Materials

- High quality materials (raw, packaging and labeling materials) should be chosen for compounding NSPs.
- Raw materials should be sourced from approved suppliers.
- Raw materials should be received, handled and stored in a manner to prevent contamination of products.
- The quality and identity of all raw materials used in compounding should be verified using a certificate of analysis from a supplier or the label claims of commercially available products used in the compounding process.
- Specifications for raw materials should be of a pharmacopoeial or equivalent standard.

2.7. Sanitation & Hygiene

- A high level of sanitation and hygiene should be practiced in every aspect of the compounding of pharmaceutical products in a programmed manner.
- The entire compounding room should be cleaned as required but not during the actual process of compounding.
- Where dust is generated, cleaning measures should be taken to avoid contamination and cross contamination.
- A high level of personal hygiene should be followed.
- Compounding personnel should wear appropriate personal protective equipment.
- Good standards of cleaning, personal hygiene and protective clothing must be assessed regularly.
- Eating and drinking must not be allowed in compounding room.
- Individuals that may have higher risk of contaminating the preparation and environment should not be assigned for compounding.
- Equipment should be cleaned effectively with a suitable detergent before and after use, and ensure that all residues of cleaning agent have been removed.

2.8. Documentation

- Good documentation practice constitutes an essential part of the quality assurance system, and, as such, should be related to all aspects of GCP.
- Documentation is necessary in order to be able to systematically trace, evaluate and replicate the steps throughout the compounding process. Thus, each step of the compounding process should be documented.
- Personnel should follow good documentation practice for both paper records and electronic records in order to assure data integrity.
- Documentation has the characteristics of being attributable, legible, contemporaneously recorded, original and accurate. These essential characteristics apply equally for both paper and electronic records.

- Pharmacists should maintain at least the following sets of records in the compounding area:
    a. Compounding formulas and procedures;
    b. Registry log of all compounded items including batch records;
    c. Equipment maintenance records, including documentation of checks of balances, refrigerators, and freezers;
    d. Record of ingredients purchased, including certificates of purity for chemicals.

- Documents should be designed, prepared and reviewed with care.
- Documents should be approved, signed, and dated by appropriate authorized persons. No document should be changed without authorization.
- Reproduced documents should be clear and legible.
- Documents should be regularly reviewed and kept up to date.

2.9. Quality Assurance System

- Quality Assurance (QA) system is intended to generate information showing that compounding facility, personnel, and equipment attain and maintain the conditions required for quality compounding of NSPs in compliance with established procedures.
- It provides a framework for integrating measurements, performing audits and evaluations.
- Quality must be built-in to the preparation from the beginning steps to evaluating the final preparation.
- Good QA program is guided by written procedures that define responsibilities and practice to ensure compounded preparations are prepared with quality attributes.
- In the context of NSPs, QA incorporates GCP and should ensure that:
    - Compounded products are formulated and prepared in accordance with GCP.
    - Preparation and QC arrangements are documented in compliance with current GCP requirements.
    - All products are prepared with suitable quality for their intended use.
    - Products are released for patient use only by a pharmacist.
    - Documentation and records comply with good documentation practice.

- QA contains a testing or preparation evaluation component to provide feedback on the accuracy and reputability of the procedure used in pharmacy.
- Compounding equipment should be calibrated in regular manner and have established maintenance plan as recommended by the manufacturer.
- Compounding personnel need to be trained and their work should be routinely observed to ensure compliance with standard procedures.
- All raw materials should comply with their specifications and preferably be of Pharmacopeial grade or bear a marketing authorization.
- Documents should be designed, prepared, reviewed and distributed with care in compliance with GCP.

2.10. Quality Control Practices

- Quality Control (QC) is concerned with sampling, specifications, test, documentation and release procedures which ensue that appropriate tests are carried out and that products are not released for use until their quality has been judged to be satisfactory.
- The extent of QC applied to a product should be proportionate with the level of risk the finished product could pose to the patient.
- At a minimum, the starting materials and finished product should be examined visually before supply to a patient.
- The following QC tests can be considered for different dosage forms:
    - Weight/fill volume, pH, conductivity, assay, identification, viscosity, organoleptic characteristics (color, odor, clarity, texture)
- The basic requirements for QC are as follows:
    - Adequate facilities, trained personnel and SOPs/standard testing procedures must be available for sampling, inspecting, and testing.
    - Records must be made to demonstrate all the required sampling, inspecting and testing procedures have been carried out
    - All test parameters should follow the instructions given in the relevant written test procedure for each material or product.

- For each batch of finished compounded products, appropriate tests should be carried out prior to release.
- Products failing to meet the established specifications or any other relevant quality criteria should be rejected.

2.11. Packaging and Labeling

- Appropriate packaging (containers and closures) materials should be used for all compounded preparations.
- A packaging procedure that maintains the integrity of compounded NSPs and the safety of patients and compounder should be developed and implemented.
- The containers and closures shall be made of suitable materials that do not interact physically or chemically with the product and not altering the strength, quality, or purity of the compounded product.
- Containers shall be selected by considering parameters like inertness, visibility, rigidity, light and moisture protection, ease of re-closure, and cost.
- Each compounded product should be appropriately labeled.
- Labels should include:
  - Generic name of active ingredients,
  - Strength or quantity,
  - Batch number,
  - Beyond-use date,
  - Special precautions, and
  - Storage condition.
- If this information cannot be included on an auxiliary label (because of size), a supplementary label should be prepared as it is considered to be an integral part of the label.
- In addition the labeling information should consider pharmacy identification (name, address and telephone number).
- If a commercial product has been used as a source of drug, the generic name of the product should be used on the label.

- Listing the names and quantities of inactive ingredients on labels is also encouraged.

2.12. Storage

- Materials used for compounding (raw, packaging and labeling materials) should be stored in clean and dry area, and protected from contamination.
- Ingredients that require special precautions when stored should be identified.
- Raw materials and compounded products must be stored and kept safely under conditions that will preserve their quality and purity.
- The temperature of the premises (pharmacy, warehouse, etc.) should be controlled and should remain within the recommended limits as per the following table:

Table 1 Storage conditions with temperature range

Storage type	Temperature range
Freezer	-25 ºC to -10ºC
Refrigerator	2 ºC to 8 ºC
Cool	8 ºC to 15 ºC
Controlled room temperature	20 ºC to 25 ºC

- Products that have been stored should be inspected before use to detect any signs of deterioration.
- Storage should not be on the floor, windowsills, under sinks, or near heating or cooling vents.

2.13. Beyond-use date and dating methods

- The Beyond-use Date (BUD) is the date after which a non-sterile compounded preparation should no longer be used and is determined from the date when the preparation is compounded.
- Compounded preparations are intended for administration immediately or following short-term storage, therefore their BUD may be assigned based on certain criteria.

- When assigning a BUD, compounders should refer literature and document with regard to stability.

- When a manufactured drug is used as the raw material, information provided by the manufacturer may be used as a reference. The manufacturer's expiry date for the drug should not be used as the BUD for the final preparation.

- Generally, BUD should be assigned conservatively by considering the following points:
    - Nature of the ingredient to be used,
    - Compounding methods,
    - Degradation mechanisms,
    - Compatibility,
    - Dosage form,
    - Potential for microbial proliferation in the preparation,
    - Container in which the preparation is packaged,
    - Storage conditions, and
    - Intended use.
- Maximum BUDs recommended for non-sterile compounded preparations that are packaged in air-tight, light-resistant containers and stored at controlled room temperature are indicated in the table below:

Table 2 Beyond-use date by type of formulation

Formulation type	BUD
Non-aqueous formulations	Not later than the time remaining until the earliest expiry date of any API or 6 months, whichever is earlier
Water-containing oral formulations	Not later than 14 days with storage at controlled cold temperatures
Water-containing topical, mucosal liquid and semi-solid formulations	Not later than 30 days

Note: The BUD of the compounded product should not exceed the expiration date of the raw materials.

Chapter three

Extemporaneous Preparation Formulary

3.1. Common Dermatological Diseases and Preparations

In developed countries effective and convenient treatments are easily available. But, In case of low- and middle income countries (LMICs) the situation is different. Significant number of essential medicines is out of stock in public sector facilities. It is especially relevant for dermatological diseases, for which many facilities cannot afford to supply all patients with ready-made dermatological ointments and creams. This makes compounding dermatological preparations important.

The following common dermatological diseases are identified through interview of dermatovenereologist from few hospitals; review from dermatological OPD clinic registrations and compounding registrations; and reported data from DHIS2. Thus, the following dermatological diseases are commonly seen in our community and could be easily managed with compounded preparations. These diseases and their formulations will be discussed in the next section of the guideline.

3.1.1. Common Dermatological Diseases

I. Dermatitis

Atopic Dermatitis (AD)

Atopic dermatitis is a chronic recurrent inflammatory skin disease that usually presents in all age group mainly in infants and childhood. It typically presents with pruritis and eczematous dermatitis which could be acute, subacute, and chronic. In acute AD, there will be papules, vesicles and oozing lesion; in subacute AD, there will be papules, scale and few drying vesicles; and in chronic AD, there will be more scale, thickening and lichenification. In infants, it involves face and extensor extremities and in young children and adults it involves the flexural side of the extremities.

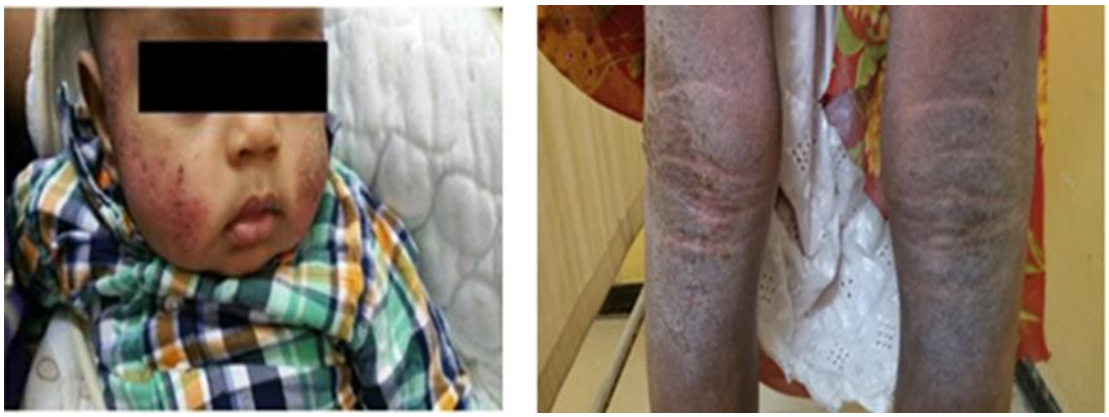


Figure 1 Acute Infantile AD (left); AD in adult (right)

Contact dermatitis

They are a group of dermatitis usually classified into Allergic Contact Dermatitis (ACD) and Irritant Contact Dermatitis (ICD). Allergic contact dermatitis generally presents as pruritis with eczematous dermatitis acute, subacute or chronic. Irritant contact dermatitis presents with redness, scaling, fissuring, oozing, pain or burning sensation. Pruritis may or may not be present and if present it is less pronounced than allergic contact dermatitis.

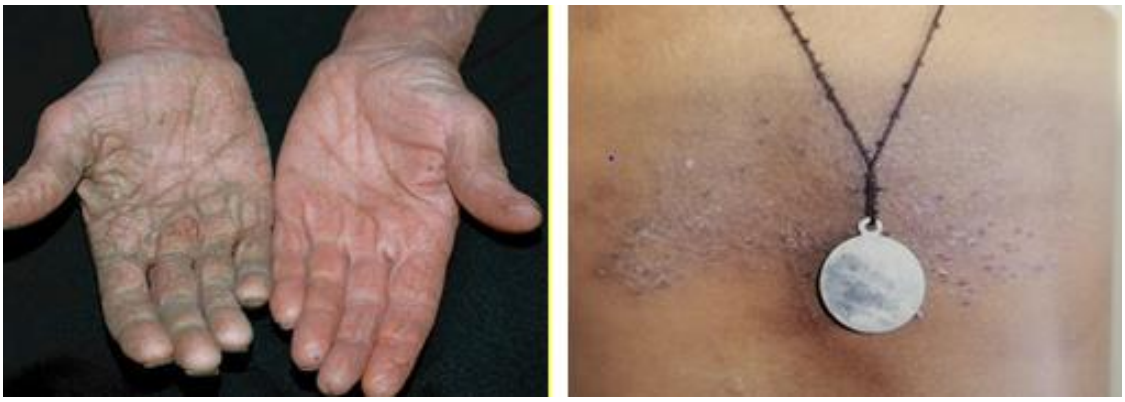


Figure 2 Chronic ICD (left); Chronic ACD (right)

Nummular eczema

It is also known as nummular dermatitis or discoid eczema. It is a chronic inflammatory skin disorder of unknown etiology. Papules and papulovesicles coalesce to form nummular plaques with oozing, crust, and scale. Most common sites of involvement are lower extremities. In women dorsal hands can also be involved. It could be acute, subacute, or chronic eczema.

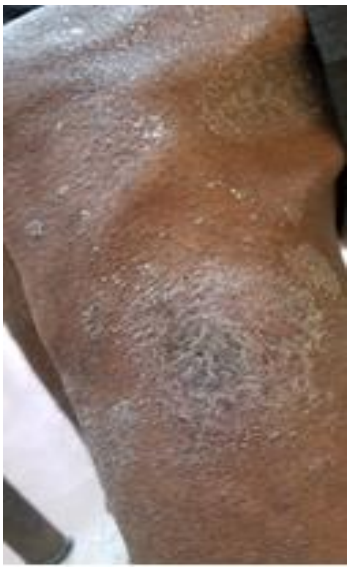
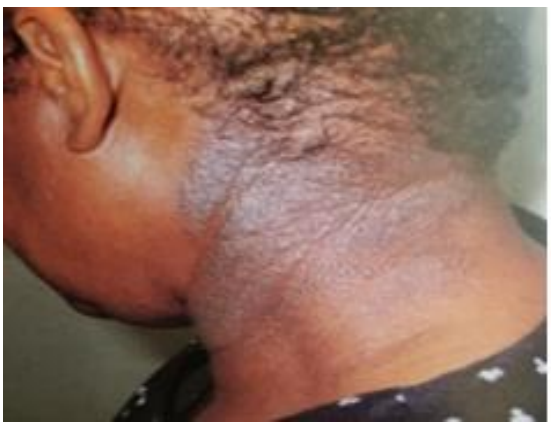


Figure 3 Nummular Eczema

Lichen Simplex Chronicus

It is a chronic, severely pruritic disorder characterized by one or more lichenified plaques**.** Most common sites of involvement are scalp, nape of neck, extensor aspects of extremities, ankles, and anogenital area.



