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# Review on: Intellectual Property Rights: An Overview on Trade Mark and Copyright

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**A B S T R A C T**

Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to rea commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is a recognition for an invention, which satisfies the criteria of global novelty, non -obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.

**Keywords**: Drug, intellectual property, license, patent, pharmaceutical

## 1. Introduction

The Intellectual Property Rights (IPR) has a key role in the development of each country. The scientists from Research and development institutions are the major contributors to the field. There are diverse intellectual Properties protected by independent laws in India. The forms of IPR are Patents, Copyrights, Trademarks, Industrial designs, Geographical indications, Layout Desig of Integrated Circuits, Protection of plant varieties And Farmer's Rights and Protection of undisclosed information/Trade secrets (Intellectual Property Facts Make in India.(n. d.)1

A key feature for pharmaceutical production is intellectual property. This applies for both the research Pharmaceutical industry, which relies heavily on intellectual property protection to recoup its investment and Defend its market position, and generic companies, which enter the market once patent protection expires or With the authorization of the patent holder. Beyond patent protection, trademarks are another form of intellectual property right used to identify and Market pharmaceutical products. Trade secrets and protection of clinical of test data are other important

***Element of this industry.***

Consequently, the set-up of a national intellectual property system is important when considering options for Local production of pharmaceuticals. The level of protection of intellectual property appropriate to meet the Needs of the society and of the local pharmaceutical industry depends on the character of the local industry,Its technological capacities and its business model. In developing the appropriate intellectual property rights Regime to promote local pharmaceutical production, attention needs to be paid to the country's level of Economic and technological development and its industrial policy objectives.For example, local producers in developing countries may seek to file patents on incremental improvements Of existing medicines or manufacturing processes, depending on their level of technological capability and Commercial needs. The appropriate level of protection of intellectual property may differ between industry Branches. For example, in the same country, the local generic pharmaceutical industry may be interested in a Flexible patent system that allows for early entry of generic products, while the Local textile industry may be Interested in stronger design protection to prevent competing Companies from copying its original designs. Therefore, consideration needs to be given to an environment that balances the long-term interests of society With the interests of (local) Producers in different sectors for commercial needs.

## 2. Various forms Of Intellectual Property

Patents

Trademarks

Copyright

Industrial Designs

Geographical Indication

Semiconductor Integrated circuit's layout – Design

Trade secrets

### *2.1 Objectives of intellectual property*

Encourage and reward creative work

The main social purpose of protection of copyright and related rights is to encourage and reward creative work. This is also relevant to protection in other areas (e.g. industrial designs and patents).

Technological innovation

Intellectual property rights are designed to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities.

Fair competition

The protection of distinctive signs and other IPRS aims to stimulate and ensure fair competition among producers.

Consumer protection

The protection of distinctive signs should also protect consumers, by enabling them to make informed choices between various goods and services.

Transfer of technology

A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing

Balance of rights and obligations

It should also be noted that the exclusive rights given to the owners of intellectual property are generally subject to a number of limitations and exceptions, aimed at balancing the legitimate interests of right holders and of users.

What is the intellectual property?

## 3. Tab Trademark

Trade marks have been defined as any sign, or any combination of signs capable of distinguishing the goods or services of one undertaking from those of other undertakings. Such distinguishing marks constitute protectable subject matter. The Agreement provides that initial registration and each renewal of registration shall be for a term of not less than 7 years and the registration shall be renewable indefinitely. Compulsory licensing of trade marks is not permitted.keeping in view the changes in trade and commercial practices, globalization of trade, need for simplification and harmonization of trademarks registration systems etc., a comprehensive review of the Trade and Merchandise Marks Act, 195 was made and a Bill to repeal and replace the 1958 Act has since been passed by Parliament and noticed in the Gazette on December 30, 1999. This Act not only makes Trade Marks Law, TRIPS compatible but also harmonizes it with international systems and practices. Work is underway to bring the law into force.

