



Pharmacy Level-IV

Based on Feb, 2018 Version 2 Occupational Standards and June, 2018 Version 1 Curriculum



Module Title:-Providing General Counseling Service on
Beauty Care

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LG #16 , LO #1-Basic knowledge on cosmetics

Instruction sheet

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- ✚ Introduction to anatomy and physiology of skin, hair and nail
- ✚ Cosmetics and cosmetic preparations

This guide will also assist you to attain the learning outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to:

- ★ Develop product knowledge and maintained by accessing relevant sources of information.
- ★ Store product range accurately identified according to product information.
- ★ Product information conveyed to other staff members as required.
- ★ Comparisons between products and services researched and accurately applied according to product information.

Learning Instructions:

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, see your trainer for further instructions or go back to “Information sheets”.



Information Sheet 1- Introduction to anatomy and physiology of skin, hair and nail

1.1. Introduction to the skin

The skin is the largest organ in the human body. It is the body's first line of defense, acting as a barrier against disease and physical hazards. It also helps control body temperature by releasing heat through sweat or by constricting blood vessels to act as insulation.

The skin (cutis) provides a waterproof and protective covering for the body, contains sensory nerve endings, and aids in the regulation of temperature. The skin is important, not only in general medical diagnosis and surgery, but also as the seat of many diseases of its own. The study of these is called dermatology

1.1.1. Structure, type and physiology of the skin

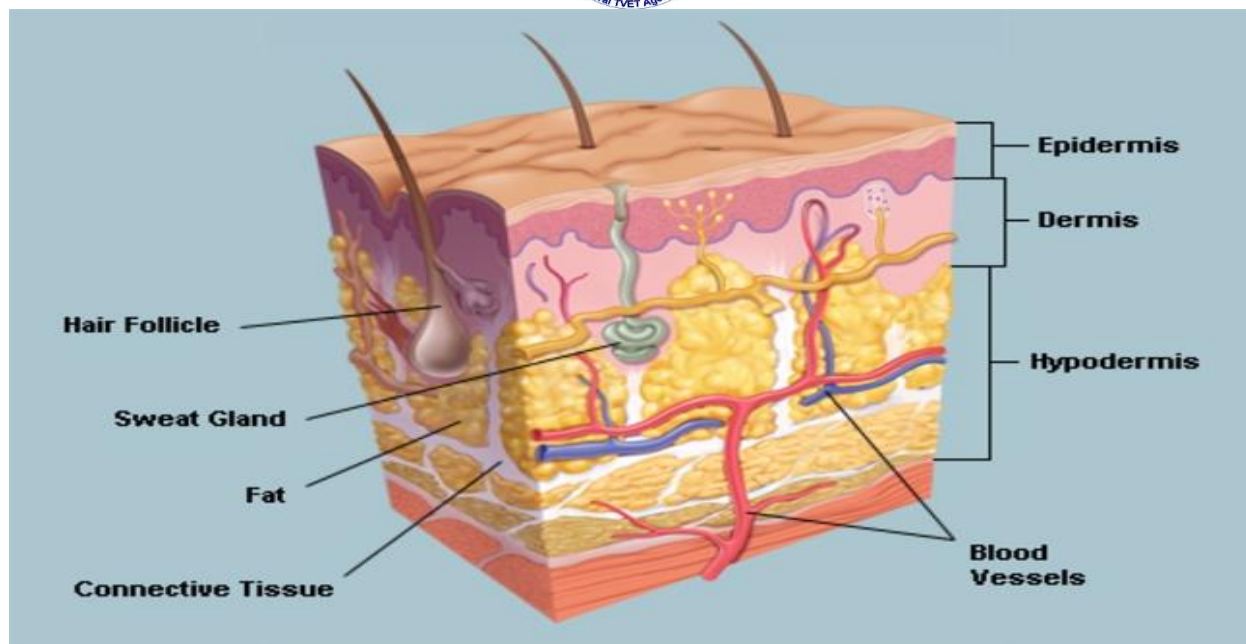


Fig 1.. Anatomy of the skin

The skin consists of two quite different layers: (1) the epidermis, a superficial layer of stratified epithelium that develops from ectoderm, and (2) the dermis, or corium, an underlying layer of connective tissue that is largely mesodermal in origin. The dermis makes up the bulk of the skin

1.1.2. Skin layers

Skin has three layers

- I. The epidermis, the outermost layer of skin, provides a waterproof barrier and creates our skin tone.
- II. The dermis, beneath the epidermis, contains tough connective tissue, hair follicles, and sweat glands.
- III. The deeper subcutaneous tissue (hypodermis) is made of fat and connective tissue.



The skin's color is created by special cells called melanocytes, which produce the pigment melanin. Melanocytes are located in the epidermis.

1.1.2.1. The epidermis

The epidermis is the outermost layer of the skin. This layer consists of many special cells, including keratinocytes and melanocytes. Keratinocytes are cells that make a special fat which gives skin its waterproof properties. Melanocytes produce melanin, which is a pigment giving us the colour of our skin. This layer is continuously shed and replaced, every 15–30 days.

The epidermis has blood or nerves and is constantly discarding dead cells. It consists of multiple layers of keratinocytes, melanocytes, and Langerhans cells.

The epidermis is sub-divided into 5 layers.

- A. Stratum corneum: The outermost layer of the epidermis. There are many cells which are tightly packed together, This allows the skin to be tough and waterproof. This layer is important in the prevention of invasion from foreign things, such as bugs and bacteria.
- B. Stratum lucidum: This layer contains several clear and flat dead cells. It is a tough layer and is found in thickened skin, including the palms of the hand and soles of the feet.
- C. Stratum granulosum: The stratum granulosum is composed of 3 to 4 layers of cells. Here, keratin is formed, which is a colourless protein important for skin strength.
- D. Stratum spinosum: This layer contains cells that change shape from columnar to polygonal. Keratin is also produced here.
- E. Stratum basale: This layer is the deepest layer of the epidermis, in which many cells are active and dividing. The stratum basale is separated from the next layer – the dermis – by a basement membrane, which is a layer made of collagen and proteins.

Main functions of each cell in the epidermis



Cell types	Main functions
Keratinocytes	Produce keratin as a protective barrier
Langerhan's cells	Present antigens and activate T-lymphocytes for immune protection
Melanocytes	Produces melanin, which gives pigment to the skin
Merkel cells	Contain specialized nerve endings for sensation

1.1.2.2. The dermis

The dermis is the second major layer of the skin. It is a thick layer made up of strong connective tissues. It is further divided into two levels – the upper is made of loose connective tissue, called the papillary region, and the lower layer is made of tissue that is more closely packed, called the reticular layer. The dermis is made up of a matrix of collagen, elastin and network of capillaries and nerves.

The collagen gives the skin its strength, the elastin maintains its elasticity and the capillary network supplies nutrients to the different layers of the skin. The dermis also contains a number of specialized cells and structures.

These include: hair follicles, sweat glands, sebaceous glands (produce sebum which helps lubricate skin & hair) and nails.

It also plays an important part in controlling our skin temperature and acts as a cushion against mechanical injury. When injured the dermis heals through the formation of granulation tissue (a tissue rich in new blood vessels and many different cells). This tissue helps pull the edges of a cut or wound back together. It takes our body from 3 days to 3 weeks to form this tissue.

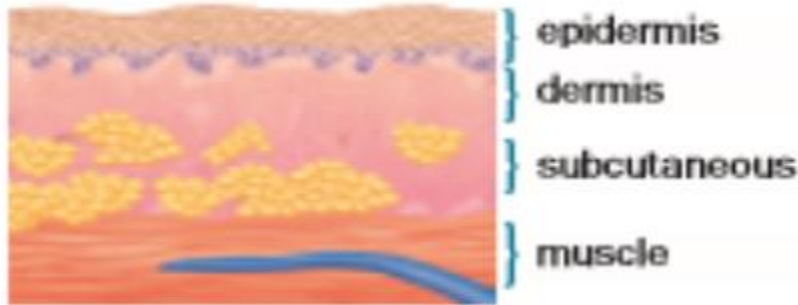


Fig 2. Layer of the skin

The dermis contains capillaries nerves, and also sebaceous glands and sweat glands. It provides a base for the epidermis and contains fibroblasts that elaborate proteins, such as collagens and elastin, which are crucial for the skin's structural integrity.

1.2. Physiology (role) of the skin

Thermoregulation

The skin helps us to maintain our body temperature. When we are hot, there is vasodilation (widening of blood vessels) at the skin surface. This cools us down by allowing more heat to escape. When we are cold, there is constriction (narrowing of blood vessels). This allows less heat to escape, helping conserve heat.

Metabolism

When we are hot or exercising, sweat glands in our skin excrete water salts and proteins. Once on the surface of the skin, sweat evaporates into the air. This cools the skin and helps us control our body temperature.

Sensation



There are many nerve endings and receptors that sense changes in the skin. This allows us to feel everyday objects, feel pain, determine hot from cold and also sense pressure.

Protection

As the skin covers our whole body and is a continuous layer, it acts as a barrier and protects the body from injury and infection. It also shields against the sun's light and radiation and prevents us from drying up.

Synthesis of vitamin D

When exposed to the sun's rays, the skin produces vitamin D3. This is essential for building strong, well shaped bones.

1.2.1. Types of skin

- There are five common skin types
 - I. Normal skin
 - II. Dry skin
 - III. Oily skin
 - IV. Combination skin
 - V. Sensitive skin

Blotting a clean tissue on your face in the morning is an easy way to find out your skin type. Individual skin type may change due to external (e.g climate , skin care) and internal (e.g medications, hormonal changes) factors over time

Knowledge of individual skin properties is helpful for choosing adequate skin care products and treatment regiments

I. Normal skin

- It display a smooth texture & clear surface, with fine pores
- Normal skin is often found in young person

II. Dry skin



- It characterized by a lack of moisture in its corneous layer , resulting in tightness and even flaking
- Dry skin can be genetically determined or triggered by factors such as climate , cosmetics and medications.
- It also can be a natural consequence of aging process

III. **Oily skin**

- Characterized by an increased amount of lipids on the skin surfaces to overactive sebaceous glands
- It is shiny and thick often with enlarged pores
- It occur more often in men and it predominantly affects adolescents and younger persons

IV. **Combination skin:** This is the common skin type

It is rather dry in some parts of the body and oily in other locations mixed facial skin tends toward dryness on the cheeks and around the eye while oily in others such as the T-zone (nose, forehead and chin area).

V. **Sensitive skin type**

This is not specific type of skin but patients tend to describe their skin as redness, itching, burning and dry.

1.3. **Anatomy and physiology of Hair**

1.3.1. **Introduction**

The hair follicle is one of the characteristic features of mammals serves as a unique mini organ. In humans, hair has various functions such as protection against external factors, sebum, apocrine sweat and pheromones production and thermoregulation. The hair also plays important roles for the individual's social and sexual interaction.



The hair follicle serves as a reservoir for epithelial and melanocyte stem cells and it is capable of being one of the few immune privileged sites of human body. Hair follicle development is related to the interactions between epithelial and mesenchymal cells. Many genes play substantial role in this interaction and also in hair follicle cycling.