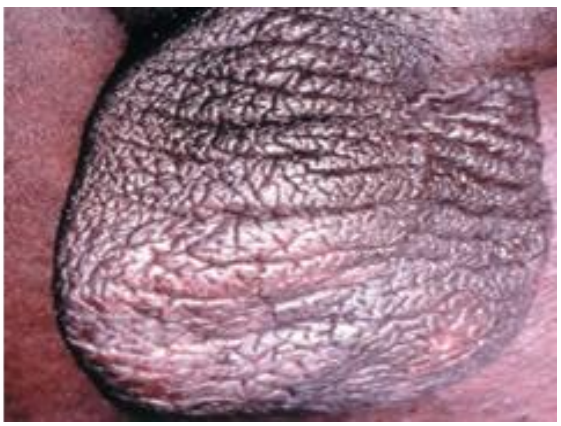


Figure 4 Lichen Simplex Chronicus on neck (left); on scrotum (right)

Seborrheic dermatitis

Seborrheic dermatitis is a common chronic, recurrent inflammatory skin disease affecting mainly infants and adults. Clinically it presents as erythematous, greasy, scaly patches and plaques on the scalp, face, ears, chest, and intertriginous areas. Severe forms like generalized erythroderma rarely occur. Etiology is unclear but may be related to abnormal immune mechanism, *Malassezia species*, increased sebaceous gland activity, and individual susceptibility.

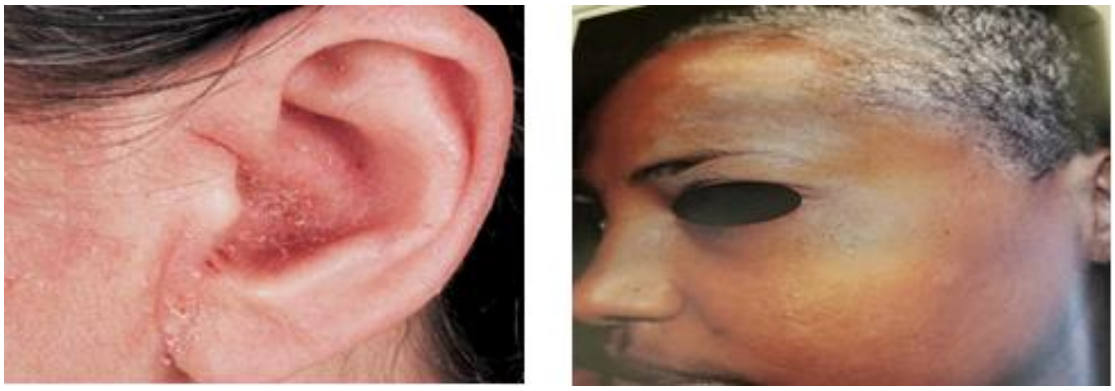


Figure 5 Seborrheic Dermatitis

II. Papulosquamous disorders

Psoriasis

It is a chronic papulosquamous skin disorder that could involve nail and joints. It has polygenic predisposition combined with triggering environmental factors such as trauma, infection, or medication. It clinically presents as an erythematous, scaly, well demarcated papules and plaques that are commonly symmetrical involving the extensor part of the extremities. Erythrodermic eruptions can occur. Most common sites of involvement are the scalp, elbows, knees, hands, feet, trunk and nails.

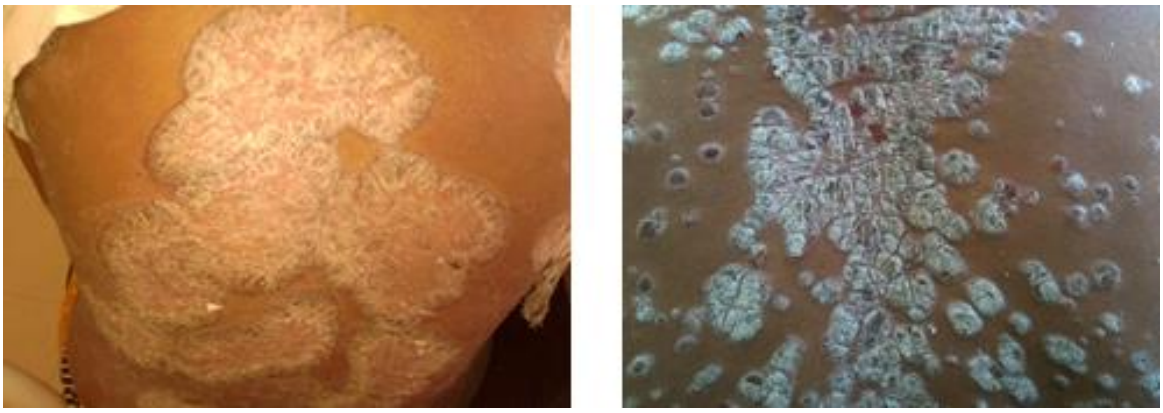


Figure 6 Psoriasis

Pityriasis Rubra Pilaris

It is a rare inflammatory papulosquamous disorder characterized by follicular keratotic papules that may evolve into plaques. There are six major variants and some of them remit within few years while others may prolong for several years. The etiology is not known.

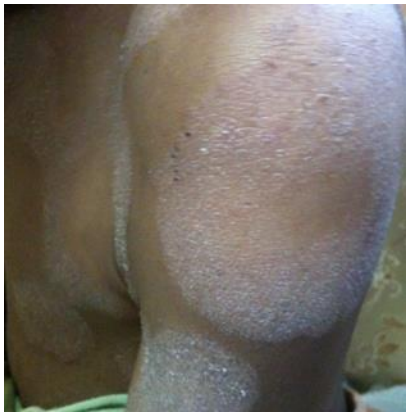


Figure 7 Pityriasis Rubra Pilaris

III. Disorders of cornification

Keratosis Pilaris

It is a genetic disorder of keratinization of hair follicle of the skin presenting with small, rough folliculocentric keratotic papules with variable erythema.

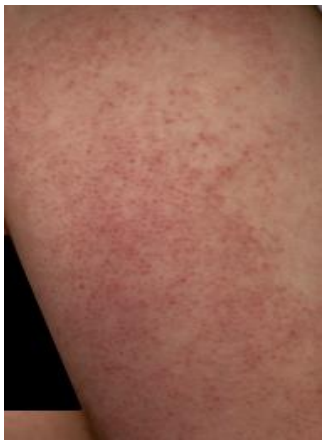


Figure 8 Keratosis Pilaris

Keratodermas

They are disorders of keratinization resulting in hyperkeratosis of the palms and soles.

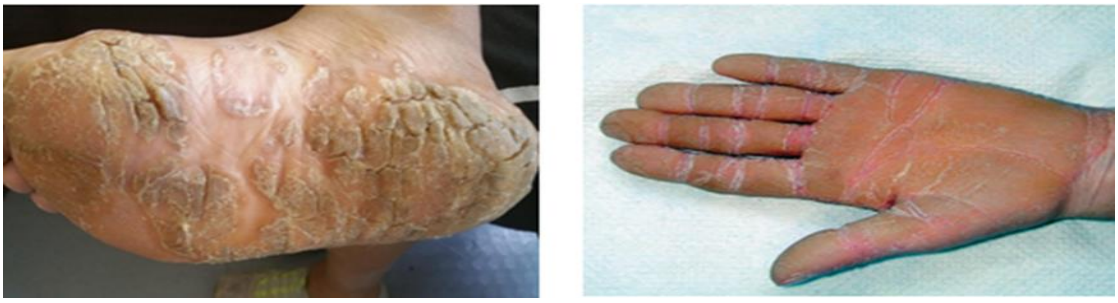


Figure 9 Keratodermas

Corns and Calluses

They result from the prolonged application of excessive mechanical shear or friction forces to the skin. Callus develops when the abnormal forces are distributed over a broad area (i.e., more than 1 cm2); whereas, Corns are confined to focused location. They produce painful symptoms often described as burning and present as keratotic papules (corn) and plaques (callus). Hard corns are found on the dorsal aspects of the toes, while soft corns are in the inter-digital web spaces. Bony protuberances, ill-fitting footwear and specific activities are contributing factors.

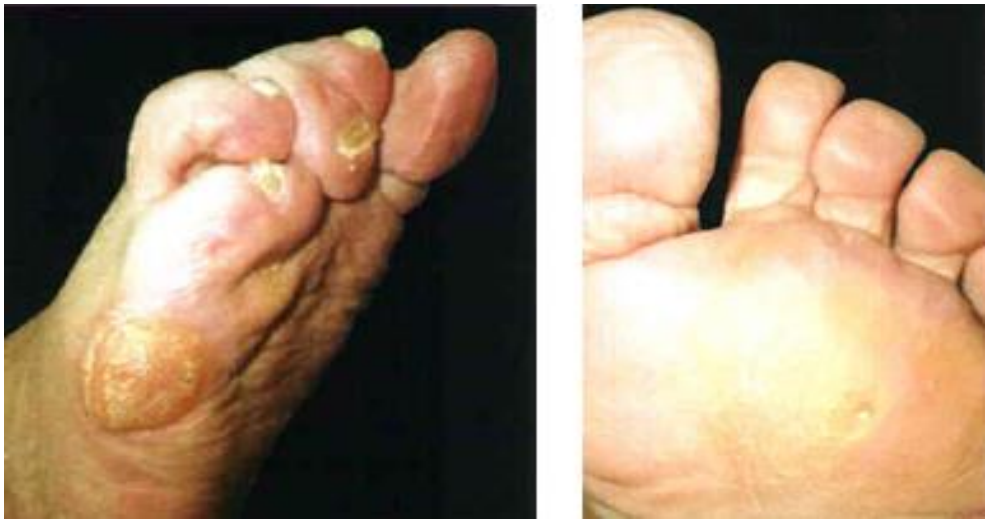


Figure 10 Callus (left); Corn (right

Ichthyosis

Ichthyosis are disorder of cornification characterized by scale and thickening of the skin. Both keratoderma and ichthyosis can be acquired or inherited.

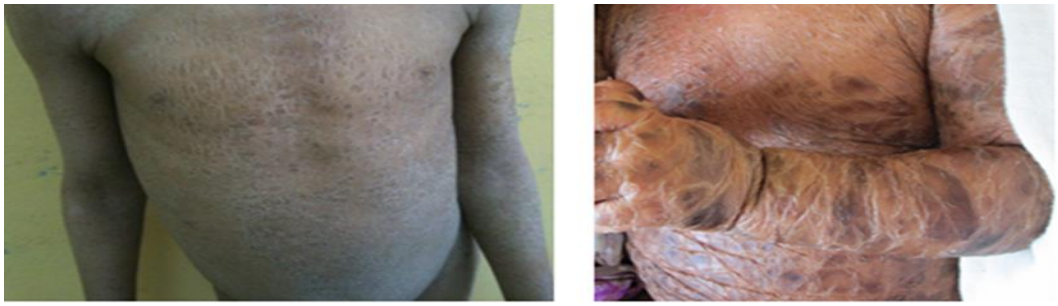


Figure 11 Ichthyosis

IV. Infections and infestations

Cutaneous wart

Cutaneous wart is a viral infection caused by human papilloma virus. It is classified based on anatomic site and serovar type. They present with verrucous papules, plaques and nodules. Some of the clinical variants are palmoplantar wart, flat wart, common wart, genital wart etc.

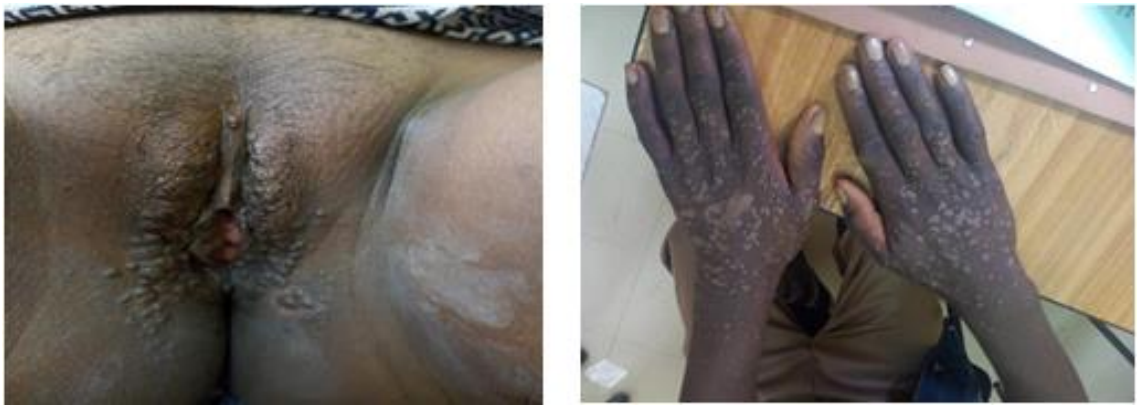


Figure 12 Genital wart (left); Common wart (right)

Molluscum Contagiosum

It is a cutaneous viral infection caused by molluscum contagiosum virus (pox virus family). Clinically it presents as skin colored centrally umbilicated papules and nodules. It is commonly seen in children and in immunocompromised individuals.

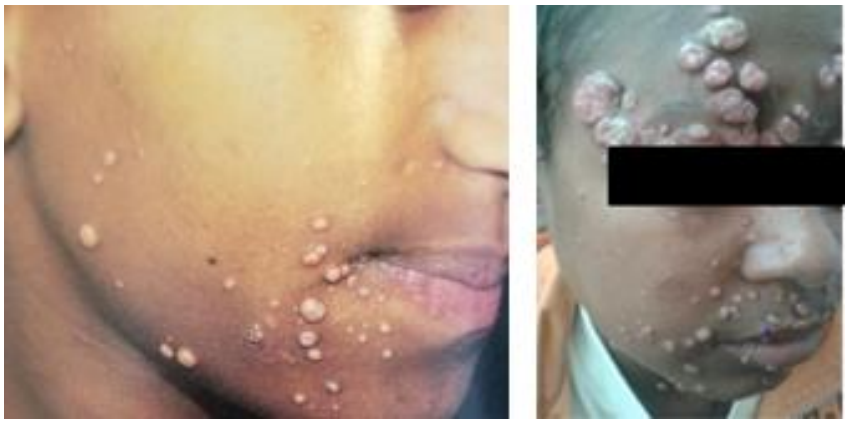


Figure 13 Molluscum contagiosum

Scabies

It is a pruritic condition caused by infestation with Sarcoptes scabiei var. hominis mite which is transmitted via direct close contact with an infested person and fomite. It typically presents with pruritic papules or nodules, sometimes surmounted by burrows that are present over the finger webs, the flexor surfaces of the wrists, the axillae, the buttocks and genitalia and the breasts of women. Pruritus is generally worst at night and when the patient is warm.

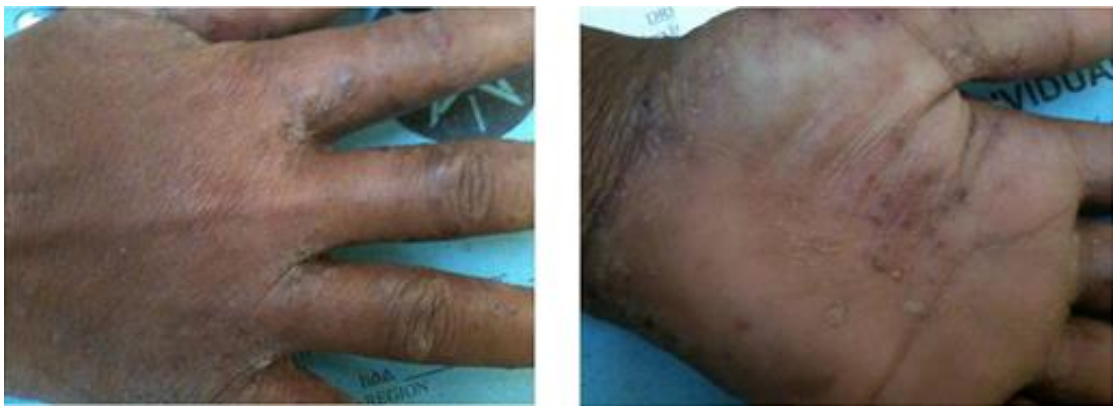


Figure 14 Scabies

V. Acneiform disorders

Rosacea

It is a common facial skin condition clinically presenting with flushing, transient erythema, persistent erythema, telangiectasia, papules and pustules. It is commonly seen in females and in 4th and 5th decade of life.