### *3.1 Types of marks:*

There are various types of marks namely

• Trademarks (marks used to distinguish certain goods as those produced by a specific enterprise),

• Service marks (Marks used to distinguish the goods or services of a person or an association of persons who is the proprietor thereof from those of others.),

• Certification marks (marks used to distinguish the goods or services that comply with a set of standards and have been certified by a certified authority) and

• Well-known marks (marks that are considered to be well-known in the market and as result benefit from stronger protection).

### *3.2 Functions of Trademark:*

A trademark is essentially a product of competitive economy where more than one person competed for the manufacture of the same product which necessitated the marking of each manufactured goods by a symbol which distinguished similar goods made by others. The modern trademark has three major functions to perform. They are origin function, quality or guarantee function, investment or advertising function.

### *3.3 Duration of trademark:*

The term of trademark is ten years and it can be renewed lifelong for every ten years. Trademark can be a word, phrase, logo, symbol, design, image, or a combination of these elements.

Example: Coco-Cola, IBM, AIRTEL etc.

### *3.4 History of trademark in India*

In India proprietary protection for marks is ancient. Around the $10^{th}$ century, a mark synonymous as "merchants mark," appeared, and symbols among traders and merchants increased significantly. These marks, which can be considered one kind of "proprietary mark," essentially were used to prove ownership rights of goods like marking cattle, potteries, trading emblems on currencies, etc.

In the 20century prior to 1940 there was no official Trademark Law in India. Serious problems aroused on infringement, passing-off, etc and these were solved by application of section 54 of the specific relief act 1877 and the registration was adjudicated by obtaining a declaration for the ownership of a trademark under Indian Registration Act 1908.

To overcome the above difficulties the Indian Trademarks Act was passed in 1940, this corresponded with the English Trademarks Act. After this, AS Trade and commerce continuously grew, there was an increasing need for more protection of Trademarks. The replacement to this act was the Trademark and Merchandise Act, 1958. India became a party to the WTO at its very inception. One of the agreements in that related to the Intellectual Property Rights (TRIPS).

### *3.5 Registration of trademarks*

On filing a trademark application, the registry issues an official receipt that has the filing date and application number. Then the Indian trademarks office examines the application, as to ensure it can be registered under the trademarks act and if any objection to registration is raised, registry issues an examination report to the applicant. The applicant is then required to file a written response or is required to give evidence of acquired distinctiveness and thereafter a hearing with the examiner is posted.If post examination and hearing, the registrar is of the view that the trademark can be allowed, letter of acceptance is issued to the applicant after which the trademark is published in the trademark journal. Post publication, it is open for opposition for 4 months from date of publication. If no objection is raised in these 4 months, certificate is issued and in case of objection, both parties are given opportunities to be heard.

Trademark registration is a tedious process and it usually takes around 18-24 months to acquire registration in cases with no objections or oppositions.

Once the trademark is registered, it is valid for a period of 10 years from the date of application. The registration can then be renewed indefinitely as long as the renewal fees are paid every 10 years.

Flow chart of trademark application filing up to acceptance

## 4. Copyright

The copy right ensures that computer programs will be protected and as literary works under the Berne Convention and outlines how databases should be protected. It also expands international copyright rules to cover rental rights. Authors of computer programs and procedures of sound recordings must have the right to prohibit the commercial rental of their works to the public. A similar exclusive right applies to films where commercial rental has led to widespread copyright, affecting copyright-owners' potential earnings from their films. The performers must also have the right to prevent unauthorized recording, reproduction and broadcast of live performances for not less than 50 years. Producers of sound recordings must have the right to prevent the unauthorized reproduction of recordings for a period of 50 years.

India's copyright law, laid down in the Indian Copyright Act, 1957 as amended by Copyright (Amendment) Act, 1999, fully reflects the Berne Convention on Copyrights, to which India is a party. Additionally, India is party to the Geneva Convention for the Protection of rights of Producers of Phonograms and to the Universal Copyright Convention. India is also an active member of the World Intellectual Property Organization (WIPO), Geneva and UNESCO.