- Hair can be defined as a slender , thread –like outgrowth from follicle in the skin
- The hair can present all over the body except for the sole , palm and lips
- It composed of structural protein called keratin.

1.3.2. Types of hair

- Human beings have several different types of hair
 - A. Lanugo
 - B. Down hair or vellus
 - C. Terminal hair
 - D. Hair of scalp , eyebrows and eye lashes

A. Lanugo :- the first to develop in human life

- It is a layer of downy , slender hairs that begin growing in the third or fourth month of the fetal life
- It shed either before or shortly after birth

B. Down hair or vellus:-

- it grow during the first few months of infancy period.
- They are fine, short and un pigmented
- They cover every part of the body except the palms of the hands the soles of the feet , undersurfaces of fingers and toes and a few other places

C. Terminal hair

- At and following puberty, down hair is supplemented by longer, coarser , more heavily pigmented hair called terminal hair



- It usually develops in the arm pits , genital regions and in male on the face and sometimes on parts of the trunk and limbs

D. Hair of the scalp , eyebrows and eyelashes

- These are separate types from the others and develop fairly early in life
- On the scalp ,where hair is usually densest , the average total number of hair is between 100,000 and 150,000
- Human hair grows at a rate of about 0.5inch(13mm)per month

Hair is continually shed and renewed. The average life of different varieties of hair varies from about 4 months for downy hairs to 3 to 5 years for long scalp hair

1.3.3.Hair anatomy

Nearly whole body surface is coated with the hairs except a few areas like palms, soles and mucosal regions of lips and external genitalia. Most of these are tiny, colorless vellus hairs. The ones located in several areas like scalp, eyebrows and eyelashes are thicker, longer and pigmented and are called terminal hairs. Humans have approximately 5 million hair follicles and 100,000 of them are located on the scalp.

Basically terminal hairs are found on scalp, eyebrows and eyelashes at birth while the rest of the body is covered with vellus hairs. In puberty, some vellus hairs (i.e. beard, trunk, axilla and genital area) by the influence of androgens differentiate to terminal hairs, which are long (>2 cm), thick (>60 μm), pigmented and medullated. The bulb of the terminal hairs is located in the subcutaneous fat; however, the bulb of vellus hairs is in the reticular dermis. Vellus hairs are thin (<30 μm), short (<2 mm) and mostly non-medullated.

The hair is classified into three main ethnic subgroups (Asian, African and European). However in a recent study, this classification is expanded to eight main subgroups by considering three parameters: curve diameter, curl index and number of waves .



Structural features of the hair follicle have to be considered during the classification process. Hair shaft diameters, hair follicle density and follicular infundibulum volume are some of them. Hair shaft diameters represent little variations and hairs are found to be thicker in androgen dependent areas. Hair follicle density is much more condense in the forehead and follicular infundibular volume is also bigger. It is important just because of the large follicular infundibular volume that is associated with more follicular reservoir ability.

1.3.3.1. Structure of the hair

Hair is consisted of two distinct structures: follicle—the living part located under the skin and hair shaft—fully keratinized nonliving part above the skin surface. The arrectorpili muscle, takes place between the hair bulge area and dermo epidermal junction. Above the insertion of the arrectorpili muscle, sebaceous glands and, in some certain regions, apocrine glands are opened into the follicle.

Hair shaft is consisted of three layers: cuticle, cortex and in certain cases medulla. Flat and square-shaped cuticle cells are adhered tightly to the cortex cells proximally. Peripheric movements of cuticle cells make the direction of the distal free edge upward and cause extensive overlapping. These imbrications are crucial. By interlocking with the cuticle cells of inner root sheath, they contribute to the follicular anchorage of the growing hair. These imbricated surfaces also facilitate removal of dirt and desquamated cells from the scalp. Cuticle has also important protective properties and barrier functions against physical and chemical insults.

During the migration of the cells from the hair bulb to compose the cortex, the shapes of them become more fusi form. These cells coalesce tightly and are placed parallel to the axis of the shaft. Axial keratin filaments (micro fibrils) that are formed from multiple hard α -keratin intermediate filaments (α -KIF) molecules, packs each cortex cells. Several microfibrils come together to form larger units called macro fibril which represents



almost 50% of the cortex material. The cortex comprises the bulk of the shaft and also contains melanin.

Medulla is located in the center of the hair shaft preferably presented in coarser fibers. The hair medulla contains structural proteins that are markedly different from other hair keratins and eosinophilic granules that are filled by an amino acid, citrulline and eventually form internal coatings within the membranes of mature cells.

The follicle is the essential growth structure of the hair and basically has two distinct parts: upper part consisting of infundibulum and isthmus whereas the lower part comprising of hair bulb and suprabulbar region. The upper follicle remains constant, while the lower part has continuous cycles of regeneration. The infundibulum, the uppermost portion of the hair follicle extending from the opening of the sebaceous gland to the surface of the skin, is a funnel-shaped structure filled with sebum, the product of the sebaceous glands. The upper part named acroinfundibulum, the keratinization of epithelium turns into the “epidermal mode”, with formation of stratum granulosum and stratum corneum like a similar manner to epidermis. The isthmus is the lower portion of the upper part of hair follicle between the opening of the sebaceous gland and the insertion of arrectorpili muscle. At the isthmus level, epithelium keratinization begins with the lack of granular layer named “trichilemmal keratinization”

The suprabulbar region of the follicle, below the isthmus and above the hair bulb, is comprised of three layers from outermost to innermost: outer root sheath, inner root sheath and hair shaft.

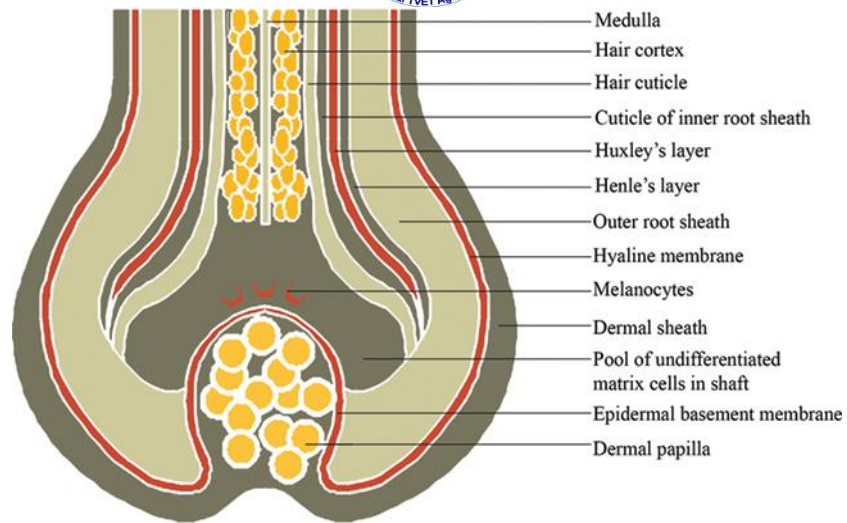


Figure-3: Diagram of proximal hair follicle

1.4. Physiology of Hair

Hair development is a continuous cyclic process and all mature follicles go through a growth cycle consisting of growth (anagen), regression (catagen), rest (telogen) and shedding (exogen) phases. The duration of the phases changes based on the location of the hair and also personal nutritional and hormonal status and age.

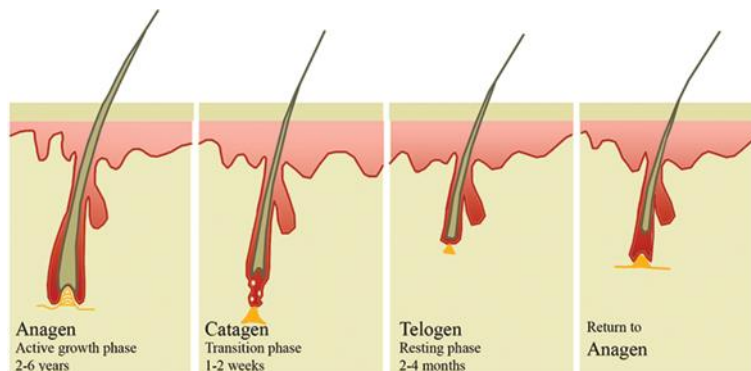


Figure-4: The hair cycle.

Anagen



The inception of anagen phase is presented by the onset of the mitotic activity in the secondary epithelial germ located between the club hair and dermal papilla in telogen hair follicle. The anagen is the active growth phase in which the follicle enlarges and takes the original shape and the hair fiber is produced. Almost 85–90% of all scalp hairs are in anagen.

Six portion of the anagen stage is demonstrated. Through the anagen I–V, hair stem cells proliferate, encloses the dermal papilla, grow downwards to the skin and begin to proliferate hair shaft and IRS, respectively. Subsequently, hair matrix melanocytes begin to develop pigment and the form of the hair shaft begins to arise; in anagen VI, hair bulb and adjacent the dermal papilla formation is realized and the new hair shaft appears from the skin. This phase can last up to 6–8 years in hair follicles.

Hair shaft synthesis and pigmentation only take place in anagen. The degree of axial symmetry within the hair bulb determines the curvature of the final hair structure [35]. Fiber length is often dependent on the duration of the anagen or actively growing phase of the follicle. The featured regulatory proteins in anagen phase are BMPs, sonic hedgehog, several WNT proteins and receptors. Insulin like growth factor-1 (IGF-1), fibroblast growth factor-7 hepatic growth factor (HGF), and vascular endothelial growth factor (VEGF) are thought to be important for anagen maintenance.

Catagen

At the end of anagen, mitotic activity of the matrix cells is diminished and the follicle enters a highly controlled involutionary phase known as catagen. Catagen lasts approximately 2 weeks in humans, regardless of the site and follicle type. During catagen the proximal of the hair shaft is keratinized and forms the club hair, whereas the distal part of the follicle is involuted by apoptosis.

Catagen phase is consisted of eight different stages. The first sign of catagen is the termination of melanogenesis in the hair bulb. Follicular epithelium, mesenchyme, neuro ectodermal cell populations and also perifollicular vascular and neural systems



demonstrates cyclic changes in differentiation and apoptosis. However, any apoptosis is occurred in dermal papilla due to the expression of suppressor bcl-2.

Catagen is a process of bulbar involution. The perifollicular sheath collapses and vitreous membrane thickens. Eventually, the lower hair follicle becomes reduced to an epithelial strand, bringing the dermal papilla into close proximity of the bulge [36]. The epithelial strand begins to elongate and finally reaches to just below the insertion of pilar muscle. After the keratinization of the presumptive club hair, the epithelial strands begin to involute and shorten progressively followed by the papilla which condenses, moves upward and locates to rest below the bulge. The column eventually reduces to a nipple and forms secondary hair germ below the club. The club hair itself is formed from cortical and cuticle cells only, and it is characterized by a lack of pigmentation [2, 37]. The presence of hairless gene mutation contributes to the failure of dermal papilla migration toward the bulge area in catagen phase [3]. FGF5 is a key inducer of catagen and FGF5-deficient mice have a prolonged anagen phase. In addition to FGF5, TGF- β 1, IL-1b, the neurotrophins NT-3, NT-4 and BMP2/4 and TNF- α have been described to induce catagen.