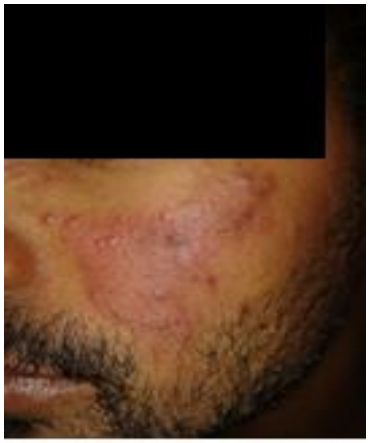


Figure 15 Rosacea

Periorificial Dermatitis

Periorificial dermatitis is an acneiform eruption that occurs in bimodal distribution in young children and young adults. It clinically presents with small inflammatory papules and pustules distributed around the mouth, nose and eyes.

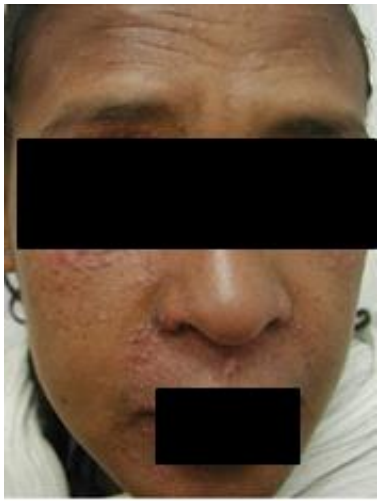


Figure 16 Periorificial Dermatitis

Acne vulgaris

Acne vulgaris is a common disorder of the pilosebaceous unit commonly seen during puberty. Typical clinical features include comedones, papules, pustules, and nodules on the face, chest, and back. Some of the variants are: neonatal acne, infantile acne, acne conglobate, and acne fulminans.

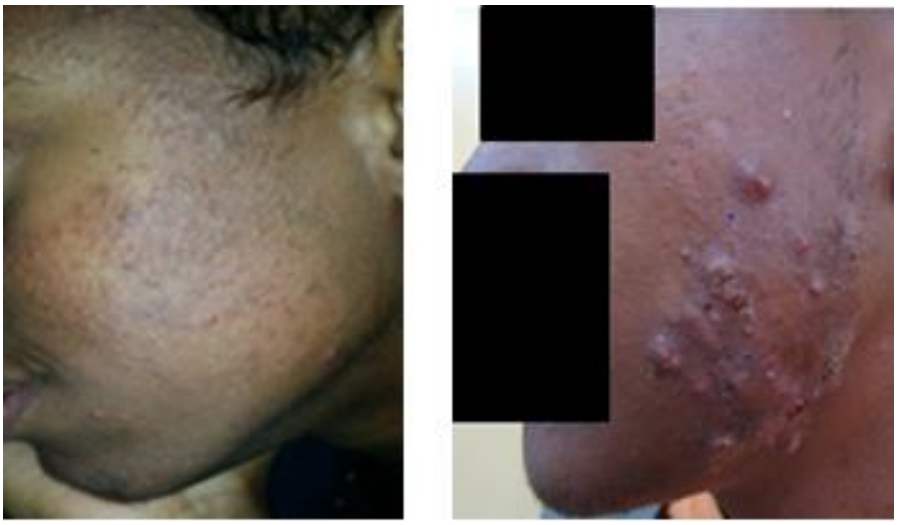


Figure 17 Acne vulgaris

Melasma

Melasma is a chronic acquired pigmentary disorder that presents with diffuse light brown to dark brown macules and patches over the face. The clinical variants of melisma are centrofacial, malar, mandibular and extrafacial.

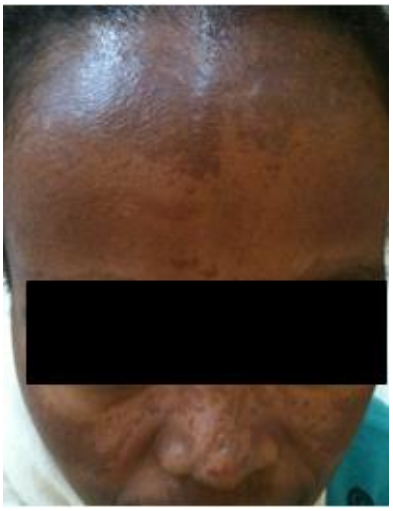


Figure 18 Melasma

3.1.2. Dermatological Preparations

BASE FORMULATIONS

Aqueous cream

Formulation

Emulsifying ointment	30 gm
Phenoxyethanol	1 gm
Purified water qs	100 ml

Preparation Procedure

1. Add the emulsifying ointment to an evaporator basin over water bath and melt at 70 °C.
2. Dissolve the phenoxyethanol in sufficient purified water (freshly boiled and cooled (FBC)) at about 60 °C to produce a total weight of about 70 gm.
3. Add the phenoxyethanol solution to melted emulsifying ointment at about 60 °C and mix.
4. Add sufficient purified water (FBC) to make 100 gm and mix.
5. Stir gently until cool.

Packaging

- Pack in a well-closed container.

Storage

- Keep at room temperature.

Indication

- As emollient (for relief of symptom of dry skin)
- As a base/vehicle

Dose and Administration

- Apply in a thin layer as required.

Side effect

- It may cause sensitivity or an allergic reaction such as red, itchy skin.

Precautions

- Use with cautions in Atopic Dermatitis as it may cause skin irritation.

Additional Information

- 1% phenoxyethanol can be substituted by various other preservatives, for example 10% propylene glycol or Methylparaben.

Basic cream

Formulation

Emulsifying wax	15 gm
Liquid paraffin	12.5 gm
White Soft Paraffin	22.5 gm
Methylparaben	0.15 gm
Water qs	100 gm

Preparation Procedure

1. Add the emulsifying wax to an evaporator basin over water bath and melt at 70°c.
2. Add soft paraffin and then liquid paraffin to the melted emulsifying wax and mix sparingly.
3. Boil sufficient water for 1 minute and dissolve the methylparaben in 50 ml of the boiled water.
4. Allow the methylparaben solution to cool to approximately 70 °C.
5. Add this solution to the mixture (step 2) and mix further.
6. Stir gently until cold.
7. Add sufficient FBC water to make 100 gm cream and mix until homogeneous.

Packaging

- Pack in a well-closed container.
- The packaging should allow stirring of the cream.

Storage

- Store preferably at temperature below 40 °C and protected from moisture.

Indication

- Used as a base (vehicle).
- Used for slight drying effect on the skin.

Dose and Administration

- Apply in a thin layer as required.
- If the cream is inhomogeneous, it should be mixed before use.

Precaution

- Sensitization due to methylparaben, white soft paraffin, and emulsifying wax may occur, but it is rare.
- If sensitization or severe irritation reactions develop, stop using this preparation.

Additional information

- Basic cream is appropriate for intermittent treatment with strong corticosteroid preparations.
- The cream is easily washed off with water, and is therefore suitable for hairy parts of the skin.
- Methylparaben can be substituted by various other preservatives, for example 10% propylene glycol or 1% phenoxyethanol.

Cetomacrogol Emulsifying ointment

Formulation

Cetomacrogol Emulsifying Wax	30 gm
Soft Paraffin	50 gm
Liquid Paraffin	20 gm

Preparation Procedure

1. Add the cetomacrogol emulsifying wax to an evaporator basin over water bath and melt at 60°c.
2. Add soft paraffin to the melted cetomacrogol emulsifying wax and mix sparingly.
3. Decrease the temperature of the water bath gradually.
4. Add the liquid paraffin and mix until congealed.

Note: - To avoid over heating use thermometer to check the temperature regularly.

Packaging

- Pack in a well-closed container.

Storage

- Store in a cool and dry place away from source of heat.

Indication

- As emollient for the symptomatic management of eczema, psoriasis and other dry skin conditions.
- Used as emulsifying agent and base.

Dose and Administration

- Apply the ointment as required, preferably at night time. It should be applied directly to areas of dry skin in the direction of hair growth to prevent blocking hair follicles.

Precautions

- Avoid contact with eyes.
- Keep away from naked flames as there is a fire hazard.
- Do not use it if there is a known allergy or sensitivity to any of the ingredients.

Cetomacrogol Emulsifying wax (Non-Ionic Emulsifying Wax)

Formulation

Cetostearyl Alcohol	80 gm
Macrogol Cetostearyl Ether (22)	20 gm

Preparation Procedure

1. Add the cetostearyl alcohol to an evaporator basin over water bath and melt at 50°c.
2. Add macrogol Cetostearyl Ether (22) to the melted cetostearyl alcohol.
3. Mix sparingly until cold.

Packaging

- Pack in a well-closed container.

Storage

- Store in a cool and dry place away from source of heat.

Indication

- Used as emulsifying agent.

Precautions

- Phenolic compounds (like salicylic acid, dithranol, hydroquinone, and etc.) are incompatible with cetomacrogol emulsifying wax.

Collodion

Formulation

Pyroxylin	4 gm
Ether	75 ml
Ethanol (90%)	25 ml

Preparation Procedure

1. Add the alcohol and the ether to the pyroxylin contained in a suitable container, and insert the stopper into the container well.
2. Shake the mixture occasionally until the pyroxylin is dissolved.

Packaging

- Pack in a well-closed container.

Storage

- Store at a room temperature and away from fire

Indication

- As vehicle

Precaution

- Collodion is highly flammable

Additional Information

- Collodion can be prepared using industrial methylated spirit instead of ethanol (90% v/v).

Emulsifying ointment

Formulation

Emulsifying wax	30 gm
Liquid Paraffin	20 gm
White Soft Paraffin	50 gm

Preparation Procedure

1. Add the emulsifying wax to an evaporator basin over water bath and melt at 70°c
2. Add the white soft paraffin and stir until melted
3. Add the liquid paraffin to the melted ingredients
4. Stir until congeal

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and protect from moisture.

Indication

- As emollient to moisturize and soften dry skin in eczema, dry cases of psoriasis and other dry skin conditions.
- As a base/vehicle.

Dose and administration

- Apply to the affected area as often as required.
- Smooth gently into the skin in the direction of the hair growth.

Side effect

- It may cause sensitivity or an allergic reaction such as red, itchy skin.

Precautions

- Contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Avoid contact with the eyes.

Emulsifying wax (Anionic Emulsifying Wax)

Formulation

Cetostearyl Alcohol	90 gm
Sodium Lauryl sulphate	10 gm
Purified Water	4 ml

Preparation Procedure

1. Add cetostearyl alcohol to an evaporator basin over water bath and melt at 95°c
2. Add the sodium lauryl sulphate and mix.
3. Add the purified water (FBC) and heat to 115 °C and maintain at this temperature.
4. Stir vigorously until frothing ceases and the product is translucent.
5. Cool quickly.

Packaging

- Pack in a well-closed container and protect from light.

Storage

- Store at room temperature.

Indication

- Emulsifying agent

Flexible collodion

Formulation

Camphor	2 gm
Castor oil	3 gm
Collodion qs	100 gm

Preparation Procedure

1. Add the camphor and castor oil in Collodion containing container and insert the stopper into the container well.
2. Shake the mixture occasionally until camphor is dissolved.

Packaging

- Pack in a well-closed container.

Storage

- Store at a room temperature and away from fire.

Indication/Use

- As vehicle

Precaution

- Collodion is highly flammable.

Liquid paraffin/White Soft Paraffin (50/50) ointment

Formulation

Liquid Paraffin	50 gm
White Soft Paraffin	50 gm

Preparation Procedures

1. Add the white soft paraffin to an evaporator basin over water bath and melt at 70°c
2. Add liquid paraffin to the melted white soft paraffin and allow the entire mixture to remain on the water bath until homogeneous mixture achieved
3. Stir until congeal

Packaging

- Pack in a well-closed container preferably made up of Polypropylene jar.

Storage

- Store at room temperature.

Indication

- As strong emollient and symptomatic relief of very dry skin conditions

Dose and administration

- Apply to the skin 3 to 5 times daily or as required.
- Apply in the direction of hair growth to reduce the incidences of folliculitis.

Precautions

- Keep away from naked flames as there is a fire hazard.

Side effect

- Rarely hypersensitive reactions.
- Prolonged use of large quantities may cause folliculitis

TREATMENT FORMULATIONS

Aluminium Chloride solution, 20% w/v

Formulation

Aluminium chloride hexahydrate	20 gm
Absolute alcohol qs	100 ml

Preparation Procedure

1. Grind Aluminium chloride hexahydrate.
2. Dissolve the required quantity of Aluminium chloride hexahydrate powder with some amount of absolute alcohol in a screw-cap bottle
3. Add the remaining absolute alcohol to make the volume 100 ml and mix until completely dissolves

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and away from flame.

Indication

- Used as a first-line therapy for Primary Hyperhidrosis.

Dose and Administration

- Apply daily at night to affected area for three to five days, then every few days as needed.
- Wash off the following morning.

Precautions

- Avoid contact with the eyes, face, mucous membrane and healthy skin.
- Do not bath immediately before use.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the solution.

Side effects

- It may cause skin irritation

Additional information

- Industrial Methylated Spirits may be used to prepare Aluminium Chloride Solution.
- Application to dry skin may reduce local irritation from aluminum chloride.
- It can be prepared from 10 to 35% w/v as required.

Benzyl Benzoate lotion, 25% w/v

Formulation

Benzyl benzoate	25 gm
Emulsifying wax	2 gm
Purified Water qs	100 ml

Preparation Procedure

1. Boil sufficient amount of purified water (FBC) and allow cooling to approximately 70 °C.
2. Add the emulsifying wax to an evaporator basin over water bath and melt at 70 °C.
3. Add the benzyl benzoate and mix.
4. Add 70 ml of warm purified water to the mixture and mix.
5. Stir gently until cold.
6. Add enough purified water (FBC) to produce 100 ml emulsion and mix well.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and protect from exposure to light.

Indication:

- For treatment of scabies and lice (Pediculosis)

Dose and Administration

- Scabies: Application 3 times (either 0, 12, 24 hours or once daily for 3 consecutive days).
  - During each application, take a hot scrubbing soap water bath initially. Apply the lotion from the neck down to the whole body and rub it into the skin. Make sure the lotion gets into contact with the whole body including skin folds. At the same time, treatment for the entire families or contact person is recommended.
- Decontaminate any household contacts like linens, towels, clothing, bed sheets, and pillowcases used in previous 4 days by hot water washing. Alternatively, seal and store in a plastic bag for 3 days.
- Lice: apply the lotion 2 to 3 times at weekly intervals.