The copyright law has been amended periodically to keep pace with changing requirements. The recent amendment to the copyright law, which came into force in May 1995, has ushered in comprehensive changes and brought the copyright law in linsatellite broadcasting, computer software and digital technology. The amended law has made provisions for the first time, to protect performer's rights as envisaged in the Rome Convention.

Several measures have been adopted to strengthen and streamline the enforcement of copyrights. These include the setting up of a Copyright Enforcement Advisory Council, training programs for enforcement officers and setting up of special policy cells to deal with cases relating to infringement of copyrights.

### *4.1 Types of work protected by copyright*

• Literary works (e.g Books, magazine, newspapers, technical papers, instruction manual, catalogs, tables and compilations of literary works.

• Musical works or compositions, including compilations;

• Dramatic works includes not only plays but also for example a sales training program captured on videocassettes

• Artistic works such as cartoons, drawings, paintings, sculptures and computer artwork

• Photographic works both on paper and in digital form

• Computer programs and software

• Some types of data base

• Maps, globe, charts, diagrams, plans and technical drawing;

• Advertisement, commercial prints and labels

• Cinematographic works, including motion pictures, television shows, and webcasts

• Multimedia products 10

• In some countries works of applied art such as artistic jewellery, wall paper and carpets.

Authorship and ownership of Copyright:

The author means in relation to

• Literary or dramatic work author of the work

• Musical wok –composer

• Artistic work – artist

• Photograph – person who takes photograph

• Cinematograph or sound recording – producer

• Computer generated work – person who creates it

• In case of a literary, dramatic or artistic work made by the author in the course of his employment by the proprietor of a newspaper, magazine or similar periodical under a contract of service or apprenticeship in the absence of the agreement to the contract, the proprietor is the first owner of the copyright.

• In the case of photograph taken, painting or portrait drawn or engraving or cinematograph film made for valuable consideration at the instance of any person – in the absence of any agreement to the contrary the person who commissioned it is the first owner.

• In the case of a work made in the course of the authors' employment under a contract of service or apprenticeship in the absence of any agreement to the contrary, the employer is the first owner. 11

• In the case of any address or speech delivers in public – the person who delivered address or speech is the first owner.

• In the case of a government work in the absence of any agreement to the contrary, the governments are the first owner of the copyright.

• In the case of a work made or first published by or under the direction or control of any public undertaking – in the absence of any agreement to the contrary, the public undertaking is the first owner of the copyright.

Duration of Copyright:

The copyright term varies according to the nature of the work (60 years from the death of author in case of literary, dramatic, musical or artistic work & 60 years after publication of a photograph, film or sound recording)

Nature of Copyright Protection

Automatic

Copyright is an unregistered right which subsists automatically as soon as the work that is eligible for protection is created and recorded on some medium.

Originality

The work protected need not be new. However, it must be original in the sense that it is not copied from some other source but is the result of an application of effort by the creator of the work.

Exclusions

Copyright protects the expression of ideas but not the idea or concept underlying a piece of work. For that reason, procedures, methods of operation and mathematical concepts are excluded from copyright protection.

### *4.2 Functions of the copyright board*

The main functions of the Copyright Board are as under.

1. Settlement of disputes as to whether copies of any literary, dramatic or artistic work or records are issued to the public in sufficient numbers.
2. Settlement of disputes as to whether the term of copyright for any work is shorter in any other country than that provided for that work under the Act.
3. Settlement of disputes with respect to assignment of copyright as dealt with in Section 19A.
4. Granting of compulsory licences in respect of Indian works withheld from public.
5. Granting of compulsory licence to publish unpublished Indian works.
6. Granting of compulsory licence to produce and publish translation of literary and dramatic works.
7. Granting of compulsory licence to reproduce and publish literary, scientific or artistic works for certain purposes.
8. Determination of royalties payable to the owner of copyright.
9. Determination of objection lodged by any person as to the fees charged by Performing Rights Societies.
10. Rectification of Register on the application of the Registrar of Copyright or of any person aggrieved.