Telogen

The telogen stage is defined as the duration between the completion of follicular regression and the onset of the next anagen phase. Telogen stage lasts for 2–3 months. Approximately 10–15% of all hair is in telogen stage. During the telogen stage, the hair shaft is transformed to club hair and finally shed. The follicle remains in this stage until the hair germ which is responsive to anagen initiating signals from the dermal papilla, starts to show enhanced proliferative and transcriptional activity in late telogen, leading to the initiation of anagen

Telogen is one of the main targets of hair cycle which is influenced by several modulatory agents like androgens, prolactin, ACTH, retinoids and thyroid hormones. No unique molecular markers associated with the telogen follicle are determined yet; however, estrogen receptor expression is reported to be limited to the telogen papilla



fibroblasts. Germ cells of telogen follicles also express basonuclin and FGF-5. The bone morphogenic protein-4 (BMP-4) as a growth factor plays an essential role in suppressing follicular growth and differentiation at telogen stage.

The macro-environment surrounding the hair follicle also takes part in regulating cycle transitions. BMPs in the subcutaneous fat are capable of maintaining follicles in a “refractory” telogen, and cessation of this inhibitory activity by BMPs enables the follicle to progress to a “competent” telogen with a hair germ that is responsive to anagen-initiation signals and capable of entering a new anagen phase

Exogen

There is less interest for the mechanism of the hair shedding but from the patient’s perspective it is probably the most important part of the hair growth. It is not unusual for human telogen hairs to be retained from more than one follicular cycle and this suggests that anagen and exogen phases are independent. The shedding period is believed to be an active process and independent of telogen and anagen thus this distinct shedding phase is named exogen

1.4.1. Hair cycle clock

Based on the observations: the hair follicle has no need for intact innervation, vascularization or other extra follicular components to maintain cycling, and the basic oscillator system which controls hair cycling is located presumably in the follicle. The principal challenge is to define the underlying “oscillator” system. Probably, the hair cycle clock is controlled by regulating the balance of the interactions between the follicle epithelium and the surrounding mesenchyme. This might be provided by the rhythmic secretions of growth/modulatory signals from follicle epithelium or mesenchyme as well as the rhythmic alterations in the expressions of corresponding receptors



1.5. Anatomy and physiology of nails, hand and foot

A **nail** is a claw-like keratinous plate at the tip of the fingers and toes in most primates. Fingernails and toenails are made of a tough protective protein called alpha-keratin. It is a horn-like envelope covering the tips of the fingers and toes. It is made from a tough protective protein called alpha-keratin. The average growth rate for nails is 0.1mm each day (1cm in 100days). The exact rate of nail growth depends on numerous factors include age and sex of the individual and the time of year .

Finger nails generally grow faster in young people, in male and in the summer. It grows faster than toe nails. The finger nails on the right hand of a right-handed person grow faster than those on their left hand and vice versa.

1.5.1. Parts of nail

- **Nail plate**- the visible parts of the nail
 - **Nail bed**- the skin beneath the nail plate
 - **cuticle**- the tissue that overlaps the plate and rims the base of the nail
 - **Nail folds**- the skin folds that frame and support the nail on three sides
 - **lunula**-the whitish half-moon at the base of the nail
 - **Matrix**- the hidden part of the nail unit under the cuticle
- ✓ Finger nail grows from the matrix
- ✓ As new cells grow in the matrix the older cells are pushed out, compact and take on the familiar flattened hardened form of the finger nail

1.5.2. Function of Nail

- Protect the finger tips from injury
- Enhance the delicate movements of the digits
- Enhance the sensitivity of the fingertip
- Function like a tool enabling the organism to cut or scrape things.



- For social grooming specifically in primates



Self-Check –1	Written Test
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Direction: Match terms in column “A” with statement stated in column “B”. Use the Answer sheet provided in the next page.

No	A	B	
1	Epidermis,	A	Produces melanin, which gives pigment to the skin
2	Melanocytes	B	Contain specialized nerve endings for sensation
3	Merkel cells	C	Produce keratin as a protective barrier
4	Dermis	D	the outermost layer of skin
5	Langerhan’s cells	E	Present antigens and activate T-lymphocytes for immune protection
6	Hypodermis	F	contains tough connective tissue, hair follicles, and sweat glands
7	Keratinocytes	G	deeper subcutaneous tissue

Note: Satisfactory rating – 3.5-7points

Unsatisfactory - below 3.5 points

Answer Sheet

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

Score = _____
Rating: _____



Name: _____

Date: _____



Information Sheet 2- Cosmetics and cosmetic preparations

2.1. Definition of cosmetic & cosmetic products

The word **cosmetic** is derived from the Greek word *kosmtikos* meaning having the power or skill to decorate.

Cosmetology is the science of *beautifying* the skin and its appendages, which play an important role in socio-sexual communication. The scientific knowledge of cosmetology *enables to give rational treatments and aesthetically acceptable* results and prevent patient's indulgence in unscientific methods.

Cosmetics: are substances used to enhance or protect the appearance or odor of the human body. They are also defined as preparation that intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance. Their use is widespread, especially among women.

Cosmetic products are defined as any substances or preparations that are intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips, eyes and external genital organs)

- Modern natural cosmetic products are free from potentially harmful substances and help promote our looks without damaging our skin.

In another word cosmetics is:

- Product that helps improves external appearance and has the ability to hide, or at least distract from, unwanted stigmata or skin defects.



- A product that changes the color of hair is a cosmetic, as is a product intended to increase the skin's tendency to tan by exposure to sun.
- Laws and rules covering the distinction between cosmetics and drugs differ from country to country.
- Soap is specifically excluded from cosmetics in the FDCA (Food, Drug, and Cosmetics Act) and no cosmetic or drug regulations are applicable to soap.
- The devices used in applying the cosmetics as brush, comb razor blades they are not included in cosmetics

Cosmetics include

- Skin-care creams,
- Lotions, powders,
- Perfumes,
- Lipsticks,
- Fingernail and toenail polishes,
- Eye and facial makeup,
- hair colors,
- Hair sprays and gels,
- Deodorants,
- Baby products, bath oils,
- Bubble baths,
- Bath salts,
- Butters and many other types of products

Therapeutic cosmetology

- Involves passage of active ingredients across the skin thereby altering the physiology of the area.

Cosmeceuticals:

- are cosmetic products that have therapeutic benefits against degenerative skin conditions. "Cosmetics" hide the age and enhance the attractive features.
- "Cosmeceuticals" do not just hide the age, they slowdown ageing.
- They do not just enhance the attractive features, they keep them long lasting.



- Cosmeceuticals: do not just benefit the skin condition, they impart therapeutic usefulness too.
- Nutricosmetics: is all about eating & drinking to attain health & beauty from within.
 - ✓ It refers to nutritional supplements which can support the function and the structure of the skin.

E.g, Vitamin C has anti-oxidant effect that reduces the impact of free radicals in the skin and also has a vital function in the production of collagen in the dermis.

2.2. Medicated and non-medicated cosmetics

- **Non-medicated** – a cosmetic only clean, beautify, alters the appearance but it does not have any medicinal effect on the body. These are cosmetic products which do not have any pharmacological active ingredients use only for its cosmetic value by the customer.
- **Medicated-** these are cosmetic products contain pharmacological active ingredients for the purpose of curing some form of dermatological problem
 - ✓ So these kinds of products have therapeutic value beside its cosmetic value

2.3. Principles in the preparation of medical cosmetics product

Cosmetics products are dissolved into or mixed with different kinds of chemical additives. The excipients may be used to bulk up cosmetic formulations with very potent target substances, to allow for convenient and accurate dosage. They are only used when absolutely necessary and in the smallest amounts possible.

The duration of cosmetic products is affected by denature of active ingredients, fall out of solution or stick to the sides of the container. So that the product may not stay for long. For these reasons, the product will be prepared with certain excipients that are important to keep the stability of the cosmetic products. This ensures that the target



ingredient stays "active", and, just as importantly, stable for a sufficiently long period of time.

All ingredients in cosmetics, as well as their chemical decomposition products are to be identified and guaranteed to be safe. These products contain three main group of substances

- ✓ active ingredients
- ✓ base (vehicle)
- ✓ .additional /auxiliary substances

2.3.1. Active ingredients

These substances have pharmacological action to cure some problems in the skin

2.3.2. Base /vehicles

These are substances incorporate in the preparation for optimized moisturizing or to maximize the penetration of active ingredients in to or through the skin

-the base can contain water, oil, alcohol or propylene glycol

2.3.3. additional /auxiliary substances

These includes preservatives, emulsifiers, absorption promoters, colorant and fragrances

The cosmetic product formula consists of:

- **Fillers/Diluents/vehicle:** fill out the amount of the product, making it practical to produce and convenient for the consumer to use.
- **Color additives:** added to improve appearance of a formulation.
- **Lubricants:** added to prevent ingredients from clumping together and from sticking the processing machines.
- **An antioxidant:** preventing the oxidation of other additives



- **Fragrances:** Give the product a fresh, pleasing odor and cover up the smell of other ingredients.
- **Preservatives:** added to keep any product that includes water and oil from decay.
- **Humectants:** a substance that absorbs water from the air and hold the moisture in the skin or helps retain the moisture. **Humectants** must have appropriate water absorption ability, maintain moisture in the skin, have lowest possible volatility, be safe, be colorless, odorless and tasteless, and have densities matching the system they are used in. E.g. Glycerine, Propylene glycol, Sorbitol, Sodium lactate.
- **Emollients:** added to soothe and lubricate rough skin by fill in the spaces between the cells in the skin.

2.4. Classification of cosmetic preparations

2.4.1. Based on physical forms

Based on physical forms cosmetic products can be classified as

- Liquid cosmetic products:- includes solution like shampoo , nail polish cleaner , perfume
- Solid cosmetic products- includes bar soaps, lip balm , solid block deodorants , eye and lip liners in the form of pencils and lipsticks
- Semisolid cosmetic products- creams, gels, bath or shower gels and waxes
- Gaseous cosmetic products- aerosol deodorants or antiperspirants

2.4.2. Based on function

Based on function we can classify cosmetics as

Cleansers: soaps, shampoos,

Beautifiers: makeup

Cosmetics alters appearance of body's structure or feature –moisturizers ,gels , hair dyes , nail polish



2.4.3. Based on body part to be applied

Cosmetics are intended to be applied externally and based on the site we can classify cosmetic in to different category. Cosmetics products that can be applied on face : skin care creams , lipsticks , eye and facial makeup and ; To the body: deodorants , lotions ,powders, perfumes ,bath oils , bubble baths and body butters

They can be classified based on widely used body parts as:

- ✚ Hair cosmetics
- ✚ Face cosmetics
- ✚ Eye make ups
- ✚ Lip decorators and carers
- ✚ Nail cosmetics
- ✚ Skin cosmetics
- ✚ Oral cosmetics

2.4.4. Hair product

2.4.4.1. Hair color (Dye)

- Hair coloring or hair dying is the practice of changing the hair color. The main reasons for this are:
 - ✓ to cover gray or white hair
 - ✓ to change to a color regarded as more fashionable
 - ✓ to restore the original hair color after it has been discolored by hair dressing process or sun bleaching



Fig. Hair Dye

2.4.4.1.1. Types of hair color

- A. **Temporary hair color:** This is a larger molecule lays on top of the hair cuticle instead of penetrating it. Because harsh chemicals are not involved in the process, you can switch things up as often as you like they last for about six weeks and tend to fade progressively with hair washing
- B. **Permanent hair color:** This is also known as oxidation because an oxidizer (such as hydrogen peroxide and ammonia) are mixed with the coloring agent before application. Permanent dyes don't have to be applied as often as semi-permanent dye. In general , permanent color will remain on your hair until hair grows , exposing the roots

2.4.4.2. Shampoo and conditioners

2.4.4.2.1. Shampoo

- A viscous cosmetic preparation with synthetic detergent used for washing hair is called shampoo. Its principle function is to clean the scalp such that it should become free from sebum and foreign substances. Shampoo also makes the hair lustrous and good looking. In olden days detergent soap were used for washing hairs, but nowadays it has been replaced by shampoo .Today shampoo has become an important hair cosmetic for both men and women. However the detergent and other raw materials selected for shampoo preparation should be



non toxic to tile scalp, eyes etc. Apart from cleaning, shampoo may also be used for medicinal purpose (i.e., medicated shampoo). After preparation each and every shampoo must be evaluated.