- Rub the lotion into all infected hairy areas and allow remaining for 24 hours. Wash off thoroughly and comb the hair with a fine comb to remove dead lice. Wash all bed sheets, pillowcases, and clothes, preferably in hot or boiling water and shake out blankets and outer wear. Repeat treatment two or three times at weekly intervals.
- Infested patient and their sexual contact should be avoided until infestation cleared.

- Itch may persist for weeks after all the mites have been killed.
- Shake well before use.

Precautions

- Avoid contact with the eyes.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the solution.

Side effects

- It may cause contact dermatitis.
- Sensitization reactions are rare, irritation reactions with a burning or stinging sensation may occur.

Additional information

- It also possible to prepare the lotion in different concentration (like 6.25% and 12.25%).
- Emulsifying wax may be substituted by cetomacrogol wax.

Calamine lotion, 15% w/v

Formulation

Calamine	15 gm
Zinc oxide	5 gm
Bentonite	3 gm
Sodium citrate	0.5 gm
Glycerin	5 ml
Liquefied phenol	0.5 ml
Purified Water qs	100 ml

Preparation Procedure

1. Dissolve the sodium citrate in 70 ml of the purified water (FBC)
2. Sieve the calamine, zinc oxide, and bentonite
3. Triturate the calamine, the zinc oxide and the bentonite with the prepared solution (step 1)
4. Add the glycerin to this solution (step 3) and transfer it to a container
5. Add the liquefied phenol and sufficient purified water (FBC) to the container to make the final volume and mix well

Packaging

- Pack in a well-closed container and protect from exposure to light.

Storage

- Store at room temperature.

Indication

- For treatment of itch, stinging or burning pain from insect bites, allergic reactions, or mild sunburn
- Used as Antiseptic

Dose and Administration

- Apply 2 to 3 times per day. It may be used, in acute disease, up to a maximum of ten times a day.
- Shake the lotion before use. It should be painted onto the skin using brush.
- Allow to dry and do not cover with wrappings or bandages.

Precautions

- It should only be used on wounds with caution because of the risk of absorption of phenol.
- Avoid contact with the eyes.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the solution.

Side effects

- It may cause sensitivity or an allergic reaction such as red, itchy skin.
- It should not be used on large parts of the body or for periods longer than 1 week due to systemic side effects of phenol.

Additional information

- Calcium hydroxide solution 3% w/v (lime water) can be substituted in place of purified water as per USP.
- The lotion without a preservative should not be stored, but can be freshly prepared for immediate use. In addition to its preservative effects, phenol also exerts medicinal activity; calamine lotion without phenol is less effective.

Dithranol cream, 1% w/w

Formulation

Dithranol	1 gm
Ascorbic acid	0.1 gm
Salicylic acid	1 gm
Basic cream	98 gm

Preparation Procedure

1. Mix the salicylic acid, ascorbic acid and dithranol.
2. Triturate this mixture carefully with approximately 2 gm basic cream until homogeneous.
3. Add the rest of the basic cream gradually and mix after each addition until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store in dark place at room temperature.

Indication

- For treatment of Alopecia areata, Psoriasis, and Plantar Wart

Dose and administration

- Alopecia Areata – Apply as thin layer once daily at night to the affected area and wash off after 30 minutes for the first 2 weeks, and then for the second 2 weeks apply once daily to the affected area and wash off after 45 minutes. For the last 2 weeks, apply once daily and wash off after 1 hour.
- Psoriasis – apply as thin layer once daily at night until the lesion resolves.
- Plantar wart – apply once daily until the lesion resolves.
- Rub the cream gently onto the skin.
- Avoid applying the cream to surrounding healthy skin. Adjacent healthy skin can be protected with white soft paraffin. Wash the hands after application.
- In the morning, remove the cream by washing with water only. Only after all the cream has been removed with water, wash the skin with water and soap.
- Mix the cream before use.

Precautions

- Avoid contact with healthy skin and eyes.

Pregnancy/breast feeding

- It should be used during pregnancy only if the benefit outweighs the potential risk.

Side effects

- It may produce a burning feeling. Only when intense pain develops, treatment should be stopped.
- It may cause sensitivity or an allergic reaction such as red, itchy skin, etc.

Additional information

- Alopecia Areata – Dithranol cream can be used in different concentration (0.5 to 2%)
- Psoriasis – Dithranol cream can be used in different concentration (0.05 to 4%)
- Plantar wart – Dithranol cream 2%
- Keep the amounts of salicylic acid (1g/100g cream) and ascorbic acid (0.1g/100g cream) the same for different dithranol preparations with other concentrations.
- Dithranol can also be incorporated in either white soft paraffin or emulsifying ointment. Dithranol in petrolatum is occlusive and less well tolerated.
- It is contraindicated in Pustular and Erythrodermic Psoriasis.

Dithranol ointment, 1% w/v

Formulation

Dithranol	1 gm
Salicylic acid	0.5 gm
Emulsifying ointment	98.5 gm

Preparation Procedure

1. Sieve the salicylic acid and dithranol and then mix.
2. Triturate the powder mixture carefully with approximately 2 gm emulsifying ointment and mix until homogeneous.
3. Add the rest of the emulsifying ointment gradually and mix after each addition until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store in dark place at room temperature.

Indication

- For treatment of Alopecia areata, Psoriasis, and Plantar Wart

Dose and administration

- Alopecia Areata – Apply as thin layer once daily at night to the affected area and wash off after 30 minutes for the first 2 weeks, and then for the second 2 weeks apply once daily to the affected area and wash off after 45 minutes. For the last 2 weeks, apply once daily and wash off after 1 hour.
- Psoriasis – apply as thin layer once daily at night until the lesion resolves.
- Plantar wart – apply once daily until the lesion resolves.
- Rub the cream gently onto the skin.
- Avoid applying the cream to surrounding healthy skin. Adjacent healthy skin can be protected with white soft paraffin. Wash the hands after application.
- In the morning, remove the cream by washing with water only. Only after all the cream has been removed with water, wash the skin with water and soap.

- Mix the cream before use.

Precautions

- Avoid contact with healthy skin and eyes.

Pregnancy/breast feeding

- It should be used during pregnancy only if the benefit outweighs the potential risk.

Side effects

- It may produce a burning feeling. Only when intense pain develops, treatment should be stopped.
- It may cause sensitivity or an allergic reaction such as red, itchy skin, etc.

Additional information

- Alopecia Areata – Dithranol cream can be used in different concentration (0.5 to 2%)
- Psoriasis – Dithranol cream can be used in different concentration (0.05 to 4%)
- Plantar wart – Dithranol cream 2%
- Keep the amounts of salicylic acid (1g/100g cream) and ascorbic acid (0.1g/100g cream) the same for different dithranol preparations with other concentrations.
- Dithranol can also be incorporated in either white soft paraffin or emulsifying ointment. Dithranol in petrolatum is occlusive and less well tolerated.
- It is contraindicated in Pustular and Erythrodermic Psoriasis.

Erythromycin gel, 2% w/v

Formulation

Erythromycin	2 gm
Propylene glycol	24 ml
Hydroxypropyl cellulose 1500 cps	2 gm
Ethyl alcohol 70% v/v qs	100 ml

Preparation Procedure

1. Dissolve the erythromycin in about 70 ml of the ethyl alcohol.
2. Add the propylene glycol and mix well.
3. Slowly sprinkle the hydroxypropyl cellulose on the agitated solution and stir until gelling occurs.
4. Add sufficient quantity of ethyl alcohol to make the final volume and mix well.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.
- Flammable, keep away from heat and flame.

Indication

- For treatment of Acne Vulgaris, Rosacea, and Periorificial dermatitis

Dose and Administration

- Apply sparingly as a thin film once or twice a day after the skin is thoroughly cleansed and patted dry.
- Spread the medication lightly rather than rubbing it in.

Precautions

- Avoid contact with eyes and all mucous membranes.

Pregnancy/breast feeding

- It should be used in pregnancy only if clearly needed.

Side effects

- Burning, desquamation, dryness, itching, and erythema.

Lactic acid cream, 5% w/w

Formulation

Lactic acid	5 gm
Propylene glycol	20 ml
Aqueous cream	75 gm

Preparation Procedure

1. Add the aqueous cream to an evaporator basin over water bath and melt at approximately 70 °C
2. Add propylene glycol and mix well until congeal.
3. Triturate lactic acid with the congealed mixture and mix thoroughly.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For the treatment of Xerosis Cutis, Ichthyosis Vulgaris, Darier's Disease.
- For the temporary relief of itching associated with the above conditions.

Dose and administration

- Apply thoroughly twice daily.
- Adjacent healthy skin can be protected with petrolatum.

Precautions

- Avoid contact with eyes, lips or mucous membranes.
- Sun exposure to area of skin treated with lactic acid cream should be minimized or avoided.
- Caution is advised when used on the face due to the potential for irritation.

Pregnancy/breast feeding

- Lactic acid cream is safe and could be given to a pregnant woman and nursing mother as needed.

Side effects

- Mild, stinging, burning or peeling may occur on sensitive, inflamed or irritated skin areas.

Additional Information

- Lactic acid can also be prepared in higher concentration for crusted scabies, Darier's disease, Keratosis Pilaris, Lichen Spinulosus, Pityriasis Rotunda, Keratoderma and Chemical peeling.
- It is contraindicated in neonates and children with erythroderma.

Hydroquinone cream, 4% w/w*

Formulation

Hydroquinone	4 gm
Ascorbic acid	1.5 gm
Basic cream	94.5 gm

Preparation Procedure

1. Reduce the size of hydroquinone granule and mix with ascorbic acid.
2. Triturate the prepared mixture with some amount of basic cream.
3. Add the remaining basic cream to make 100 gm and mix well.

Packaging

- Pack in a well-closed light resistant container.

Storage

- Store at room temperature.

Indication

- For treatment of Hyper-pigmented skin conditions such as melasma, freckles, lentigines and Post inflammatory hyperpigmentation.

Dose and administration

- Apply and rub well once or twice daily at night.
- Use sunscreen during the therapy.

Precautions

- Avoid contact with eyes and mucous membranes.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the cream.

Side effects

- Irritant dermatitis, contact dermatitis, post inflammatory pigmentation, cutaneous ochronosis.

Additional Information

- Instead of basic cream, aqueous cream can be used as vehicle.

** The formulation is included based on experts' opinion*

Malathion lotion, 0.5% w/v

Formulation

Malathion	0.5 gm
Isopropyl alcohol 70%	70 ml
Ethanol 95% qs	100 ml

Preparation Procedure

1. Disperse the Malathion in the isopropyl alcohol.
2. Add sufficient quantity of ethanol to volume and mix well.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and away from flame.

Indication

- For treatment of Pediculus (head lice and their ova) of the scalp hair.

Dose and administration

- Apply sufficient amount on dry hair and scalp thoroughly.
- Allow hair to dry naturally and remain uncovered. After 8 to 12 hours, wash the hair.
- Rinse and use a fine-toothed (nit) comb to remove dead lice and eggs. Repeat after 7 - 9 days as required.
- Wash hands after applying to scalp.
- Wash combs, brushes, hairs clips, clothing, underwear, pajamas, hats, sheets, pillowcases, and towels, and other personnel items in hot water.

Precautions

- Avoid contact with the eyes. Use only on scalp hair.
- Compound this preparation in a well-ventilated area.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the lotion.

Side effects

- It may cause a mild, stinging, and burning or peeling.

Additional Information

- Flavoring agent can be used in the preparation.
- Malathion lotion should not be used in children less than 2 years of age and should be used with caution in children 2-6 years of age.

Menthol spirit, 1% w/v

Formulation

Menthol	1 gm
Ethanol 70 % v/v qs	100 ml

Preparation Procedure

1. Dissolve menthol with equal amount of ethanol.
2. Add the remaining amount of ethanol to make 100ml.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and away from flame.

Indication

- Antipruritic effect and symptomatic treatment for Herpes Zoster and urticaria.

Dose and administration

- Apply to affected area up to 3 to 4 times daily.

Precaution

- It is highly flammable and volatile.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the spirit.

Side Effects

- It may cause contact dermatitis.

Additional Information

- Usually the concentration employed 0.25% to 2% w/v in alcoholic solution or paste.
- It should not be used in infants and children.

Metronidazole cream, 0.75 % w/w*

Formulation

Metronidazole	0.75 gm
Aqueous cream qs	100 gm

Preparation Procedure

1. Make size reduction to metronidazole powder.
2. Incorporate metronidazole powder with equal amount of aqueous cream and mix until homogeneous.
3. Add the remaining aqueous cream to make 100 gm and mix well.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and protect from direct heat and light.

Indication

- For treatment of Rosacea and Periorificial Dermatitis.

Dose and administration

- After washing, apply and rub in a thin layer once or twice daily.

Precautions

- Avoid contact with the eyes.
- It should be used with care in patients with evidence of, or history of blood dyscrasia.

Pregnancy/breast feeding

- It should be used in pregnancy only if clearly needed.

Side effects

- Skin discomfort (dryness, burning and stinging) followed by erythema, skin irritation, pruritus and worsening of rosacea.

Additional Information

- It can also be prepared in 1% w/w concentration.

** The formulation is included based on experts' opinion*

Potassium Hydroxide (KOH) solution, 5% w/v

Formulation

Potassium hydroxide	5 gm
Purified water qs	100 ml

Preparation Procedure

1. Dissolve the potassium hydroxide (KOH) pellets with some amount of purified water (FBC) in a screw-cap bottle.
2. Add the remaining water to make the volume 100 ml, and mix until completely dissolves.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For treatment of molluscum contagiosum lesion and genital wart.

Dose and administration

- Apply once to twice daily using cotton swab to all lesions until it undergoes inflammation and superficial ulceration.
- Protect the surrounding skin with white soft paraffin.

Precautions

- Protect skin, clothing, and equipment.
- Avoid contact with eyes (highly corrosive).

Pregnancy/breast feeding

- No studies are currently identified regarding the reproduction/developmental toxicity of potassium hydroxide.

Side effects

- Stinging or burning sensations, temporary dyspigmentation.

Additional Information

- Topical potassium hydroxide solution 10% w/v can be used for treatment of molluscum contagiosum lesion and genital wart.

Salicylic acid ointment, 5% w/w

Formulation

Salicylic acid	5 gm
White Soft Paraffin	95 gm

Preparation Procedure

1. Grind and sieve the salicylic acid.
2. Triturate the salicylic acid with an equal amount of white soft paraffin.
3. Add the rest of the white soft paraffin gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- As adjuvant therapy for the treatment of Hyperkeratotic conditions (Psoriasis, Chronic Eczema, and Seborrheic Dermatitis) and Pityriasis Amiantacea.

Dose and administration

- Apply the ointment as a thin layer once to twice daily after washing the skin.

Precautions

- Prolonged use may lead to systemic toxicity.
- Over dose (> 2 gm in 24 hours) or frequent use of salicylates may cause salicylism.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using salicylic acid.

Side effects

- Sensitization reactions, local irritation, acute inflammation, ulceration (with use of high concentration), and systemic toxicity

Additional information

- Excessive or long-term use of salicylic acid containing preparations may cause systemic intoxication and characterized by:
  - Slight intoxication: sweating, abdominal pains, dehydration and loss of hearing.

- More severe intoxication: excitation, confusion, fever and convulsions.
- Severe intoxication: respiratory alkalosis followed by a metabolic acidosis and CNS depression, resulting in coma and death.

<u>Note</u>: - Salicylic acid ointment can be used in different concentration (2-40%) based on severity, site of application, and disease type. The above master formula and procedures can be used in order to compound other strengths of salicylic acid preparations.

- Salicylic acid ointment 2-6% - as adjuvant therapy for the treatment of Hyperkeratotic conditions (Psoriasis, Chronic Eczema, and Seborrheic Dermatitis) and Pityriasis Amiantacea.
- Salicylic acid ointment 12-40% - for chemical peeling and for the treatment of hyperkeratotic conditions such as Corn, Wart, Callus, Keratoderma and Hyperkeratotic nail.
- Acne is treated with a drying preparation with a lower concentration. Salicylic acid strong ointment should not be used for acne or psoriasis.
- For higher doses (> 10%) protect the surrounding skin with white petrolatum or plaster.
- Liquid paraffin or aqueous cream can be used as vehicle for scalp purpose.

Salicylic acid solution, 5% w/v

Formulation

Salicylic acid	5 gm
Industrial methylated spirit 70% v/v	100 ml

Preparation Procedure

1. Dissolve the salicylic acid with some amount of the industrial methylated spirit in a screw-cap bottle.
2. Add the remaining industrial methylated spirit to make the volume 100 ml, and mix until completely dissolves.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For the treatment of acne

Dose and Administration

- Apply once to twice daily after washing the skin and drying.
- Apply the solution with some cotton wool or a clean piece of cloth, allow to dry.

Precautions

- Prolonged use may lead to systemic toxicity.
- Over dose or frequent use of salicylates may cause salicylism.
- Close the bottle well after each use.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using salicylic acid.

Side effects

- Sensitization reactions, local irritation, acute inflammation, ulceration (with use of high concentration), and systemic toxicity

Additional information

- Lower concentrations of salicylic acid (2% w/v) may be used.

- Excessive or long-term use of salicylic acid containing preparations may cause systemic intoxication and characterized by:
  - Slight intoxication: sweating, abdominal pains, dehydration and loss of hearing.
  - More severe intoxication: excitation, confusion, fever and convulsions.
  - Severe intoxication: respiratory alkalosis followed by a metabolic acidosis and CNS depression, resulting in coma and death.
- Aqueous cream can be used as vehicle.

Salicylic acid, 3 % w/w + Coal tar, 5% w/w ointment

Formulation

Salicylic acid	3 gm
Coal tar	5 gm
White Soft Paraffin	92 gm

Preparation Procedure

1. Make size reduction for salicylic acid powder.
2. Levigate the salicylic acid powder with small amount of melted white soft paraffin.
3. Add equal amount of white soft paraffin and mix well.
4. Incorporate the coal tar and mix until homogenous mixture is achieved.
5. Add sufficient amount of white soft paraffin and mix thoroughly.

Packaging

- Pack in a well-closed container and protect from exposure to light.

Storage

- Store at room temperature and in a dry place.

Indication

- For treatment of Psoriasis, chronic Eczema and Seborrheic Dermatitis

Dose and administration

- Apply to the affected area once daily.
- Wash your hands before and after use.

Precautions

- Exposure to sunlight should be avoided during tar therapy at least until 24 hours after the last application.
- Avoid application to large skin surfaces and healthy parts of the skin.
- Do not apply on broken skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using coal tar and salicylic acid.

Side effects

- A Stinging sensation on the skin

- Dryness of skin and increased sensitivity of the skin to the sun
- Over dose or frequent use of salicylates in children may cause salicylism

Additional information

- The ointment can be used in different concentration based on severity, site of application, and disease type.
- For scalp use, the vehicle should be liquid paraffin.

Salicylic acid, 17% w/v + Lactic acid, 17% w/v collodion*

Formulation

Salicylic acid	17 gm
Lactic acid	17 gm
Absolute alcohol	25 ml
Flexible Collodion qs	100 ml

Preparation Procedure

1. Make size reduction and sieve the salicylic acid and lactic acid.
2. Mix the salicylic acid and lactic acid powders.
3. Add the mixed powder to the absolute alcohol and mix well.
4. Add sufficient amount of flexible collodion to make 100ml and mix thoroughly.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature and away from flame.

Indication

- For treatment of Wart (particularly palmoplantar wart, verruca vulgaris and mosaic wart), Corn and Callus

Dose and Administration

- Wash the skin carefully and apply as a thin layer once daily.
- Protect the surrounding area with white soft paraffin or plaster.

Precautions

- Avoid contact with the eyes, face mucous membrane, and healthy skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

Side effects

- It may cause skin irritation and ulceration.

Additional Information

- The collodion solution can also be prepared in different concentration salicylic and lactic acid (10-17% w/v).
- It should not be used in infants and children.

**The formulation is included based on experts' opinion*

Salicylic acid, 10% w/w + Lactic acid, 10% w/w ointment*

Formulation

Salicylic acid	10 gm
Lactic acid	10 gm
White soft Paraffin	80 gm

Preparation Procedure

1. Make size reduction and sieve the salicylic acid and lactic acid.
2. Mix the salicylic acid and lactic acid powders.
3. Levigate the mixture using levigating agents to form paste.
4. Triturate the mixture carefully with equal amount of white soft paraffin and mix until homogeneous.
5. Add the remaining white soft paraffin gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container and protect from light.

Storage

- Store at room temperature.

Indication

- For treatment of Cutaneous Warts and Corn or Callus and Keratodermas.

Dose and Administration

- Wash the skin carefully; hydrate the skin by keeping it wet for 10 to 15 minutes and then apply as a thin layer once to twice daily.
- Protect the surrounding area with white soft paraffin or plaster.

Precautions

- Avoid contact with the eyes, face mucous membrane, and healthy skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

Side effects

- It may cause mild skin burning, redness, and peeling of the treated area.

Additional Information

- The ointment can be prepared in different concentration (10-17% w/w) based on severity, disease type, and prescriber's decision.

**The formulation is included based on experts' opinion*

Salicylic acid, 5% w/v + Steroid lotion

Formulation

Salicylic acid	5 gm
Very and Moderate Potent Steroid ointment	10 gm
Liquid paraffin	85 gm

Preparation Procedure

1. Grind and sieve the salicylic acid.
2. Levigate the salicylic acid using some amount of liquid paraffin.
3. Add the steroid ointment and mix well.
4. Add the remaining liquid paraffin gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container and protect from light.

Storage

- Store at room temperature.

Indication

- For treatment of Pityriasis Rubra Pilaris (PRP) on scalp and Seborrheic Dermatitis with extensive scale

Dose and Administration

- Apply as a thin film once daily at bedtime using covered or gloved hand.

Precautions

- Avoid contact with the eyes, face, mucous membrane, and healthy skin.
- Over dose or frequent use of salicylates may cause salicylism.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

Side effects

- It may cause burning, itching, irritation, dryness, thinning and other skin problems.

Additional Information

- The ointment can be prepared in different concentration (salicylic acid 5-6% w/w) for management of Psoriasis (on scalp).

- The ointment can be prepared using different amount of steroid ointment (10gm – 60gm) based on severity, disease type, site of application, coverage of body surface area, and age of patient.
- Selection of topical corticosteroids depends on disease conditions, site of application, and age of the patient (see table below).
- The use of corticosteroids is contraindicated in conditions such as viral skin infections (like vaccinia, varicella and herpes simplex), acne rosacea, fungal skin infections, perioral dermatitis, and ulcerative conditions.

Table Potency class of selected topical corticosteroid preparations

Potency	Topical Corticosteroid Preparations
Ultra-high potent	Clobetasol propionate cream (0.05%)
High potent	Betamethasone dipropionate ointment (0.05%) Betamethasone dipropionate cream (0.05%) Betamethasone valerate ointment (0.1%) Mometasone furoate ointment (0.1%) Triamcinolone acetonide ointment (0.1%)
Moderate potent	Betamethasone dipropionate lotion (0.02%) Betamethasone valerate cream (0.1%) Hydrocortisone butyrate cream (0.1%) Mometasone furoate cream (0.1%) Triamcinolone acetonide cream (0.1%)
Low potency	Betamethasone valerate lotion (0.05%) Hydrocortisone acetate cream (1%)

Salicylic acid, 10% w/w + Steroid ointment*

Formulation

Salicylic acid	10 gm
Potent and Moderate Potent Steroid ointment	15 gm
White Soft Paraffin	75 gm

Preparation Procedure

1. Grind and sieve the salicylic acid.
2. Triturate the salicylic acid with an equal amount of white soft paraffin.
3. Add the steroid ointment and mix well.
4. Add the remaining white soft paraffin gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container and protect from light.

Storage

- Store at room temperature.

Indication

- For treatment of Pityriasis Rubra Piralis (PRP) on trunk and extremities; Psoriasis (trunk/extremity)

Dose and Administration

- Apply as a thin film once daily at bedtime using covered or gloved hand.

Precautions

- Avoid contact with the eyes, face, mucous membrane, and healthy skin.
- Over dose or frequent use of salicylates may cause salicylism.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

Side effects

- It may cause burning, itching, irritation, dryness, and thinning.

Additional Information

- The ointment can be prepared in different concentration for management of psoriasis (trunk/extremity).

- The ointment can be prepared using different amount of steroid ointment (10 – 60gm) based on severity, disease type, site of application, and age of patient.
- Selection of topical corticosteroids depends on disease conditions, site of application, and age of the patient.
- Steroid potency and amount varies depending on the severity of lesion, anatomic sites, and percentage body surface area involved (see for potency class of selected corticosteroids)
- The use of corticosteroids is contraindicated in conditions such as viral skin infections (like vaccinia, varicella and herpes simplex), acne rosacea, fungal skin infections, perioral dermatitis, and ulcerative conditions.

**The formulation is included based on experts' opinion*

Salicylic acid (2% w/w) + Sulfur (2% w/w) cream

Formulation

Salicylic acid	2 gm
Sulfur	2 gm
Aqueous cream	96 gm

Preparation Procedure

1. Make size reduction and sieve the salicylic acid and sulfur.
2. Triturate the salicylic acid and sulfur along with a small amount of aqueous cream to make a smooth paste.
3. Gradually incorporate the remaining aqueous cream to make 100 g.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For treatment of seborrhoeic dermatitis of the scalp and acne.

Dose and Administration

- Apply once or twice a day.

Precautions

- Avoid contact with metals.
- Prolonged use may lead to systemic toxicity.

Pregnancy/breast feeding

- It should be used in pregnancy only if clearly needed.

Side effect

- Local irritation
- Mild cold or burning sensation at the site of application
- Severe allergic reaction

Additional Information

- Keratolytics based on salicylic acid (2–6 %) with or without sulfur (2–5 %) help the removal of adherent scales.
- The cream can be prepared in different concentration for management of acne.

Salicylic acid, 10% w/w + Urea, 10% w/w + Lactic acid, 6% w/w ointment*

Formulation

Salicylic acid	10 gm
Urea	10 gm
Lactic acid	6 gm
White Soft Paraffin	74 gm

Preparation Procedure

1. Make size reduction and sieve the urea, salicylic acid, and lactic acid.
2. Mix the urea, salicylic acid, and lactic acid powders.
3. Levigate the mixture using levigating agents to form paste.
4. Triturate the mixture carefully with equal amount of white soft paraffin and mix until homogeneous.
5. Add the remaining white soft paraffin gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container and protect from light.

Storage

- Store at room temperature and keep away from flame.

Indication

- For treatment of Keratoderma, Cutaneous Wart, Corn and Callus

Dose and Administration

- Wash the skin carefully; hydrate the skin by keeping it wet for 10 to 15 minutes and then apply as a thin layer once to twice daily.
- Protect the surrounding area with white soft paraffin or plaster.

Precautions

- Avoid contact with the eyes, face mucous membrane, and healthy skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

Side effects

- It may cause mild skin burning, redness, and peeling of the treated area.

Additional Information

- The ointment can be prepared in different concentration based on severity, disease type, and prescriber's decision.

** The formulation is included based on experts' opinion*

Salicylic acid, 2% w/w + Zinc oxide paste

Formulation

Salicylic Acid	2 gm
Zinc oxide paste 25% w/w	98 gm

Preparation Procedure

1. Make size reduction and sieve the salicylic acid.
2. Add salicylic acid with some amount of zinc paste and mix well.
3. Add the remaining paste gradually until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For the treatment of juvenile Plantar Dermatosis

Dose and administration

- Apply twice daily.

Precautions

- Avoid contact with eyes, lips or mucous membranes.
- Prolonged use may lead to systemic toxicity.
- Over dose or frequent use of salicylates in children may cause salicylism.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the paste.

Side effects

- It may cause mild stinging, burning or peeling, sensitization.

Silver nitrate solution, 0.5% w/v

Formulation

Silver nitrate	0.5 gm
Purified Water qs	100 ml

Preparation Procedure

1. Weigh the silver nitrate using watch glass.
2. Dissolve the silver nitrate with some amount of the purified water (FBC).
3. Add the purified water (FBC) to make the volume 100 ml, and mix until completely dissolves.

Packaging

- Pack in a well closed and dark colored glass bottle. This bottle should not have a metallic cap.

Storage

- Store in a cool and dark place.

Indication

- For infection prevention in large deep burns
- For treatment of leg ulcers, Pyogenic Granuloma, Molluscum Contagiosum, and Wart
- As a wet dressing in the treatment of infected eczema, gravitational ulcers, and other weeping and/or infected skin lesions caused by Gram-positive or Gram-negative bacteria.

Dose and administration

- Apply the solution on the affected area 2 to 3 times per week using cotton applicator.
- Burns: silver nitrate treatment should be started immediately after burning, or at least within a few hours. The dressings have to be saturated with silver nitrate solution every two hours. Dressings should be changed once daily.
- Ulcers: leg ulcers infected with Pseudomonas species are treated with silver nitrate compresses. The dressings should be changed every hour.
- Protect the surrounding skin with white soft paraffin.

Precautions

- Avoid prolonged contact with skin.

- The use of silver nitrate solution on large burns may cause hypochloremia.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using silver nitrate solution.

Side effects

- It causes burning, skin irritation, and staining of wounds and skin (argyria).

Additional information

- When the water to prepare silver nitrate solution is rich in chlorides, a silver chloride precipitate will be formed. To avoid this reaction, use distilled water for the solution.

Sulphur cream, 10% w/w

Formulation

Sulphur	10 gm
Basic cream	90 gm

Preparation Procedure

1. Make size reduction to sulphur.
2. Triturate the sulphur with equal amount of basic cream.
3. Add the remaining basic cream gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For treatment of scabies

Dose and administration

- Apply the cream on 3 consecutive evenings after washing the skin.
- Mix the cream before use and make sure the cream contacts the whole body, including skin folds. Wash away in the morning. Repeat this every evening for 3 consecutive days.
- Wash all clothes, bed sheets and pillowcases that have been in close contact with the skin, preferably in hot or boiling water, to prevent re-infestation.
- Itch may persist for weeks after all the mites have been killed.