- . It is used by applying it to wet hair, massaging the product in to the hair , and then rinsing it out with water. The goal of using shampoo is to remove the unwanted build-up in the hair with out stripping out to much sebum as to make hair unmanageable. It is generally made by combining a surfactant , most often sodium laury sulfate or sodium laureth sulfate, with a co-surfactant , Other ingredients are generally included in shampoo to maximize the following quality
 - ✓ pleasing foam, ease of rinsing
 - ✓ minimal skin and eye irritation
 - ✓ Low toxicity, Good biodegradability
 - ✓ No damage to hair
 - ✓ Repair of damage already done to hair

Specialty shampoos are available for people with dandruff, color-treated hair, baby shampoo(less irritating) . There are also shampoos intended for animals that may contain insecticides

Properties:

- It should have optimum viscosity such that it facilitates ease during application.
- It should have good spreading properties.
- It should produce sufficient lather after application.
- It should be able to remove waste material such as debris, soil, sebum, dead cells,
- It should not form any kind of film on scalp.
- It should rinse out completely after washing.
- It should produce lather with both hot and cold water.
- It should facilitate ease of combing after shampooing.
- After drying, the hair should not give rough appearance.



- It should provide lustre to the hair.
- It should produce good odour both before and after shampooing.
- It should not produce any kind of irritation or itching to the scalp.
- It should not support any microbial growth.
- It should be stable and have a half life of about 2 to 3 years.
- It should be economical.

2.4.4.2.1.1. Types of shampoo

Various types of shampoos are available and they are classified based on their consistency. They are as follows:

- I. **Clear Liquid shampoo:** These are clear liquid preparations that are most widely used. They are usually made by using detergent of low cloud point.
- II. **Liquid cream shampoos:** These are called as lotion shampoos which are modification of clear liquid shampoos.
- III. **Cream shampoos:** These shampoos have a paste like consistency and are packed in a collapsible tube. They find great use in hair salons.
They are also available in jars with wide mouth. The paste consistency is developed by addition of alkyl sulphates, also Cetyl alcohol is added, which serves as a builder.
- IV. **Gel shampoos:** These are transparent and thick usually made by incorporating a gelling agent, (e.g., cellulose). There is great use in hair salons and beauty parlors. The principle ingredient is detergent which can be used either alone or in combination with soap.
- V. **Powder shampoos:** As name suggests, it is available in the form of dry powder, initially it was prepared from dry soaps, but nowadays dry synthetic detergents are used for their preparation. Powder shampoo is prepared where addition of water or other solvent reduces the activity of the components, especially in case of medicated shampoo. Nowadays, these shampoos are not used due to the difficulty experienced in their application.



VI. **Aerosol shampoos (Foam type):** They are called aerosol shampoos because they are packed in aerosol containers .Their formulation, preparation and packing is complicated as an additional propellant is included. The propellant added must be compatible and should not reduce the activity of shampooing ingredients. The container opening is provided with a valve. Shampoo comes out as foam when the valve is pressed .Hence also called as foam type shampoo.

VII. **Special shampoos:** These are the shampoos which are meant for special purpose. They are

(a) Medicated Shampoo: These shampoos contain medicinal agents. These agents treat the disorders of the scalp or hair. Examples of medicated shampoos are: Anti-lice shampoo, Antidandruff shampoo, Anti-baldness shampoo etc,.

The medicinal agent added should not irritate the sebaceous glands. It should not sensitize the scalp. The degree of itching and scaling should also be reduced. Among all, anti dandruff type of medicated shampoo is most widely used.

(b) Conditioner Shampoos: These shampoos serve for hair conditioning. Initially they clean the hair (and scalp) and keep them in smooth and lustrous condition. They also prevent sticking of hairs. Conditioner shampoo nowadays is widely used by both men and women. Most of the conditioners are made from Quaternary ammonium compounds. These compounds have the property of reducing electric charges between the hair, as a result hair become lustrous easily manageable. These compounds can also exhibit a bactericidal effect.

2.4.4.2.2. Conditioner

This is a hair care product that change the texture and appearance of hair. This is often a viscous liquid that is applied and massaged in to the hair. It is usually used after washing the hair with shampoo



- Hair conditioners may contain moisturizers , oils and sunscreen, among with other ingredients

2.4.4.2.2.1. **Types of conditioner**

Pack conditioners

- are heavy and thick ,with a high content of surfactants that are able to bind to the hair structure.
- These are usually applied to hair for a longer time.

Leave-in conditioners

- Are thinner and have different surfactants , forms thinner layer on the hair
- This is designed to be used in similar way to hair oil , preventing the tangling of hair and keeping it smooth
- Its use is particularly prevalent by those with naturally curly or kinky hair

Ordinary conditioners

- Combine some aspects of pack and leave in conditioners
- This is generally applied directly after using shampoo

Hold conditioners

- These hold the hair in a desired shape
- These have a function and composition similar to diluted hair gel.

2.4.4.2.2. **Ingredients used to make conditioner**



- **Moisturizers** - hold moisture in the hair . usually contain high proportions of natural oils
- **Re constructors** - role is supposedly to penetrate the hair and strengthen its structure
- **Acidifiers, acidity regulators** - which maintain the conditioners pH at about 3.5.
- **Thermal protectors** - usually heat absorbing polymers, shielding the hair against excessive heat caused by e.g. blow-drying, curling irons or hot roller
- **Glossers-** light reflecting chemicals which bind to the hair surface usually silicones e.g. dimethicone
- **Oil** (EFAs- essential fatty acids) -help dry/porous hair become more soft and pliable.
 - The scalp produces a natural oil called sebum. EFAs are the closest thing to natural sebum
- **Surfactant** – hair conditioners usually contain cationic surfactants , which don't wash out completely, because their hydrophilic ends strongly bind to keratin . the hydrophobic ends of the surfactant molecules then act as the new hair surface
- **Hair Tonics:** Are preparation which are applied to the hair for curing baldness, relieving oily or dry skin and to prevent or cure dandruff. It contains a combination of at least 2 to3 ingredients i.e sebaceous gland stimulant, rubefacient and an antiseptic.
- **Hair growth promoter:** Are preparations made by adding various pharmaceutical agents to an alcohol-water solution which are applied to the scalp to normalize its functions

E.g. Minoxidil promotes a growth of fine hair any place on the skin where there are hair follicles.
- **Hair removers (depilatory):** Used to remove unwanted hair from the body. They are available as solid, semisolids (as cream form)



- Lubricant
- Preservatives
- Sun screen for protection against protein degradation and color loss

2.4.4.3. Hair styling aids

- These products used to change the texture and/or shape of hair , or to hold a hairstyle in place.

2.4.4.3.1. Types of hair styling aids

Hair gel

- Is used to stiffen hair into a particular hairstyle
- The end result is similar to, but stronger than, those of hair spray and hair wax
- It is most commonly used in the hairstyling of men , but it is not gender specific
- It can come in tubes, pots, small bags or even in spray form

Hair wax

- Is a thick hair styling product containing wax , which helps hold hair in place
- Unlike some products such as hair hard in texture , hair wax leaves the hair pliable

Hair spray

- Is used to stiffen hair into a certain style. Weaker than hair gel or hair wax, it is sprayed directly on to the hair to hold styles for long periods of time.
- It sprayed directly onto the hair to hold periods of time



- It sprays evenly over the hair using a pump or aerosol spray nozzle

2.4.4.4. Hair ornaments

Hair accessories are functional or ornamental objects wrapped, tied ,twisted ,inserted or otherwise attached to the hair. Hair ring and hair bands are cylindrically shaped hair accessories wound around the hair, designed to hold hair away from the face , or otherwise confine strands of hair.

2.4.4.5. Brushes, combs

Hair brushes

- is a stick brush with rigged or soft bristles used in hair care for smoothing , styling and combing human hair .
- It can also used for styling with a curling iron or blow dryer.

Hair comb

- Is a toothed device used for styling, cleaning and managing hair and scalp. Combs are among the oldest tools found by archaeologists , having been discovered in very refined forms from settlements dating back to 5000 years ago in Persia.

2.4.4.6. Hair blow dryers

- A hair dryer or blow dryer is an electromechanical device designed to blow normal or hot air over damp hair to accelerate the evaporation of water particles and dry the hair.Types of hair blow dryer

There are two major types

- ✓ Hand held blow dryer
- ✓ Rigid hood blow dryer





2.4.5. Beautifying products (additive, properties, preparation, use, application)

2.4.5.1. Skin care products for face and body

Face cosmetics

- Face powder – prevents facial sweating
- foundation – a cream or powder applied to the face as a base for other make-up
- Cold cream- is the cosmetic preparations which are applied on the face. The name cold cream is given because of cooling effect of such preparation on the skin.
- vanishing creams- are o/w type emulsion

Characteristics of face powder:

- It should be very fine and should not have any gritty particles; the ingredients should be evenly distributed; non-toxic and non-irritant to the skin; chemically and physically stable; spread easily and adhere to the skin; good absorbing property; good to remove shine from the face, and so forth.
 - ✓ A color corrector; is a type of makeup used to cover pimples, dark circles and other small blemishes visible on the skin. It is mainly used by women but also by some men
 - ✓ **Rouge (Blush)**: to redden the cheeks to provide a more youthful appearance, and to emphasize the cheekbones in the forms of compact, liquid, cream and stick. It is a cosmetic typically used by women.