Precautions

- It may cause skin irritation that may predispose the skin to infections.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using sulphur.

Side effects

- Sensitization and may also cause skin irritation.

Additional information

- Sulphur can be used in lower concentrations (2-3% w/w) in the same cream for acne vulgaris.
- Sulphur can be used in lower concentrations for scabies in infants and other indications.
- When basic cream is unavailable, sulphur ointment can be used instead.

Sulphur lotion, 3% w/v

Formulation

Sulphur	3 gm
Zinc oxide	20 gm
Bentonite	3 gm
Sodium citrate	0.5 gm
Glycerin	5 ml
Liquefied phenol	0.5 ml
Purified Water qs	100 ml

Preparation Procedure

1. Dissolve the sodium citrate in 70 ml purified water.
2. Make size reduction and sieve the sulphur, zinc oxide, and bentonite.
3. Mix the sulphur with the zinc oxide and bentonite.
4. Triturate this mixture with the glycerin and 20 ml the sodium citrate solution (step 1).
5. Add the remaining of the sodium citrate solution and mix until homogeneous.
6. Finally add the liquefied phenol and sufficient purified water (FBC) to produce 100 ml and mix well.

Packaging

- Pack in a well-closed container and protect from exposure to light.

Storage:

- Store at room temperature.

Indication

- For treatment of Acne and Rosacea
- Used as antiseptic and antipruritic agent

Dose and administration

- Apply the lotion once to twice daily using cotton or clean cloth after washing the skin. Allow to dry and leave exposed to the air.
- Shake the lotion before use.

Precautions

- Avoid contact with the eyes.
- It should cautiously be used on wounds because of the risk of phenol absorption.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using sulphur.

Side effects

- Sensitization reactions with a burning feeling may occur.

Additional information

- Other concentrations of sulphur (up to 6% w/v) can be used.

Sulphur ointment, 10% w/w

Formulation

Sulphur	10 gm
Emulsifying ointment qs	100 gm

Preparation Procedure

1. Make size reduction and sieve the sulphur.
2. Triturate the Sulphur with equal amount of emulsifying ointment.
3. Add the remaining ointment gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For treatment of scabies

Dose and Administration

- Apply the cream on 3 consecutive evenings after washing the skin and make sure the ointment contacts the whole body, including skin folds.
- Wash away in the morning. Repeat this every evening for 3 consecutive days.
- Wash all clothes, bed sheets and pillowcases that have been in close contact with the skin, preferably in hot or boiling water, to prevent re-infestation.
- Itch may persist for weeks after all the mites have been killed.

Precautions

- It may cause skin irritation that may predispose the skin to infections.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using sulphur.

Side effects

- Sensitization and may also cause skin irritation.

Additional information

- Sulphur can be used in lower concentrations in this ointment for scabies in infants and other indications.
- Sulphur ointment can be prepared using white soft paraffin as a base.
- Sulphur can also be prepared for children using liquid paraffin with polysorbate 60 as suspension.

Tar cream, 3% w/w

Formulation

Coal tar	3 gm
Basic cream	97 gm

Preparation Procedure

1. Weigh coal tar using wax paper or watch glass.
2. Triturate the coal tar with equal amount of basic cream.
3. Add the remaining basic cream gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- For treatment of Psoriasis, Parapsoriasis, Eczema, and Pityriasis Lichenoides Chronica

Dose and administration

- Apply as thin layer once daily at night time to the affected parts of the skin after washing the skin.
- Apply using covered or gloved hands.

Precautions

- Avoid exposure to sunlight.
- Avoid application to large skin surfaces and healthy parts of the skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using tar.

Side effects

- It may cause skin irritation and folliculitis.

Tar paste, 5% w/w

Formulation

Coal tar	5 gm
Zinc paste	95 gm

Preparation Procedure

1. Weigh coal tar using wax paper or watch glass.
2. Mix the coal tar carefully with equal amount of zinc paste. Gentle heat may be used.
3. Add the remaining zinc paste gradually and mix until homogeneous.

Packaging

- Pack in a well closed container.

Storage

- Store at room temperature.

Indication

- For treatment of Psoriasis, Parapsoriasis, Eczema, and Pityriasis Lichenoides Chronica

Dose and Administration

- Apply the paste as layer just thick enough once daily at night time after washing the skin.
- Apply using covered or gloved hands.

Precautions

- Avoid exposure to sunlight.
- Avoid application to large skin surfaces and healthy parts of the skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using tar.

Side effects

- It may cause skin irritation and folliculitis.

Additional information

- Lower concentrations of tar are prepared by further diluting the paste.
- Not suitable for hairy areas.
- Tar paste has a protective effect.

Tar solution, 20% w/v

Formulation

Coal tar	20 gm
Polysorbate 80	5 gm
Industrial methylated spirit 95% v/v qs	100 ml

Preparation Procedure

1. Weigh coal tar using wax paper or watch glass.
2. Mix the coal tar with the polysorbate 80.
3. Pour 80 ml of industrial methylated spirit 95% v/v into the mixture (step 2). Shake the mixture occasionally during one hour.
4. Allow to stand for 24 hours.
5. Decant and filter.
6. Add sufficient amount of industrial methylated spirit to produce 100 ml and mix well.

Packaging

- Pack in a well-closed container.

Storage

- Store in cool place and protect from flame.

Indication

- For the treatment of Psoriasis and Eczema.

Dose and administration

- Apply the solution once daily at night time after washing the skin.
- Apply using covered or gloved hands.
- Close the bottle well after use.

Precautions

- Avoid exposure to sunlight.
- Avoid application to large skin surfaces and healthy parts of the skin.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using tar.

Side effects

- It may cause skin irritation and folliculitis.

Additional information

- Lower concentrations of tar may be used.

Trichloroacetic acid solution, 30% w/v

Formulation

Trichloroacetic acid	30 gm
Purified water qs	100 ml

Preparation Procedure

1. Dissolve 30 gm of trichloroacetic acid with some amount of purified water.
2. Add the remaining water to make the volume 100 ml and mix until completely dissolves.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature (15-25 ^{o}C) and away from fire.

Indication

- For treatment of flat warts (facial peels (10% to 35%)), cutaneous warts, and anogenital warts (80-90%).
- For treatment of Grover Disease (20–30 %), Actinic Keratosis (30%) and Molluscum Contagiosum (25- 50%).

Dose and Administration

- It is applied sparingly on the affected area either by a cotton tip or an applicator, on a weekly basis.
- The solution should be applied to individual papular lesions for a few seconds until they turn white.
- Protect the surrounding area with white soft paraffin or plaster.
- Higher concentration of TCA has to be applied by physician and cannot be applied by patient.

Precautions

- Avoid contact eyes and healthy skin.

Pregnancy/breast feeding

- It is safe during pregnancy.

Side effect

- It causes a burning sensation, inflammation or tenderness.

Urea cream, 10% w/w

Formulation

Urea	10 gm
Basic cream	90 gm

Preparation Procedure

1. Make size reduction and sieve the urea.
2. Triturate the urea carefully with equal amount of basic cream and mix until homogeneous.
3. Add the remaining basic cream gradually and mix until homogeneous.
4. Add the remaining basic cream gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature

Indication

- For treatment of Ichthyosis, Atopic Dermatitis, and hyperkeratotic skin conditions
- Used for softening nail before surgical removal

Dose and administration

- Apply as a thin layer twice daily after hydrating the skin by keeping it wet for 10 to 15 minutes.
- For nail softening: Apply on the nail under occlusion and leave for 24-72 hours.
- Protect the surrounding area with white soft paraffin or plaster (Urea above 20% w/w).

Precautions

- Avoid contact with the eyes.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using urea.

Side effects

- It may cause burning feeling, particularly when used in the face or on broken skin.

Additional Information

Note: - Urea cream can be used in different concentration (5-40% w/w) based on severity, site of application, and disease type.

- Urea cream 5-10% w/w - As moisturizer
- Urea cream 10-40% w/w - As keratolytic agent for the treatment of Hyperkeratotic conditions (such as dry, rough skin, Dermatitis, Psoriasis, Xerosis, Ichthyosis, Eczema, Keratosis Pilaris, Keratosis Palmaris, Keratoderma, Corns and Calluses, as well as damaged, ingrown and devitalized nails onychomycosis) and Pityriasis Rotunda.

Urea ointment, 10% w/w

Formulation

Urea	10 gm
Water	20 gm
Emulsifying ointment	70 gm

Preparation Procedure

1. Make size reduction and sieve the urea.
2. Dissolve the urea in 20 ml of water.
3. Triturate the urea solution carefully with equal amount of emulsifying ointment
4. Add the remaining emulsifying ointment gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store in a cool place.

Indication

- For treatment of Ichthyosis, Atopic Dermatitis, and hyperkeratotic skin conditions
- Used for softening nail removal before surgical removal

Dose and administration

- Apply as a thin layer twice daily after hydrating the skin by keeping it wet for 10 to 15 minutes.
- For nail softening: Apply on the nail under occlusion and leave for 24-72 hours.
- Protect the surrounding area with white soft paraffin or plaster (Urea above 20% w/w).
- Mix the ointment before use.

Precautions

- Avoid contact with the eyes.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using urea.

Side effects

- It may cause burning feeling, particularly when used in the face or on broken skin.

Additional information

- The water is used for easier processing of urea and to ensure homogeneous distribution in the ointment.

Zinc paste, 25% w/w

Formulation

Zinc oxide	25 gm
Starch	25 gm
White Soft Paraffin	50 gm

Preparation Procedure

1. Make size reduction and sieve the zinc oxide and starch powder.
2. Mix zinc oxide and starch powder in warm mortar.
3. Melt the White Soft Paraffin over gentle heat.
4. Triturate the mixture with some amount of melted white soft paraffin until smooth.
5. Add the remaining white soft paraffin gradually and mix until homogeneous.

Packaging

- Pack in a well-closed container.

Storage

- Store at room temperature.

Indication

- As photo protective and vehicle agent
- Diaper Dermatitis

Dose and administration

- Apply the paste as required
- The paste layer may be covered with a loose bandage.

Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the paste.

Additional information

- Talc can be used instead of starch.
- Zinc paste can be prepared in different concentration (50% w/w zinc oxide and 50% w/w white soft paraffin).
- Starch is inappropriate for hot and humid climates because it is usually highly contaminated with micro-organism

General Preparation Tips

- Between 2 and 4 grams of an ointment may be lost in the compounding process. The ointment is lost as it adheres to beakers, ointment tiles, or ointment pads. To compensate for this loss, make an excess of the ointment. Some general rules might be to add 10%- or 3-grams excess to the prescribed amount.
- When heat is used to melt ingredients, use a water bath or special low temperature hotplate. Most ingredients used in ointment bases will liquefy around 70°C These two heating devices provide adequate control over the heating and will ensure that the ingredients are not over heated. A water bath will only heat to the boiling point of water which is 100°C. Special "low temperature" hotplates (full range is 25°C to 120°C) are not a standard laboratory type hotplate; those hotplates heat at 125°C to 150°C at their lowest setting.
- When both an oil and aqueous phase are being mixed together to make an ointment, it is helpful to heat the aqueous phase a few degrees higher than the oil phase prior to mixing. The aqueous phase tends to cool faster than the oil phase and may cause premature solidification of some ingredients. However, use the lowest temperature possible and keep the time of heating as short as possible. This will minimize the quantity of water lost through evaporation.
- When melting a number of ingredients, melt the ingredient with the highest melting point first. Then gradually reduce the heat to melt the ingredient with the next lowest melting point. Continue this process until all ingredients have been added. This will ensure that the ingredients were exposed to the lowest possible temperature and thus enhance the stability of the final product.
- The cooling step in an ointment's preparation is an important part of the compounding process.
- Do not accelerate the cooling process by putting the melt in water or ice. This will change the consistency of the final product making it more stiff than desired.
- If adding volatile ingredients such as oils, flavors, or drugs, add them when the product is "cool to the back of the hand." The melt will still be fluid enough for adequate mixing but not hot enough to evaporate the ingredient.

- Ointments should be cooled until just a few degrees above solidification before they are poured into tubes or jars. They should be thick, viscous fluids. This will minimize "layering" of the ointment in the packaging container. However, this is not the preferred method of packing an ointment tube or jar.
- Most bases achieve their final consistency and texture several hours after they are compounded.

3.1.1. Antiseptics and Disinfectants

Alcohol Based Hand Rub - ABHR (Ethanol, 80% v/v), 1 liter

Formulation

Ethanol, 96% v/v	833.3 ml
Hydrogen peroxide, 3% w/v	41.7 ml
Glycerol, 98% v/v	14.8 ml
Purified water qs	1000 ml

Preparation Procedure

1. Add glycerol using a measuring cylinder to a final mixing container.
2. Pour the measured quantity of hydrogen peroxide into the final mixing container.
3. Add the measured amount of ethanol gradually in 3-4 doses and mix between each addition.
4. Add the required quantity of distilled or FBC water needed to complete the final volume of solution to 1000 ml.

Indication/Use

- Antiseptic

Storage

- Store in a cool and well-ventilated and away from flames.

Ethanol solution, 70% v/v

Formulation

Ethanol, 96% v/v	729 ml
Distilled water qs	1000 ml

Preparation Procedure

1. Dilution of 96% v/v stock solution to prepare 1000 ml of 70% v/v as follow:

The calculation is based on dilution formula:

$$C_1V_1 = C_2V_2$$

- ✓ where, C_1 and V_1 are concentration and volume of stock solution (96%), respectively
- ✓ C_2 and V_2 are concentration and volume of dilute preparation (70%), respectively

$$V_1 = \frac{C2V2}{C1} \quad V_1 = \frac{70\% \; x \; 1000 \; ml}{96\%}$$

$$V_1 = 729 \; ml$$

2. Measure 729 ml of 96% ethanol and transfer into a 1000 ml beaker/measuring cylinder.
3. Add the required quantity of distilled water to the beaker/measuring cylinder to make the final quantity 1000 ml.
4. Shake the mixture.

Indication/Use

- Disinfectant

Storage

- Store in a cool and well-ventilated room and away from flames.

Hydrogen peroxide 3% w/v

Formulation

Hydrogen peroxide, 30% w/v	100 ml
Distilled water qs	1000 ml

Preparation Procedure

1. Dilution of 30% w/v stock solution to prepare 1000 ml of 3% w/v as follow:
2. The calculation is based on dilution formula:

$$C_1V_1 = C_2V_2$$

- ✓ where, C_1 and V_1 are concentration and volume of stock solution (30%), respectively
- ✓ C_2 and V_2 are concentration and volume of dilute preparation (3%), respectively

$$V_1 = \frac{C2V2}{C1} \quad V_1 = \frac{3\% \; x \; 1000 \; ml}{30\%}$$

$$V_1 = 100 \; ml$$

3. Measure 100 ml of 30% H_2O_2 stock solution and transfer into 1000 ml beaker/measuring cylinder.
4. Add the required quantity of distilled water to the beaker/measuring cylinder to make the final volume 1000 ml.
5. Shake the mixture.

Caution: Hydrogen peroxide is a corrosive and oxidizing chemical; therefore, handle it with care.

Indication/Use

- Disinfectant

Storage

- Store it in a cool dark place, preferably at 2–8 °C.

Iodine tincture, 2% w/v

Formulation

Iodine	2 gm
Potassium Iodide	2.5 gm
Industrial methylated spirit, 95% v/v	50 ml
Purified water qs	100 ml

Preparation Procedure

1. Dissolve the potassium iodide in 5 ml water.
2. Dissolve the iodine in this solution.
3. Add the industrial methylated spirit to this solution.
4. Add the required quantity of purified water to make the final volume 100 ml.

Indication/Use

- Antiseptic

Storage

- Store below 30 °C in tight containers protected from light.

Povidone iodine solution, 10% v/v

Formulation

Povidone Iodine	11 gm
Sodium Dihydrogen Phosphate Anhydride	1.36 gm
Citric Acid Monohydrate	0.88 gm
Purified water qs	100 ml

Preparation Procedure

1. Dissolve the sodium dihydrogen phosphate and the citric acid in approximately 70 ml water.
2. Slowly add the povidone iodine while stirring.
3. Continue stirring until homogeneous, heat should not be used.
4. Make up to volume with water.

Indication/Use

- Used for disinfection of the skin and for wounds.

Storage

- Store below 35 °C in tight container protected from light.

3.1.2. Other chemical

Lugol's solution

Formulation

Iodine crystals	5 gm
Potassium iodide	10 gm
Distilled water qs	100 ml

Preparation Procedure

1. Transfer potassium iodide to a brown bottle with 100ml capacity.
2. Add about a quarter of the volume of water, and mix until the potassium iodide is completely dissolved.
3. Add iodine crystals slowly while shaking to the potassium iodide solution.
4. Mix until the iodine is dissolved.

Indication/Use

- Graves' disease, thyrotoxicosis for young patients.

Storage

- Store in a dark place at room temperature.

Annex I List of Some Raw Materials

1. Acetone
2. Aluminium magnesium silicate Powder or flake
3. Ammonium oxalate
4. Ascorbic acid (Vitamin C) Powder
5. Basic fuchsin (Carbol fuchsin)
6. Bentonite Powder
7. Benzoic acid powder
8. Benzyl benzoate
9. Calamine powder
10. Cetostearyl Alcohol
11. Chlorhexidine diacetate powder
12. Chlorhexidine digluconate stock solution 20%
13. Citric acid monohydrate, powder
14. Coal tar
15. Dithranol powder
16. Ethyl alcohol, 96% (Absolute)
17. Erythromycin powder
18. Emulsifying Wax
19. Gentian violet crystal
20. Glacial acetic acid
21. Glycerin or glycerol
22. Hydroxypropyl cellulose 1500 cps
23. Hydrogen peroxide stock 30%, 50%
24. Industrial methylated spirit 98% (methanol)
25. Iodine crystal
26. Lactic Acid
27. Liquid paraffin (mineral oil)
28. Liquefied phenol
29. Macrogol Cetostearyl Ether (22)
30. Methylene blue
31. Propylene glycol
32. Phenol (carbolic acid) crystal
33. Phenoxyethanol
34. Methylparaben (methyl hydroxybenzoate)
35. Metronidazole powder
36. Petrolatum (petroleum jelly, white soft paraffin)
37. Potassium Hydroxide pellet
38. Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate)
39. Potassium iodide powder

40. Povidone Iodine powder
41. Safranin
42. Salicylic acid powder
43. Silver nitrate powder
44. Sodium chloride Crystal
45. Sodium Lauryl Sulphate
46. Sodium dihydrogen phosphate
47. Sodium thiosulfate
48. Sulphur powder
49. Trisodium citrate
50. Urea (carbamide)
51. Wright stain powder
52. Yellow Soft Paraffin
53. Zinc oxide powder

Annex II List of Basic Compounding Equipment

S.N	Equipment/material	Description
1.	Working bench	Level, smooth, impervious, free of cracks and crevices and non-shedding; covered with protector sheets of plastic, rubber or absorbable paper when appropriate
2.	Mortar and pestle	250 ml capacity or more; glass type and porcelain type
3.	Water distiller	Stainless steel of 20 litter capacity or more
4.	Water bath	Stainless steel of 4 openings or more
5.	Electrical hotplate	Various Sizes and Features
6.	Evaporating dish	Stainless steel and porcelain type
7.	Spatula	Stainless steel/plastic type, flexible and non-flexible, different blade lengths.
8.	Gloves	disposable, non-sterile
9.	Glass rod	Different length and thicknesses
10.	Wash bottle	250ml capacity, polyethylene
11.	Funnel	Glass type and plastic type (polyethylene)
12.	Beakers	Glass type; different capacity
13.	Volumetric flask	Glass type; different capacity
14.	Balances	Prescription, torsion, triple beam, electronic; capacities of not less than 300 gm; sensitivity of greater than 0.1 mg.
15.	Ointment tile	Glass type
16.	Micropipettes	Glass type; different capacities (less than 1ml); with pipette bulb
17.	Pipettes	Glass type; different capacities (1ml-100ml); with pipette bulb
18.	Cylindrical graduate	Glass and plastic type; different capacity
19.	Conical graduate	Glass and plastic type; different capacity
20.	Weighing dishes	Plastic, aluminum, stainless steel type
21.	Weighing paper	Normal paper; grease-proof for semisolids
22.	Thermometers	Fridge and wall thermometer
23.	Scientific calculator	Electronic calculator that can show its output in scientific notation

Annex III Compounding Record Template

Name of the dispensary/health institution _____ Date _____

Batch number/control number_____ Batch Quantity _____

Description of ingredients				**Name or initials of person in charge**
Name	**Source**	**Batch number**	**Quantity**	
Description of the steps of the preparation				
Results of QC procedures				
Beyond use date: …….				
Total Quantity Compounded: …… **Loss: ……** **Reason for loss: ……..**				
Prepared by: Name _____ Signature _____ date _____				
End control before release of the product				
Parameters	**Comment**			
Approved by: Name _____ Signature _____ date _____				

Annex IV Master Formulation Record Template

Name, Strength of the preparation: _____ **Dosage Form:**_____ **Route of administration**_____	**Patient Information:**_____ **Prescribing date:**_____ **Date of prescription arrival:**_____ **Date of preparation:**_____

General Instructions for Recording

1. Never leave fields blank; write "NA" in case of not applicable/not available entry.
2. Fill all the blanks accurate, neat & clean.
3. Hand writings in this record form must be legible. The document shall be filled by blue or black pen.
4. Never over write mistakes or errors. In case of wrong entry strike through as shown in the bracket (~~Strike through~~), write the correct one & sign in such a way that the wrong entry is also readable.
5. Entries must be done by the relevant personnel only. Fill the entries right at the time of activity is performed; avoid false entries.
6. The document is invalid if records are incomplete and/or does not bear the Pharmacy control stamp.

Check points	**(Yes/No/NA)**
Previous compound product and documents are removed	☐ ☐ ☐
Electronic Weighing balances verification takes place as per the SOP	☐ ☐ ☐
Compounding area and equipment are updated with current status	☐ ☐ ☐
Workers are followed about their personal hygienic and clothing as per instruction	☐ ☐ ☐
Gloves are ready	☐ ☐ ☐
Current product documents are in place	☐ ☐ ☐
Batch size or quantity of preparation: _____ Batch number or Unique number of preparation:_____	

Formula

Ingredients	**Quantity**	**Physical description**	**Batch no, Expiry date**

Additional information about the chemicals used:

Notes on calculations and measurements:

- *Perform any raw calculation here , related to the preparation*

Required equipment, instruments and materials

- *Indicate all materials and equipment that were required to compound the NSPs*

Compounding method

- *Describe all steps of the compounding process.*

QCs

- *Specify all QC procedures that were carried out during compounding.*
- *Specify all QCs that were carried out by the pharmacist on the final compounded NSP. Indicate the expected specifications, as applicable*
- *Write NA, if not applicable*

QC parameter	Expected Specification	Result (tick one)
Physical appearance	E.g. clear, colorless solution with no visible particle	Comply/not-comply
Assay		Comply/not-comply
Fill volume		Comply/not-comply
Weight check		Comply/not-comply
PH		Comply/not-comply
Identification		Comply/not-comply

Packaging

- *Describe the type of packaging in which the final compounded NSP shall be presented to the patient.*

Stability and storage (as applicable)

- *Specify the preservation requirements of the compounded NSP*
- *Specify the beyond-use date for the compounded NSP*
- *Indicate the references used to determine the beyond-use date.*

Labeling Information	Affix sample label
• Indicate mandatory information that must be on the label	

Information about Compounding Personnel

Name of Compounder:_____
Title:_____
Date:_____
Start time:_____
End time:_____
Signature:

Final Product release declaration

Completed by:_____ **Title:**_____	**Checked by:**_____ **Title:**_____

Annex V Standard Operating Procedures

SOP 1 Use of Measuring Balance

Purpose: This SOP describes the optimal use and maintenance of a laboratory balance used to measure mass to a high degree of precision.

Procedure

- ✓ Check whether the sensitivity of the balance is appropriate for the amount of material to be weighed.
- ✓ Zero the balance before use.
- ✓ Put material to be weighed in a suitable container or on weighing paper, never directly on the pan of the balance.
- ✓ Determine the mass of the weighing container or paper. And then press tear to deduct the weight of the paper or container
- ✓ Place the material to be weighed in the container or on the weighing paper in the middle of the pan to avoid corner-load error.
- ✓ Note the mass of the substance being weighed from the screen of the balance.
- ✓ To prevent contamination of stock material, do not return unused substance to the stock bottle.
- ✓ Clean the balance with a soft, clean brush after use. Refer to manufacturer's manual for other instructions on cleaning. Balance pans and the working area can be disinfected with 70% ethanol.

SOP 2 Operations and Verification of Weighing Balance

Standard Operating Procedure on operation and verification of weighing Balance			
Status:			
Prepared by:	Reviewed by:	Approved by	
Name:	Name:	Name:	Effective date:
Position	Position:	Position	
Sig:	Sig:	Sig:	
Date:	Date:	Date:	Supersedes:

Prior calibration and verification (internal calibration) of weighing balance are very crucial operational step to ensure accuracy and precision in weighing. A calibration procedure assures the compounder that the balance is working correctly.

Abbreviation

SD=Standard deviation

gm=gram

Purpose: To lay down a procedure for calibration and Operation of the analytical balance/weighing scale used for pharmaceutical compounding

Scope: This procedure is applicable for balances equipped in the compounding room of pharmacy department of [_____] hospital.

Responsibility

Technical assistant: for using the procedure.

Supervisor: Checking the implementation of the procedure in operation and verification of weighing balance during compounding.

Equipment and material

- Weighing balance
- Standard weights
- Forceps for Standard handling

Procedure

Tarring

1. Open the slide door, or level the balance away from vibration area
2. Place a container/ watch glass/weighing bottle/butter paper on weighing pan
3. Press the O/T key. The display changes to zero, 0.000g

Operation procedure

1. To switch the balance ON briefly touch the ‘’ ON/OFF’’ key after the main power supply of the balance has been switched on.
2. Check the level of the weighing balance; centre the position of the air bubble.
3. When the display indicates 0.0000g, place the sample on the weighing pan and close the sliding doors.
4. To switch the balance off briefly touch the ‘’ ON/OFF’’ key.

Perform internal calibration (verification)

Checking Accuracy

Place 5g on the weighing pan (as per weighing range of the analytical balance)
Note the weight
Calculate the difference between the weight in the certificate and observed weight
Repeat the above steps using 50gram and 100gram weights
Record the reading

Checking Precision

Place 5 gm, in the weighing pan
Note the weight
Repeat the above two steps nine times
Record the weight
Calculate the standard deviation
Calculate the measurement uncertainty using following equation

$$\textbf{Measurement of uncertainty} = \frac{\textbf{2 x SD}}{\textbf{Actual weight from Certificate}}$$

Frequency

Internal Calibration and accuracy daily

Daily Calibration Record

Analytical balance ID.no:_____

Standard weight ID.no: _____

For Precision

Theoretical weight	Actual weight from certificate	Observed weight	Measurement un-certainty	Tolerance
5g				Not more than 0.1
		SD=		

Daily Calibration Record

Name of the Instrument: Weighing/Analytical balance

Identification number: _____

Weight box ID. no: _____

For Accuracy

Date	Internal calibration	Observed weight for 5gm	Difference	Observed weight for 50gm	Difference	Observed weight for 100gm	difference

Limit

No.	Theoretical weight	Actual weights from certificates	Tolerance
1.	5gm		±5mg
			±5mg
			±5mg

SOP 3 Cleaning of Equipment and Accessories

Purpose: To prevent contamination of health supplement products by ensuring that proper cleaning procedure for equipment and accessories in the manufacturing area is in place.

Scope: This standard operating procedure applies to the cleaning of equipment and accessories in the manufacturing area of compounding pharmacy.

Procedure

Cleaning of Major Manufacturing Equipment

1. Dismantle all the removable parts of the equipment to be cleaned.
2. Adhere “To be cleaned” sticker on the equipment and transfer the removable parts to the designated washing area.
3. Clean the immobile part of the equipment according to the manufacturer’s suggested cleaning procedure then fill-out the Equipment Log Book after completion.
4. Reassemble all the cleaned removable parts to the cleaned equipment after assuring that every part is dried.
5. Affix the signed and dated “Cleaned” sticker on the reassembled cleaned equipment. The “Cleaned” sticker must identify previous batch being processed by the equipment.
6. Use the cleaned equipment within 72 hours from the date of cleaning. Wipe all product contact parts with clean lint-free cloth prior to next use.
7. If the equipment is not used within 72 hours after the date of cleaning, adhere “To be cleaned” sticker on the equipment and perform cleaning procedure again before use.

Cleaning of Accessories and Utensils

1. Transfer the accessories and utensils to the designated washing area.
2. Wash with sufficient potable water.
3. Clean with nylon brush or cleaning pad using potable water and disinfectant solution.
4. Wash off clean with potable water until no bubbles are present.
5. Final rinse with purified water.
6. Rinse or wipe with 70% v/v solution of Alcohol
7. dried accessories and utensils
8. Affix signed and dated “Cleaned” sticker, with identification of previous product, on the bag.
9. Store the cleaned accessories and utensils in designated equipment storage area until next use

SOP 4 General Cleaning of Compounding Premises

Compounding premises and Storage facilities should be clean and free from liter and dust. Cleaning equipment should be chosen and used in order not to be a source of contamination

Standard Operating procedure on general cleaning of compounding premises		**Copy Nº:**
Status:		
Prepared by	Approved by	
Name:	Name:	Effective date:
Position:	Position	
Sig:	Sig:	
Date:	Date:	Supersedes:

Purpose: To ensure that the Compounding premise is maintained clean, tidy at the highest level of cleanliness.
Scope: This SOP applied in [_____] hospital pharmacy compounding room. That is used to clean compounding area, floors, walls, windows; shelves and stock will be done in the medicine store.