- ✓ **Foundation:** skin colored cosmetics which give uniform color the face and conceal flaws (defect) to produce an impression of health and youth which are usually prepared as a liquid, cream, or powder.
- ✓ **Cold cream:** cosmetic preparation which applied to smooth face and remove makeup

Eye cosmetics (make up)

- **Eye liner:** is a cosmetic used to define the eyes to create a variety of beautiful appearance.
- **Eye shadow:** Is applied to eyelids and corners of the eyes to create shadow and produce a sense of relief in order to emphasize the beauty of the eyes.
 - ✓ The quality requirements for eye shadows include:
 - ✓ They should be easy to apply smoothly and have good skin adhesion
 - ✓ They should have no oily luster when applied
 - ✓ There should be no change in color
 - ✓ They should not be spoiled by sweat or sebum and maintain a good appearance
 - ✓ They should be highly safe as they used around the eyes
- **Mascara:** is a cosmetic used to darken, thicken and define eyelashes to emphasize, thicken, lengthen, and define lashes. It is available with tube and wand applicators.
- Quality requirement for mascara are as follows.
 - ✓ They should: be non-irritating, not harden the eyelashes; make the eyelashes look thick and long, have an appropriate shine, have an appropriate drying time not go on the lower eyelids and their appearance, must not be spoiled by sweat, tears or rain; be easy to remove; be easy; and not be contaminated by microorganism.
- **Eye wrinkle care products:** are products that produce humectants effects used to prevent the skin around the eyes from drying.



- **Eyebrow cosmetics:** Are used after adjusting the form of the eyebrows with razors or scissors or by plucking out hairs to draw in the desired form, to make darker in color or brighter
- **Eye makeup remover:** To remove the different types of makeup

Skin cosmetics

These are cosmetics are applied to the dead cells of the corneal layer.

- Soap
- Skin cleansing liquids
- Skin moisturizers
- Skin whitening products
- Shaving preparations
- Antiperspirants and deodorants

The basic function of skin cosmetics

- ✚ Anti-drying, cleansing, ultraviolet damage prevention, anti-oxidation and invigoration
- ✚ Clean up skin problems
- ✚ Whitening effect to combat skin aging associated troubles
- ✚ Prevent wrinkles, sagging skin and acne
- ✚ To mask body odor

Moisturizers (emollients)

- ✚ Hold moisture in the skin.
- ✚ Work best when applied while the skin is still wet from a bath or shower.
- ✚ Don't actually add moisture to skin.
- ✚ Form a physical barrier that hinders evaporation of water from the skin.

Anti-aging cream



Moisturizer based skin care products marketed with the promise of making the consumer look younger by reducing visible wrinkles, expression lines, blemishes, pigmentation changes, discolorations of the skin.

✚ **Retinol:** to reduce fine lines and pores.

✚ **Epidermal Growth Factor:** to stimulate cell renewal and collagen production in the skin and strengthen elasticity and structure.

Alpha hydroxyl acids: help dissolve the intracellular "glue" that holds the dead cells together on the skin and enhances the exfoliation of the dead cells.

✚ **Antioxidant**

Depilatories: have the property of removing hair from the skin

Bronzers: are cosmetic product that darken skin color

Antiperspirants and deodorants: Cosmetics for preventing body odor contain antiperspirant perfumes and antibacterial agents

Antiperspirants: Are topically applied products designed to reduce underarm wetness by limiting eccrine sweat production?

- Zirconium and aluminum chlorides, aluminium hydrochloride, potassium aluminum sulfate, zinc oxide and zinc parphenolsulfonate

Deodorants: Are topically applied products designed to reduce underarm odor.

✚ Application forms for deodorant actives

✚ Typical application forms are sticks, roll-ons, creams, pump sprays, aerosols, and gels

✚ Sunscreen formulation: block sun induced skin problem which are available in creams and lotions.

Lip decorators and carer

Lip gloss: is a cosmetic product used to give the lips shine and sometimes subtle color prepared as a liquid or a soft solid.



Lip balm: is a lip cosmetic product which generally has medicinal purposes

Lipstick (Lippy): is a cosmetic product containing pigments, oils, waxes, and emollients that applies color and texture to the lips.

-



Quality of good lipstick, it should

- ✚ Be non-toxic and non-irritating
- ✚ Be free from gritty particles
- ✚ Be easily applicable and easily removable if need arises
- ✚ Be good odor
- ✚ Give shine and smooth appearance
- ✚ Be not dry on storage
- ✚ maintain its lip color long after application
- ✚ not break during use and it should maintain its firmness till whole of it is used up

Oral cosmetics

- ✚ Divided into oral cleansing products and mouth fresheners oral cleansing products
- ✚ Preparation for external use which clean the teeth and surrounding them, cleanse and refresh the inside of the mouth, prevent dental caries and periodontal disease
- ✚ Divided in to dentifrices and mouthwash

Dentifrices (Toothpastes)

- ✚ Preparation meant to be applied to the teeth with a tooth brush for cleansing the accessible surfaces of the teeth to enhance appearance of the teeth, reduce tooth decay and bad odor of the mouth and make the gum healthy
- ✚ Dentifrices are found in the form of tooth powder, toothpaste and liquid-form dentifrices
- ✚ Ingredients include: polishing agents (abrasive), surface active agents (detergent), humectants, binders, sweetening agents, Flavoring agents, preservatives



Qualities of dentifrices

- ✚ It must remove foreign particles, food substances, plaque and clean the teeth
- ✚ Must be non-toxic
- ✚ Must be properly flavored and sweetened
- ✚ Must leave the mouth with a refreshing after-taste

Mouth washes (Mouth rinse): Used to clean the inside of the mouth, prevent halitosis and refresh the mouth.

- ✚ Similar in form to a liquid-form dentifrice but used without toothbrush
- ✚ Ingredients: ethanol, and other solvents, humectants, solubilizers, flavoring agents, preservatives and pH regulators

Mouth Freshener: Is preparation for internal use designed to prevent nausea and other feelings of discomfort.

- ✚ They are found in the form of pills, lozenges and liquids
- ✚ Ingredients used to flavor mouth fresheners have a strong freshening effect and include
 - cinnamon, mint oil, fennel oil, D-camphor, L-menthol
 - Depending on the form of mouth refreshner, other diluting agents, flavoring agents and preservatives are also used

2.4.5.2. Sunscreen and tanning products

2.4.5.2.1. Sunscreen

- A cream or lotion rubbed on to the skin to protect it from the sun.

Uses

Sunscreens are used to protect the skin from the harmful effects of the sun. They help to prevent sunburn and premature aging (such as wrinkles, leathery skin).



Sunscreens also help to decrease the risk of skin cancer and also of sunburn-like skin reactions (sun sensitivity) caused by some medications (including tetracyclines, sulfa drugs, phenothiazines such as chlorpromazine). The active ingredients in sunscreens work either by absorbing the sun's ultraviolet (UV) radiation, preventing it from reaching the deeper layers of the skin, or by reflecting the radiation. Wearing sunscreen does not mean that you can stay out longer in the sun. Sunscreens cannot protect against all of the sun's radiation. There are various types of sunscreens available in many forms (e.g., cream, lotion, gel, stick, spray, lip balm).

How to use Sunscreen Gel

Sunscreens are for use on the skin only. Follow all directions on the product package. If you have any questions, ask your doctor or pharmacist. Apply sunscreen generously to all exposed skin 30 minutes before sun exposure. Reapply the sunscreen after swimming or sweating or drying off with a towel or if it has rubbed off. If you are outside for long periods, reapply sunscreen every 2 hours. If you are using the lip balm form, apply to the lip area only.

The spray form is flammable. If using the spray, avoid smoking when applying this medication and do not use or store it near heat or open flame. When applying sunscreen to the face, be careful to avoid contact with the eyes. If the sunscreen gets in your eyes, rinse thoroughly with water. Use cautiously or avoid use on irritated skin. Do not use sunscreen on infants younger than 6 months unless the doctor directs you to do so. It is best for infants to stay out of the sun and wear protective clothing (e.g., hats, long sleeves/pants) when outdoors. If you develop a serious sunburn, or if you think you may have a serious medical problem, seek immediate medical attention.

2.4.5.3. Nail, hand and foot care products

2.4.5.3.1. Nail cosmetics

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Nail polish: Nail lacquers or nail paints

Nail lacquers or nail paints may be defined as viscous or semi-liquid preparations that are intended for the decoration of the nails of the fingers and toes. Nail lacquers form the most commonly used the most popular type of manicure preparations. Nail polishes are quite distinct from those of nail lacquers and are regarded as a type of manicure preparations that produce a gloss by means of huffing action. The action is mainly by causing abrasion on the surface of the nail and secondly by drawing more blood into the capillaries of the nail.

- is a polish that is applied to the nails of both the fingers and toes, usually cosmetically for an aesthetic advantage

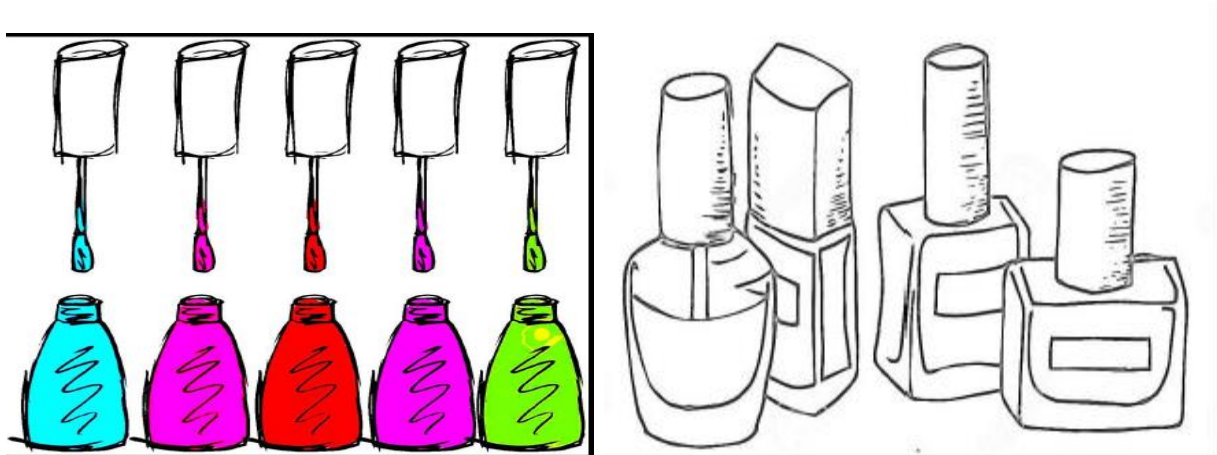


Fig. Nail lacquers

The perfect nail polishes (lacquers)

- ✓ Has to be easy to apply, and it should dry quickly



- ✓ Should leave a shiny, smooth, even, hard, and flexible film that is able to last five days
- ✓ Should be removed without leaving any trace and should not have any side effects
- ✓ Should be stable in the bottle
- ✓ Should offer a wide range of colors, enabling one to get the expected aesthetic effect

Unwanted Effects of Nail Polishes

- The nail polishes can cause an orange staining of the nail plate
- Nail lacquer can cause keratin granulation
- Nail varnishes can also cause allergic contact dermatitis, more rarely, contact urticarial

Nail Polish Remover

- Dissolve nitrocellulose and remove lipids from the nail plate.
- They mainly contain a mixture of organic solvents, with small amounts of oils added to counteract the drying effect of the solvents.
- Should not be used more than once a week and should not be left too long in contact with the nails and the skin



Self-Check -2	Written Test
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Direction:-Match column “A” with column “B”. Use the Answer sheet provided in the next page.