Responsibility

- Cleaners are responsible to follow the SOP.
- It is the responsibility of the supervisor to ensure that these procedures are followed

Equipment and Material

- Sponge mop
- Rubber mop
- Broom
- dust bin
- Detergents
- Disinfectant and Detergents (different types)
- Protective equipment

Cleaning principles

- All areas of Compounding premises such as Compounding areas, weighing area, storage area should be cleaned on programmed basis.
- The compounding unit should execute a cleaning regimen as required (i.e. on a daily, weekly, monthly and annual basis)
- Cleaning should performed using protective equipment like gloves, aprons, boots, face mask etc., as necessary during cleaning procedures
- All cleaning chemicals and materials should be properly labeled and stored separately from medical warehouse / kept in utility room/
- Disinfectants that are used to disinfect compounding area and equipment should be applied rotationally, in order not to produce resistant strain to ward s specific detergent

Daily cleaning basis

- ⇨ All rubbish and non-essential product, packaging and wrapping should be Removed from the compounding room and disposed off.
- ⇨ Sweep floors of all of compounding room should be cleaned every morning.
- ⇨ Clean shelves and stock after cleaning/sweep the floors
- ⇨ De-dust all shelve in the chemical store with a dry duster
- ⇨ Avoid messing up the labels of containers
- ⇨ Squeeze the mop or duster hard to leave it almost dry before cleaning shelves and container
- ⇨ All waste bins should be emptied and fresh bin liners put in place
- ⇨ Cleaning floors under the pallet [daily basis cleaning basis]
    - Move movable equipment from the floor
    - Start sweeping from the furthest point of the store
    - Collect clean water for a quantity enough to clean the store
    - Collect a clean mop and Powder detergent to use for mopping the floor
    - Dissolve powdered detergent or other suitable detergent in the clean water
    - Squeeze the mop as dry as is possible before mopping the floor
    - Do not use dirty water

Wall and window cleaning [Monthly cleaning basis]

- ⇨ Remove free dust and dirt using a dry duster
- ⇨ Apply window cleaner onto clean cloth and wipe off the dirt from the window
- ⇨ Use water and hose for cleaning the outside of high windows. Make sure the windows are tightly closed
- ⇨ Wipe away dirt from the walls using a mop and clean water with soap or detergent

Tube lights & high area [Annually basis]

- ⇨ Switch off the power supply and clean high level areas. Clean high level areas by using clean and dry closes.
- ⇨ All cleaning recorded in the Cleaning Log (Appendix ---/----).This should include a description of the area cleaned and cleaning agents used.
- ⇨ The person performing the cleaning sign and date the log.
- ⇨ The cleaning should be checked by a second person and this check should be recorded in the log.
- ⇨ Cleaning records should be reviewed on a regular basis and this review should be recorded on the Cleaning Log

Compounding equipment cleaning

- When the same product of different batch produced cleaning approach is different when different product compounded with the same equipment.
- Use stringent cleaning approach when different compound from the previous will be compounded with the same equipment. In this case use hot water, and suitable detergent to remove the previous product from the surface of the equipment (Spatula, ointment slab, mortar and pestle, and others).
- In case when the same preparation with the previous residue will be compounded, less stringent cleaning approach can be used.

Daily /weekly/monthly cleaning basis records

Date	Area cleaned	Cleaning agent used	Cleaned by	Checked by	Signature

Reviewed by: _____ Date_____

SOP 5 Compounding Process (self-evaluation)

To avoid errors and maximize the therapeutic effect for the patient, compounding personnel must follow these steps:

S.N	Elements to cover in training	Compliant (√)	Non-compliant (√)
1	The compounded preparation prescribed is analyzed by the compounding pharmacist and considered appropriate and safe for the patient, based on the therapeutic intention.		
2	The calculations required determining the necessary quantities of active ingredients and added substances have been carried out properly and verified.		
3	The instruments and apparatus required for the preparation have been properly selected.		
4	The compounding area and the instruments and apparatus required to compound the preparation have been cleaned.		
5	Staff responsible for compounding the preparation wear the appropriate clothing and wash their hands properly.		
	➢ Staffs are wearing clean clothes appropriate for the tasks they are to perform. They are using the required protective accessories (Head cover, mask, gloves, etc.).		
	➢ A clean laboratory coat or a clean disposable gown is always worn for non-sterile compounding.		
	➢ For preparations that contain hazardous products, staffs wear the appropriate protective clothing: cap, safety goggles, two pairs of gloves, N95 mask and face protection, a gown and shoe covers, depending on the substance used.		
6	To avoid microbial contamination of the preparations being compounded, the written procedures include instructions on attire and restrictions on staff working with open lesions or certain diseases.		

7	Compounding personnel compound only one preparation at a time.		
8	The procedures are such that the compounder avoids mixing up preparations to be compounded for different patients (e.g., having a different basket for each patient or a bin system to separate baskets of prescriptions for drug products to be compounded, etc.).		
9	Compounding is in line with the requirements for the various non-sterile compounded preparations.		
10	All the necessary compounding equipment has been assembled and is ready for use		
11	Compounding of the preparation is in line with the master formulation record and the prescription, as well as with good practice and pharmacy science.		
12	The QCs stipulated in the procedures have been performed, specifically: ➢ Verification of the appearance of the final preparation (clarity, odor, color, consistency, pH, etc.) ➢ The controls performed are in line with the description in the master formulation record		
13	Container libeling complies with provincial/territorial regulatory authority		
	➢ The batch number assigned to the preparation by the pharmacy has been added		
	➢ The expiry date has been determined and it is marked on the label		
	➢ The storage information has been added		
14	The required forms have been completed and signed by the compounding personnel		
15	The uniformity, identity and strength of the preparation, as well as its quantity and the purity of the preparation ingredients are as required.		
16	The required information has been noted in the various logs.		

17	A description of the appearance of the finished product can be found in the master formulation record. Conformity of the appearance of the final preparation has been verified.		
18	The equipment was: ➢ Cleaned immediately after use according to manufacturer's directions or standards, and dried ➢ Properly stored in a cabinet		
19	The products and ingredients were put away immediately after use.		

SOP 6 Labeling

Standard operating procedures for labeling		**Copy №:**
Status:		
Prepared by	Approved by	
Name:	Name:	Effective date:
Position	Position	
Sig:	Sig:	
Date:	Date:	Supersedes:

Labeling should be done according to Ethiopian Food and Drug Authority (EFDA) regulations. Usually, labeling information should include:

1. Generic or chemical names of the active ingredients,
2. Strength or quantity,
3. Batch number,
4. Beyond-use date, and
5. Any special storage requirements

Purpose: To ensure that all prepared pharmaceuticals are labeled suitably with appropriate information.

Scope: This Standard Operating Procedure applies for all pharmaceuticals compounded in the health facility vicinity.

Responsible Person

Compounding unit case team leader

- Ensure that the compounded preparation is labeling according to IACP.
- Document daily labeling activities.
- Ensure the labeling SOP is properly followed.
- Ensure uniform labeling is done.
- Design and prepare the labeling materials

Compounder

- Label the prepared products in accordance with IACP
- Prepare daily labeling materials.

Materials and equipment

- Different size self-adhesive labels
- Printed type labeling materials
- Inedible ink Pen
- Adhesives with brush
- Cutting materials

Procedure

1. Clean the packing materials before filling the prepared materials
2. Select the appropriate packing materials
3. Select the appropriate labeling materials
4. Read the prescription information and prepare labeling
5. Check the prepared labeling information with ordered prescription/form
6. Finally stick the labeling materials to the dispensing package
7. Record to the final dispensing logo

Note: Write the necessary information on the Labeling materials if you are using printed type of labeling materials. But, if it is ready made self-adhesive labeling materials, stick to the dispensing materials.

Sample labeling format

_____*Hospital Pharmacy*
Ingredient
Action and use:
Dose and administration:
Preparation date:
Beyond use date:
Batch number:
Checked by:
EXTERNAL USE ONLY/INTERNAL USE ONLY

SOP 7 Monitoring Temperature and Relative Humidity in compounding room

Standard Operating Procedure for Monitoring Temperature and Relative humidity in compounding room			
Prepared by	Approved by	Revised by	Version N$^{o.}$
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

1. Introduction

- Temperature and/or relative humidity monitoring is essential in pharmaceutical product compounding room and warehouses where sensitive medical equipment and pharmaceuticals product stored. Failure to store such items within the specified temperature range may affect their quality and effectiveness. Failure to monitor and record temperatures and relative humidity accurately can mean that health professionals may be unaware of these potential effects on medical product.

2. Purpose

- The purpose of this SOP is to describe the procedure followed when monitoring and recording of temperatures and/or relative humidity of compounding room.

3. Scope

- This SOP applicable to monitor and record temperature and RH in [health facility] hospital pharmacy compounding room during prescription pharmaceutical products.

4. Responsibility

- Compounding Pharmacist
- Compounding Pharmacy technician

5. **Materials and equipment**

- Temperature and humidity recording log sheet
- Calibrated thermo hygrometer

6. Procedure

1.1.Monitoring and recording compounding room

1.1.1. Ensures calibrated temperature monitoring device located at suitable location.
1.1.2. Control and monitor temperatures using calibrated monitoring device.
1.1.3. Conduct monitoring at points representing the extremes of the temperature range (hot spots or cold spots)
1.1.4. Record twice daily and it contains date, time, minimum and maximum temperatures and name and sign of person recording.

1.1.5. Check the thermometer used for monitoring at suitable predetermined intervals.
1.1.6. Record the results of such checks and retain the record.
1.1.7. Calibrate thermometer at least once in a year (as needed).
1.1.8. Report any deviation in temperature and relative humidity to compounding supervisor
1.1.9. Keep all monitoring records for a minimum of 2 years period.
1.1.10. Investigate any deviation and take appropriate corrective and preventive action.
1.1.11. Record the action taken.

1.2.Monitoring and Recording of Refrigerators and Freezer Temperature

1.2.1. Calibrated control sensors/thermometer positioned at the hot and cold spots as determined by study or experiences.
1.2.2. Check the maximum, actual and minimum fridge temperature between intervals.
1.2.3. Record the Maximum, Current/Actual, and Minimum temperature twice daily. (Annex 1)
1.2.4. Keep temperature logs close to the refrigerator/freezer (but not inside)
1.2.5. Use a separate temperature record for each refrigerator/freezer.
1.2.6. Calibrate the thermometer at least once a year.
1.2.7. Record any activity which may affect the temperatures recorded e.g. tidying, re-stocking, cleaning, defrosting at the time it takes place.
1.2.8. The temperature log signed and date by individuals checks.
1.2.9. Investigate out of specification reading and take corrective action and preventive action.
1.2.10. Record action taken.
1.2.11. Keep all monitoring records for [put document retain period].

1.3.Humidity control and monitoring

1.3.1. Ensures calibrated relative humidity monitoring device placed at the storage area.
1.3.2. Monitor the reading of the relative humidity between intervals.
1.3.3. Record the reading of the relative humidity measuring device twice daily.
1.3.4. Keep all monitoring records for [put document retain period].
1.3.5. Investigate out of specification reading and take corrective and preventive action
1.3.6. Record the action taken.

7. Distribution

This SOP will be distributed to:

- Head of pharmacy service
- Compounding supervisor
- Store keeper/warehouse manager

Room and refrigerator temperature recording format

Max and Min temperature /acceptance limit/_____

Month_____

ID.no_____

Date	Time	Actual Temperature reading	Recorded by		Action/comment or outcomes when temperature excursion/
			Name	Sign	

Relative humidity recording format

Max and Min relative /acceptance limit/_____

Month_____

ID.no_____

Date	Time	Actual relative humidity	Acceptance limit		Recorded by		Action/comment or outcomes
			Min. Temp	Max. Temp.	Name	Sign	

SOP 8 Daily Room Temperature Monitoring Form

Month ……. Year ……

Date	Time	Room Temperature (°C)	Checked by Initials
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

SOP 9 Training of Compounding Personnel and Cleaning Personnel

This indicates the skills and abilities on which staff training should focus. Any training, professional development and upgrading programs in the area of compounding taken by staff should be noted in their personnel files. Compliance with operating procedures and application of non-sterile compounding techniques should be evaluated regularly and be included in the skills assessment program for compounding staff. The results of these evaluations and any corrective action taken must be noted in the employee's file.

A. Training of compounding personnel

S.N	Elements to cover in training		
1	**For the compounding of NSPs**	**PH***	**PT***
1.1	Know the relevant legislation and regulations related to pharmacy compounding, as well as other governing standards, guidelines.	X	X
1.2	Know and apply all policies and procedures related to the pharmacy compounding of NSPs, especially those related to hand hygiene, garbing, airflow principle, facilities, material, equipment, behavior of personnel in compounding rooms, forms and logs to be completed, labeling, storage, distribution to patients, QCs (sampling), maintenance and disinfecting of compounding areas.	X	X
1.3	Know physical and chemical properties, such as stability, physical–chemical compatibility and incompatibility.	X	
1.4	Know pharmaceutical and medical abbreviations.	X	X
1.5	Know and understand the importance of particulate and microbial contamination	X	X
1.6	Perform pharmacy non-sterile compounding tasks meticulously, precisely and competently.	X	X
1.7	Know the operation and correct use of equipment, materials and automated devices available for the NSPs to be compounded.	X	X
1.8	Have a good command of the pharmaceutical calculations required to compound NSPs.	X	X
1.9	Understand the importance of and apply accurate measurements.	X	X
1.10	Apply cleaning measures for NSP compounding rooms, facilities and materials.	X	X
1.11	Have a good command of the pharmaceutical calculations required to	X	X

	compound NSPs.		
1.12	Know the data to be monitored in controlled rooms (temperature, pressure, heating, ventilation and air conditioning system) and document the data in the appropriate logs. Know and apply the corrective measures to be applied when irregularities are identified.	X	X
1.13	Know and apply quality assurance measures for the various compounded NSPs.	X	X
1.14	Know and follow the verification process.	X	X
1.15	Know drug delivery systems.	X	X
1.16	Know and establish levels of risk and beyond-use dates.	X	X
1.17	Know and apply quality assurance measures for the various compounded NSPs.	X	X
2	**For the compounding of hazardous NSPs**		
2.1	Identify hazardous products in the composition of preparations.	X	X
2.2	Know and apply deactivation and decontamination measures.	X	X
2.3	Know and use the protection measures necessary to avoid exposure to hazardous products.	X	X
2.4	Know and use personal protective equipment specifically for handling hazardous products and preparations.	X	X
2.5	Safely handle hazardous products (i.e., receive, unpack, store and deliver hazardous products).	X	X
2.6	Know and use the emergency measures to be applied in the case of accidental exposure, accidents or spills.	X	X
2.7	Know how to safely destroy hazardous products and the materials used in their preparation.	X	X
* PH = pharmacist; PT = pharmacy technician			

B. Training of cleaning and disinfecting personnel

S.N	Elements to cover in training	PH*	PT*	C&D*
1	**For cleaning and disinfecting the general area for compounding of NSPs**			
1.1	Know all policies and procedures related to cleaning and decontaminating the equipment, furniture and facilities, notably those related to hygiene, personal protective equipment, and cleaning and disinfecting tasks.	X	X	X
1.2	Know and use personal protective equipment specifically for	X	X	X

	handling hazardous products.			
1.3	Know and use the emergency measures to be applied in case of accidental exposure, accidents or spills.	X	X	X
*PH = pharmacist; PT = pharmacy technician; C&D = cleaning and disinfecting personnel				

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