No	A	B	
1	Hair wax	A	Is a toothed device used for styling, cleaning and managing hair and scalp.
2	Minoxidil	B	Are preparation which are applied to the hair for curing baldness
3	Hair comb	C	Is a thick hair styling product containing wax , which helps hold hair in place
4	Depilatory	D	Is used to stiffen hair into a particular hairstyle
5	Hair Tonics	E	Used to remove unwanted hair from the body
6	Hair gel	F	Promotes a growth of fine hair any place on the skin where there are hair follicles.
7	Face cosmetics	G	Foundation
8	Eye cosmetics	H	Dentifrices
9	Skin cosmetics	I	Mascara
10	Oral cosmetics	J	Deodorants

II. Write true for correct statements and false for incorrect statements

1. A cosmetic has no healing effects.
2. Soap is not considered as cosmetics.
3. Mouth fresheners is used to prevent nausea and other feelings of discomfort.
4. Moisturizers work best when applied while the skin is still wet from a bath or shower.



5. Mascara is a cosmetic used to darken, thicken and define eyelashes.

Note: Satisfactory rating - 10points

Unsatisfactory - below 10 points

Answer Sheet

Score = _____
Rating: _____

Matching

1. _____
2. _____
3. _____
4. _____
5. _____

True/ False

1. _____
2. _____
3. _____
4. _____
5. _____

Name: _____

Date: _____



L #17, LO # 2- Provide information on cosmetics

Instruction sheet

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics:

- ✚ Required information on cosmetic Brand options
- ✚ Customer requirements
- ✚ Advising customers
- ✚ Legislative requirements
- ✚ Cosmetics storage policy and procedure

This guide will also assist you to attain the learning outcomes stated in the cover page. Specifically, upon completion of this learning guide, you will be able to:

- ✚ Evaluate Products according to customer needs and product information.
- ✚ Demonstrate Features and benefits of products to customer to create a buying environment.
- ✚ Apply knowledge of cosmetics product to provide accurate advice to customers regarding product performance according to manufacturer's information and legislative requirements.
- ✚ Explain Products fully and clearly according to store policies and procedures and legislative requirements.
- ✚ Advise/demonstrate to customers who are unfamiliar with aspects of product use.
- ✚ Follow according to store Policy

Learning Instructions:



1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described below.
3. Read the information written in the “Information Sheets”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-checks” which are placed following all information sheets.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-checks).
6. If your performance is satisfactory proceed to the next learning guide,
7. If your performance is unsatisfactory, see your trainer for further instructions or go back to “Information sheets”.



Information sheet 1- Providing information on cosmetics

Role of the Pharmacy professional in providing cosmetics product information

The expected role of pharmacy technicians is:

- ✦ Provide information on cosmetics
- ✦ Delivering product knowledge developed and maintained by accessing relevant sources of information.
- ✦ Storing product accurately according to product information and informing the consumers too.
- ✦ Transmitting product information to other staff members as required.
- ✦ Helping customer choose the best product suit to him/her
- ✦ Comparing between products and services researched and accurately applied according to product information.



Self-Check -1	Written Test
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Direction: Answer the following questions. Use the Answer sheet provided in the next page.

1. Discuss the roles and responsibilities of pharmacy technicians' cosmetic product information.

Note: Satisfactory rating - 5points

Unsatisfactory - below 5points

Answer Sheet

1. _____

Score = _____
Rating: _____

Name: _____

Date: _____



Information sheet 2- Legislative requirements

1.1. DEFINITIONS:

According to Ethiopian Food, Medicine and Healthcare Administration and Control Authority; Cosmetics and Sanitary Items Directive;

Without prejudice to the definitions provided under Proclamation No. 661/2009 and Regulation No.299/2014, in this directive, unless the context otherwise requires:

1. **“Cosmetics”** includes ordinary, medicated and functional cosmetic;
2. **“Ordinary Cosmetic”** means any substance or preparation intended to be applied to external part of a human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body’s structure or functions. This shall also include any substance intended for use as component of a cosmetic;
3. **“Medicated cosmetic ”** means any substance or preparation containing active drug ingredients which helps for preventing, healing or treating skin diseases or disorders, or having a therapeutic claim, and intended to be rubbed, poured, sprinkled or sprayed on or introduced in to or otherwise applied to external part of a human body or part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and substances intended for use as a component for such substances; It shall include antiseptics and disinfectants;
4. **“Functional cosmetic ”** means any substance or preparation having whitening, antiwrinkling or anti-aging effect; any substance or preparation intended for clarification or bleaching of the skin or a substance or preparation with primary sunscreen effect having Sun Protection Factor (SPF) greater than four, or



secondary sunscreen effect having Sun Protection Factor (SPF) greater than twenty;

5. **Claim**” means any message or presentations including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a product has particular characteristics relating to its origin, function, nature, composition or any other characteristics;
6. **“Whitening agent”** means a cosmetic product that is designed to whiten the skin tone;
7. **“Anti-wrinkling agent”** means a cosmetic that is designed to minimize the appearance of the lines in the face or body;
8. **“Sunscreen”** means a cosmetic product that is designed to protect the skin from the Ultra Violet A (UVA) and Ultra Violet B (UVB) rays of the sun or to develop natural looking tanning of the skin;
9. **“Primary sunscreens”** means a sunscreen cosmetic intended for therapeutic purpose;
10. **“Secondary sunscreens”** means a sunscreen cosmetic having a primary purpose of moisturizing and containing a sunscreen for secondary purposes;
11. **“Ultra Violet (UV) filter”** means a substance which is added to a sunscreen cosmetic for the purpose of filtering UV rays to protect the skin;
12. **“Mouth washes”** means a liquid or spray oral hygiene products for prevention of mouth odor or breath fresheners;
13. **“Body deodorizer”** means a preparation for external use for prevention of body odor;
14. **“Heat rashes powder”** means a powder for external use for prevention of heat rashes;
15. **“Dentifrice”** includes tooth pastes, tooth powders, tooth liquids containing hydrogen peroxide, fluoride, precipitated calcium and silicon dioxide;
16. **“Bath preparation”** means a product for external use for bath which may contain soap as body deodorant or a skin disease assisting treatment;



17. **“Laundry soap”** means a product consisting primarily of an alkali salt of fatty acid;
18. **“Sanitary item”** means any preparation used in the maintenance of cleanliness of human, household, and includes pads, diapers, tampons, dentifrices, sweat-bands and detergents;
19. **“Detergent”** means any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, molded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes;
20. **“Auxiliary washing preparation”** means a product intended for soaking (prewashing), rinsing or bleaching clothes, household linen, etc;
21. **“Laundry fabric-softener”** means a product intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;
22. **“Surfactant”** means any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces;
23. **“Biodegradability”** means the structural change or transformation of a surfactant by microorganisms results in the loss of its surface active properties due to the degradation of the parent substance and consequential loss of the surface active property;
24. **“Ultimate biodegradability”** means the level of biodegradability achieved when the surfactant is totally used by microorganisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water, and mineral salt of any other element present;
25. **“Misbranded cosmetic ”** means a regulated product under this directive which is falsely labeled, having misleading labeling or if it does not bear the required



labeling information in accordance with this directive and/or other applicable laws;

26. **“Adulterated cosmetic ”** means a regulated product under this directive which bears or contains any poisonous or deleterious substance that may render it injurious to user; a product consisting in whole or in part of any filthy, putrid, or decomposed substance; a product consisting a substance other than its content or by substituting its content in whole or in part by such other substance or by storing or manufacturing it under unsanitary conditions whereby it may have been contaminate;
27. **“Label”** means any material which is written, printed, graphic matter or affixed to a packing material which provides the necessary information about regulated product under this directive, and includes an insert;
28. **“Product”** means cosmetic and sanitary items as defined under this directive;
29. **“Expiration date”** means the date after the product will be expired and should not be used anymore;
30. **“Period after Opening” (PAO)** means the time after which the product may cease to comply with the general safety requirement;
31. **“Special shop”** means a shop specially designed to sold or distribute cosmetics in self-contained or separated area within the supermarket or other firms; and
32. **“Authority”** means the Ethiopian Food, Medicine and Healthcare Administration and Control Authority.

The purpose of this directive shall be to:

- 1) Protect the public from adulterated, mislabeled or otherwise unsafe cosmetics and sanitary items;
- 2) ensure safety and effectiveness of medicated cosmetic and functional cosmetic; and
- 3) Provide guidance for importers, exporters and distributors with regulatory information concerning minimum requirements in the marketing of regulated products under this directive.



Scope

This directive shall be applicable on all products and raw materials of cosmetic and sanitary items.

Principles

1. In order to market regulated products exporters, importers, and distributors shall have a certificate of competence issued by the Authority.
2. Notwithstanding to sub-article (1) of this article, medicated cosmetic and functional cosmetic products shall also be registered in accordance with this directive. Where the product is to be imported, a pre-import permit granted by the Authority shall accompany the product.
3. Subject to applicable provisions of this directive, ordinary cosmetic and sanitary items may be imported without prior registration.
4. Without prejudice to the preceding provisions, regulatory requirements in relation to cosmetics and sanitary items shall be enforced through inspection at ports of entry, storage, and during and after distribution.
5. Appropriate administrative measures shall be taken against violating products.
6. Importer and distributor, as appropriate, shall be responsible for the safety problems associated with their marketed products.

1.2. Requirements and issuance of a certificate of competence

- a) Any person who wants to import, export, or wholesale a regulated product under this directive shall apply for a certificate of competence in accordance with ANNEX-I.
- b) An exporter, importer, or distributor of regulated products applying for a certificate of competence under this directive shall fulfill minimum requirements in relation to location, building design and construction, materials and manpower as defined from Article 7 to Article 10 of this directive.



- c) Where the applicant intends to operate trade in ordinary cosmetics together with medicated and function cosmetics, it shall fulfill particular requirements provided for medicated and functional cosmetics.
- d) Notwithstanding to sub-article (1) of this article, and depending on the nature of the product, other appropriate factors may be considered in granting a certificate of competence.
- e) In order to determine compliance with this directive, the Authority shall conduct an onsite inspection of the intended facility by at least two inspectors. Where inspection results find out one or more set requirements to be corrected, reinspection may be carried out free of charge. However, an inspection beyond the second time may only be made against payment of service fee required by the Authority.
- f) If the inspection result conducted under sub-article (5) of this article warrant granting of the certificate of competence, the Authority shall issue the same against payment of the prescribed service fee.

Location

- 1) The facility shall
 - ✦ be self-contained
 - ✦ be reasonably away from flood and swamp prone areas, offensive and waste disposal site;
 - ✦ have basic infrastructures including road, electricity, and water;
- 2) The premise shall be free of conditions which might lead to contamination including excessive dust, foul odors, smoke, pest and insect infestations, airborne microbial and chemical contaminants, and other similar conditions.

1.3. Building design and construction

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- ✦ The store shall provide sufficient space for all activities carried out proportional to the amount of the products including a storage room, dispatch room, separate quarantine and rejected products storage room or area.
- ✦ The store shall be constructed in such a way that it does not compromise the safety and quality of products.
- ✦ The building shall be constructed with materials that do not affect the safety and quality of the product;
- ✦ The storage room shall be separate or separately enclosed.
- ✦ Floor of the storage room shall be made in cement, concrete, ceramic or similar materials; easily washable, free from cracks, be smooth and not convenient to harbor dirt and water.
- ✦ Wall of the storage room shall be easily cleanable, free from cracks, and not convenient to harbor dirt.
- ✦ The roof shall be constructed from materials that do not allow the entry of direct sun light and which do not adversely affect the temperature of the room.
- ✦ Rooms shall be constructed in such a way to allow adequate air and light circulation.

1.4. Materials and equipment

- ✦ Shelves or pallets shall be placed in such a way that they are at least 10cm away from the floor and 20cm away from the walls and 30cm from the ceiling. Each shelf shall be placed 50cm away from each other.
- ✦ Depending on the climatic conditions of the area there shall be ventilator or air conditioner.
- ✦ Any materials in the store having contact with the regulated product shall not compromise the safety and quality of products;
- ✦ An enclosed waste bin, fire extinguisher and first aid kit shall be available.
- ✦ Necessary safety materials for workers including glove and working cloths.
- ✦ Where products that need refrigerator for their storage, it shall have refrigerator or cooling equipments.



- ✚ Where the facility holds or distributes medicated and functional cosmetics, it shall have equipment to measure moisture and temperature.

1.5. Professional requirements

- ✚ Any person engaged in import, export or distribution of regulated products under this directive shall have an adequate number and appropriate technical and other personnel.
- ✚ For a person to engage in trade in medicated and functional cosmetics, the person who runs the business as technical personnel shall be druggist or pharmacist.
- ✚ If the person wants to engage in trade in ordinary cosmetics alone or sanitary items, it shall have a person who completed at least grade 10 in accordance with the new education policy or grade 12 in accordance with the prior education policy as technical personnel.
- ✚ The technical personnel described under sub-article (3) of this article shall be familiar with basic knowledge regarding the handling, storage, transportation, use, nature, content, side effects and other related character of the product.

Displaying certificate of competence

- Original of the certificate of competence shall be placed in a conspicuous place where it can be easily seen by clients and regulatory officers.

Replacement of certificate of competence

- Any person whose certificate of competence is damaged or lost may request replacement by submitting a signed and dated application to the Authority

Change of address and technical personnel

- No person may change location and technical personnel of the facility without notifying and securing the permission from the Authority.



Renewal of the certificate of competence

- A certificate of competence shall be renewed between Hamle 1 and Nehase 30 of the Ethiopian calendar up on the confirmation of regulatory compliance through annual inspection, and payment of prescribed service fee.
- If the certificate of competence is not renewed in accordance with sub-article (1) of this article, it shall be renewed with 50% increment penalty for each of the coming two months.
- If the certificate of competence is not renewed in accordance with sub-article (2) of this article, the certificate of competence shall be considered cancelled

1.6. ILLUSTRATIVE LIST OF COSMETICS AND REGISTRATION

Illustrative list of ordinary cosmetic

- Ordinary cosmetic products shall include deodorants, skin washes, moisturizer, cleanser, cream, scrub, astringent, toner, lotion, toothpastes and gels that contain 1000 mg/kg or less of fluoride ion, mouthwashes that contain an antibacterial substance, mouthwashes that contain 220 mg/L or less of fluoride ion, primary sunscreen products where their SPF is less than four, moisturizers containing a sunscreen as a secondary purpose and those products listed under Annex-III of this directive.
- The moisturizers containing a sunscreen as a secondary purpose expressed under sub-article (1) of this article shall meet the definition of secondary sunscreen product and shall not be water-resistant.
- Any ordinary cosmetic product having a therapeutic claim shall be regulated as a medicated cosmetic and pass through the registration procedure required under this directive.

Illustrative list of medicated cosmetic

- Medicated cosmetic includes antiperspirant, antidandruff preparations such as antidandruff shampoos, antidandruff hairdressings, antidandruff lotions,



antidandruff oil, antidandruff creams; antibacterial skin cleansers, anti-acne products; toothpastes, mouthwashes, gels having 1000 mg/kg or more fluoride ion; antiseptics, disinfectants and intimate products.

- For the purpose of this directive “antiperspirant” means a product that reduces the extent of sweating, with or without the presence of perfumes, as well as the occurrence unsightly sweat marks on clothing. These products serves as temporarily reducing the extent of normal sweating by modifying the organic function of sweat glands, minimizing body odors, and decreasing the occurrence of unsightly sweat marks on clothing.
- For the purpose of this directive “intimate product” means personal products intended for soothing or lubricating the intimate part of human organ for sexual activity.
- Notwithstanding to sub-article (1) of this article, antiperspirant preparations that derive their antiperspirant properties from inorganic salts such as aluminum, zinc or zirconium and indicated for hyperhidrosis or otherwise providing a more permanent effect or treat or mitigate a disorder shall be classified as medicine.

Illustrative list of functional cosmetic

- Functional cosmetic is as defined under article 2(4) of this directive and include such products with anti-wrinkling, anti-aging, whitening, anti-hair loss products or sunscreen claims or ingredients.

Registration requirement

- Any person who wants to market medicated cosmetic and functional cosmetic shall have its product registered in accordance with the following articles.

Administrative documents

1) Application for registration

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- a) A duly filled separate registration application shall be required for every product type and products with different ingredients or same products manufactured at different manufacturing sites. Application for the registration of medicated cosmetic or functional cosmetic shall be made in accordance with Annex-IV of this directive
- b) An applicant shall submit actual sample of the proposed product, its primary and secondary packaging materials and labeling information together with the hard and electronic copy of registration file.
- c) The Authority may require the applicant additional information or samples for clarification during evaluation of the product.
- d) If the applicant fails to submit written response for the information or documentation required under sub-article (1) (c) of this article within six months, or if the queries has been reissued for the third time and the applicant provide unsatisfactory responses, the application shall be deemed to be withdrawn. An applicant whose application is rejected in accordance with this article may reapply for registration.
- e) An applicant whose application is considered withdrawn in accordance with sub-article (1) (d) of this article may lodge new registration application.
- f) The entire registration file shall be submitted in English or Amharic. Where original certificate are in other languages, copies shall be presented together with authenticated translation.

2) Good manufacturing practice, free sale certificate and manufacturer profile

- a) Certificate of Good Manufacturing Practice (GMP) from local regulatory authority; and free sale certificate issued by competent organ in the country of origin and, authenticated by Ethiopian embassy or consulate shall be submitted.
- b) In appropriate circumstances, internationally accepted certification or certificate of quality management system may be accepted in lieu of GMP.
- c) Background information including year of establishment, development of the company since establishment, organo gram and full address of the manufacturer



shall be submitted. Manufacturer profile may be omitted if the manufacturer is already registered with the Authority.

Technical documents

1) Chemical and analytical data for raw materials

- a) Manufacturer shall indicate reference to each ingredients used for the preparation of the product to be registered. Reference may be made to the International Cosmetic Ingredient Dictionary (ICID), European Union Cosmetic Ingredients Compendium (EUCIC), or other compendiums accepted by the Authority.
- b) If the reference and /or specification of an ingredient are in-house, the manufacturer shall submit definition of the ingredients, identification (both the method of identification and result obtained by the indicated method), method of manufacturing or preparation, and analytical data and test method for the raw materials.
- c) All substances used in the preparation must be given in the qualitative and quantitative formula. This could be: active ingredients, preservatives, antioxidants, chelators, buffering agents, solvents and other additives.
- d) The basic and minimum specifications active ingredient of medicated and functional cosmetic shall have include chemical identity, physical form, purity of the chemical, characterization of impurities or accompanying contaminants, solubility, partition coefficient(Log Pow), additional relevant physical, microbiological and chemical specifications.
- e) In addition to requirements mentioned under sub-article (1) (d) of this article, certificate of analysis should be submitted to provide full characterization of the test chemical.

2) Formulation data

a) Data on composition

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Composition data shall indicate all the lists of ingredients, including the quantity and quality specification. The name used for and ingredient shall be identified by its common name as provided for in the common ingredients nomenclature or, in the absence of nomenclature or of a common name, by its chemical name, its Cosmetic, Toiletry, and Fragrance Association (CTFA) name, its European pharmacopoeia name, its international non-proprietary name as recommended by the World Health Organization, its Inventory of Existing Commercial Substance (INECS), International Union of Pure and Applied Chemistry (IUPAC) or Chemical Abstract Service (CAS) identification reference or its color index number.

b) Method of manufacture (preparation)

- i. The method of manufacture shall show flow chart for the method of manufacture, concise description of the method of preparation mentioning the quality and quantity of the raw materials used including the final packaging and labeling procedures.
- ii. Method of preparation including all physical, chemical, enzymatic, biotechnological and microbiological steps shall be clearly stated.
- iii. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated.

3) Data on method of analysis and specification of the finished product

- a) Manufacturer of a regulated product under this chapter, where appropriate, shall mention relevant control parameter for the finished product and their limit of specification. The final product specification may indicate appearance (clarity, color, homogeneity and odor), consistency, particle size, pH, average weight or volume, microbiological limit and assay.
- b) Method of analysis for the finished product shall indicate all the test method and specification. The test methods shall mention including the equipment, reagent and method.

4) Stability data

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Stability data shall be submitted and it shall indicate:

- a) the formulation;
- b) minimum of two batch numbers and batch type;
- c) date of manufacture;
- d) Expiry date or any comparable statement including, “use withinYears from the date of manufacture” or “best before’
- e) type and chemical nature of the packaging materials;
- f) analytical methods that will quantitatively measure the characteristic structural and chemical properties of each active or functional ingredients of a dosage form and distinguish them from their degradation products so that active ingredient content can be measure;
- g) Initial and all subsequent results of chemical, physical and/or biological testing. The frequency of testing must be every three months including the initial for the first year and every six months for the second year and every year thereafter; and
- h) Summary of the study and storage recommendations based on the generated data.

4) Data demonstrating safety and efficacy

- a) To determine the margin of safety for human use, relevant toxicity tests shall be submitted. Where appropriate, single dose toxicity, primary skin irritation, ocular or mucous membrane irritation test, skin sensitization, photo toxicity and photosensitivity, and repeated human irritation test shall be submitted.
- b) For sunscreen products, SPF test method and expression of SPF shall be submitted.
- c) For Whitening agents, in vivo tyrosine activity, in vitro melanin synthesis inhibition assay, and DOPA autoxidation test shall be submitted.
- d) For anti-wrinkle products, cell proliferation assay, collagen synthesis assay, and elastase inhibition assay shall be submitted.
- e) For fluoride containing tooth paste, enamel solubility reduction test, and fluoride enamel uptake test shall be submitted.



Notification of variation and re-registration

- Where there is any variation of a registered medicated cosmetic and functional cosmetic aftermarket authorization, the responsible person shall have the obligation to notify of the variation to the Authority before marketing this product. For the purpose of this article, the “responsible person” means, an importer of the product.
- A product registered in accordance with the preceding article shall be valid for five years. The authorized person shall have the obligation to apply for re-registration within 120 days before the due date. Re-registration requirements shall include current GMP certificate and a confirmatory letter that the method of manufacture or preparation is not changed.

PACKAGING AND LABELLING

1. The packaging material shall be made out of substances, safe and suitable for its intended use and the product shall be packed in container which will safeguard its hygienic, safety and quality.
2. The immediate container of an ordinary cosmetic, medicated cosmetic and functional cosmetic shall be affixed or written on with a label bearing the following particulars in clearly legible and indelible letters at least in Amharic or English:
 - a. Name of the product;
 - b. Name and full address of the manufacturer, including country of origin;
 - c. Form of the product;
 - d. Intended use of the product;
 - e. Instructions of use;
 - f. Net content;
 - g. List of ingredients;
 - h. Batch or lot number;
 - i. Precautions and warnings, where necessary; and
 - j. Storage condition, as appropriate.



3. Expiry date, best before or period after opening or comparable terms shall be clearly written on the immediate container of medicated cosmetic and functional cosmetic product.
4. Expiry date best before or period after opening or comparable terms shall be clearly written on immediate container of the product, where necessary.
5. Notwithstanding to sub-article (4) of this article, expiry date shall be specified for an ordinary cosmetic whose shelf life is thirty months or less.
6. Period after opening (PAO) may be used when, after opening, the deterioration of the product may lead to harm to the consumer. PAO symbol or term may not be necessary where no physical opening of the product as in the case of products presented in containers where there is no possibility of contact between the product in the container and the external environment (e.g. aerosols), and the product is a single-use item.
7. Where the size, shape or nature of the container or package does not permit all the information provided under this directive to be displayed, leaflets, pamphlets, hang tags, display panel; shrink wrap and the like shall be used. However, these particulars must appear on the container indicating the name of the product, batch or lot number and expiry date, where appropriate.
8. All ingredients on the label of the product shall be listed in accordance with the following sub-articles:
 - a. List of ingredients, which will be present in the final product including both the quantity and quality specification. The name used for and ingredient shall be identified by its common name as provided for in the common ingredients nomenclature or, in the absence of nomenclature or of a common name, by its chemical name, its International Non-proprietary name as recommended by the World Health Organization, its International Union of Pure and Applied Chemistry (IUPAC) or Chemical Abstract Service (CAS) Identification reference or its color index number.



- b. In case of decorative cosmetic marketed in a range of color shades, all coloring agents used in the range may be listed if they are preceded by the symbol "+/-" or "±" or the phrase "may contain";
 - c. Botanicals must be listed by specifying at least genus and species portions.
 - d. Ingredients that are present at a concentration of 1% or less and all coloring agents, regardless of their concentration may be listed in random order after the ingredients that are present at a concentration of more than 1%.
9. Liquid or oral hygiene products (e.g. Mouth washes, fresheners) and all cosmetic vaginal products (eg. douches, tablets) must be packed in a tamper resistant package. The feature may involve the immediate or outer container or both. The package must also bear a prominently placed statement alerting the consumer to the tamper-resistant feature. This statement must remain unaffected if the tamper resistant feature is breached or missing.
10. In addition to the general requirement for labeling, a hair dye product label should indicate the categories of hair dye (Permanent, Semi permanent or temporary hair colors), and coal tar containing hair dye product label shall bear direction for patch test and should bear the following caution, "This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."
11. Any SPF or equivalent category description shall be disclosed on the label of sunscreen products.
12. The SPF or equivalent category description disclosed on the label shall be determined by acceptable International Standards for the precise formulation.
13. Label claims must be true, verifiable and accurately communicate product features, characteristics and performance. In particular, the following statements are prohibited:



- a. "Recommended by doctors" or any other word or words or pictorial representation implying that medical practitioners in general recommend its use.
 - b. A claim that conveys that the product possesses health-giving properties shall, unless such word, indication or claim can be scientifically substantiated.
14. Where an ordinary cosmetic product is prepared for use for a specific facility (such as hotels and other hospitality institutions), and the name of the institution is affixed or written on the product, labeling requirements provided under this article may not be applicable.

Leaflets

1. Medicated cosmetic and functional cosmetic shall have leaflets or package insert accompanying the product.
2. Every leaflet or package insert of functional and medicated cosmetic shall at least include the following particulars in clearly legible and indelible letters at least in Amharic or English:
 - a. Name of the product;
 - b. Form of the product;
 - c. Intended use of the product;
 - d. Instructions of use of the product;
 - e. Net content given by weight or volume, in metric system;
 - f. Name and full address of the manufacturer, including country of origin;
 - g. List of ingredients;
 - h. Precautions and warnings;
 - i. Its adverse effect ;
 - j. Storage condition where applicable; and
 - k. Pregnancy and lactation related issues.

2.6. Storage, transportation and distribution



- Applicable safety standards of detergents, ordinary cosmetic, medicate cosmetic, and functional cosmetic shall be observed during storage, handling and transportation.
- Products shall be stored in their appropriate condition according to instructions on the label.
- Deteriorated, expired, and damaged products shall be stored separately from products until disposal.
- Every effort shall be made to make sure products are stored in such a way that it supports the first expired first out (FEFO) and first in first out (FIFO) principles.
- Inspection of a regulated detergents and cosmetic facility shall be carried out based on identified adverse event, complaints or agency self-initiated compliance investigation.
- Importer or distributor of medicated cosmetic and functional cosmetic may only distributes products for retails.
- For the purpose of this article, “retailer” includes drug shop, pharmacy and special shop.
- Medicated cosmetic and function cosmetic shall be held by trained professional in the field and an authorized facility.

2.7. Import requirements for detergent and cosmetics raw materials

2.7.1. Labeling

Importers of raw materials for detergent, ordinary cosmetic, medicated cosmetic and functional cosmetic shall at least include the following particulars on the primary container in clearly legible and indelible letters at least in Amharic or English

- ✓ Name of the product;
- ✓ Name and full address of manufacture, supplier, distributor, importer, as appropriate
- ✓ Batch or lot number, where appropriate;
- ✓ expiry date, where necessary;



- ✓ Precautions and warnings, where necessary; and
- ✓ Storage condition, where necessary.

2.7.2. Required documents

An importer of raw materials intended for use in the production or use of detergent, cosmetic, medicated cosmetic and functional cosmetic shall submit

- ✓ Application letter;
- ✓ Certificate of origin;
- ✓ Safety data sheet and/or certificate of analysis;
- ✓ Invoice;
- ✓ packing list;
- ✓ pre-import permit for active raw materials intended for medicated cosmetic and functional cosmetic; and
- ✓ Airway bill or bill of loading.

2.8. Prohibitions and restriction of ingredients

1. An importer shall take every effort to make sure products introduced in to this country do not contain prohibited ingredients or violate restriction of ingredients as provided from Annex V to Annex-X of this directive.
2. Where a product is found suspicious to have or confirmed to have prohibited or restricted ingredients, the Authority may take appropriate administrative measures.
3. A product intended to be placed in the market shall not contain any of the following:
 - a. A prohibited ingredient as provided in Annex V of this directive;



- b. Any substance listed in column b of Annex VI of this directive unless the requirements in column c, d, e and f of that annex in relation to that substance are satisfied;
- c. Any coloring agent which is not listed in Annex VII of this directive;
- d. Any preservative listed in column 2 of Annex VIII of this directive unless the requirements in column 3, 4, and 5 of the Annex in relation to that preservative are satisfied;
- e. Any preservative which is not listed in Annex VIII of this directive;
- f. Any UV filter listed in column 2 of Annex IX of this directive unless the requirements in column 3 and 4 of the Annex are satisfied.

2.9. ADMINISTRATION MEASURE AND COMPLIANT HANDLING

- 1. Any importer, exporter, or wholesaler who violates requirements of this directive or other applicable laws may be subjected to appropriate administrative measure in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
- 2. The person against whose product or whom an administrative measure is taken in accordance with sub-article (1) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
- 3. Complaints may be submitted by the licensee, owner of the business or a duly authorized agent of the owner or licensee. The complaint shall be submitted within 30 days from the time when administrative measure is taken.
- 4. Without prejudice to sub-article (1) of this article, the following may be used as illustrative lists for suspension and revocation:

2.9.1. Suspension of a license

Without prejudice to grounds of suspension provided under relevant laws, and based on the severity of the violation, the Authority shall suspend certificate of competence of the importer, exporter, or wholesaler from one month to six months, if it:



- I. fails to allow inspection of its premise or products;
- II. fails to submit, accurately or on time, or falsify information requested by the Authority;
- III. allows a professional who is not duly licensed or who has been suspended by a competent authority from practicing his/her profession to work in the facility;
- IV. found holding products with the absence of authorized personnel or technical manager;
- V. fails to notify the Authority of any change to professionals or premises design and/or place without approval;
- VI. commits other comparable violations; and
- VII. Is suspended by other government organ (for the same duration of time).

2.9.2. Revocation of a License

Without prejudice to grounds of revocation provided under relevant laws, and based on the severity of the violation, the Authority shall revoke certificate of competence of importer, exporter, or wholesaler, up to two years, if it:

1. obtained its certificate of competence through fraudulent acts;
2. intentionally possess or sale a product in any manner from a person having no certificate of competence;
3. add or mix any substance to the product so as to increase its bulk or weight, or make it appear better or for any other similar purpose;
4. import, export or distribute a product other than the product type the certificate of competence issued for;
5. possess or sale any unregistered, adulterated, counterfeited; expired or unlabeled product;
6. continue operating its business against the terms and conditions of any suspension measures;
7. is prohibited from doing its business by another appropriate government organ;
8. impedes the work of inspectors; and



9. engage in any act which constitutes a serious violation in accordance with the directive on Administrative Measure Taking and Complaint Handling and the violation is subject to revocation measure;



Self-Check -2	Written Test
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Direction: Answer the following questions. Use the Answer sheet provided in the next page.

Say **true** or **false**

1. Products shall be stored in their appropriate condition according to instructions on the label
2. The packaging material shall be made out of substances, safe and suitable for its intended use.

Short answer

1. List at least five information that should be included on cosmetic product leaflets

Note: Satisfactory rating - 7points

Unsatisfactory - below 7points

Answer Sheet

1. _____

2. _____

Score = _____

Rating: _____



Name: _____

Date: _____

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The trainers who developed the learning guide

No	Name	Qualification	Educational background	Region	E-mail
1	ALEMSEGED WORKNEH	A	Pharmacy	Harari	yealemwerk@gmail.com
2	ABEBE FEYISSA	B	Pharmacy	Benishangul	afeyissaa@gmail.com
3	FARHAN YUSUF	B	Pharmacy	Jigjiga	farhanyuusuf926@gmail.com
4	ABDIWAHAB ALI	B	Pharmacy	Somali/Jigjiga	raram938@gmail.com



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Answer Key for self check on Beauty care

LO1

Self check1

1. D	2. A	3. B	4. F	5. E	6.G	7.C
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Self check 2

Part I

1.C	2. F	3. A	4. E	5. B
6. D	7.G	8.I	9.J	10.I

Part II.

1. False	2. false	3. True	4. True	5. True
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