**Assignment of copyright**

The owner of the copyright in an existing work or the prospective owner of the copyright in a future work, may assign to any person the copyright Section 18 of the Copyright Act provides for the assignment of copyright in an existing work as well as future work. In both the cases an assignment may be made of the copyright either wholly or partially and generally or subject to limitations and that too for the whole period of copyright or part thereof. However, in case of assignment of copyright in any future work, the assignment has the real effect only when the work comes into existence.Section 18(3) explains that an assignee in respect of assignment of the copyright in future work include the legal representative of the assignee, if the assignee dies before the work comes into existence.

Sections 17 and 18 of the Copyright Act, 1957 show where the copyright vests. If a work is done by an author for a consideration for a publisher, the copyright in it would normally vest in the publisher subject to any contract to the contrary, as is provided by Section 17 of the said Act. It can be legitimately said that this Section has been inserted in the Act of 1957, but the rule of law has been same even prior to this statutory provision. Secondly as provided by Section 18, the copyright could be assigned, and if it is so done it would be vested in the purchaser.

### *4.3 Registration of Copyright*

Chapter X of the Act containing Sections 44 to 50A deal with various aspects of registration of copyright. The mechanism for registration of copyright has been contemplated under Section 44 of the Act. It is evident from the provisions of the aforesaid section that registration of the work under the Copyright

Act is not compulsory and is not a condition precedent for maintaining a suit for damages, if somebody infringes the copyright. Registration is not a prerequisite for acquisition of a copyright.

Chapter VI of the Copyright Rules, 1956, as amended, sets out the procedure for the registration of a work. Copies of the Act and Rules can be obtained from the Manager of Publications, Publication Branch, Civil Lines, Delhi or his authorised dealers on payment. The procedure for registration is as follows:

-Application for registration is to be made on Form IV (Including Statement of and Statement of Further Particulars) as prescribed in the first schedule to the Rule

-Separate applications should be made for registration of each work;

-Each application should be accompanied by the requisite fee prescribed in the second schedule to the Rules and

The applications should be signed by the applicant or the advocate in whose favour a vakalatnama or Power of Attorney has been executed. The Power of Attorney signed by the party and accepted by the advocate should also be enclosed.

P Ka value is the pH at which acidic or basic groups attached to molecules exist as 50% ionized and 50% nonionized in aqueous solution

Solubility: The extent of solute dissolved in a unit amount of solvent in certain conditions of temperature, and PH.

Module 4: Partition coefficient, flow properties

Guidant: The glidants improve the flowability of the tablet granules or powder by reducing the friction between particles, preventing formation of lumps e.g. Talc, Corn starch, Colloids silicates.

Hyper discriminating solvents: Solvents less polar than octanol. E.g. oleyl alcohol, nitrobenzene, chloroform, Carbon tetra chloride, cyclohexane etc.; reflect more the lipophilicity of blood brain barrier.

Hypodiscriminating solvents: Solvents more polar than octanol. E.g. butanol, pentanol; reflect more the lipophilicity of buccal region.

Week 2: Preformulation II

Module 5: Hydrolysis, Oxidation and reduction

Hydrolysis is a two-stage process, where a nucleophile, such as water or the hydroxyl ion adds to, for example, an acyl carbon, to form an intermediate from which the leaving group breaks away in the second stage.

Oxidation: Removal of hydrogen atoms from a carbon atom or addition of an oxygen atom to a carbon atom.

Reduction: Removal of an oxygen atom from a carbon atom or addition of hydrogen atoms to a carbon atom is called reduction.

Module 6: Racemization

Racemization is a process that occurs when a compound undergoes a reaction in which the transformation produces an equal mixture of both possible enantiomers. When two compounds are classified as enantiomers of one another, it means they are non-superimposable mirror images."

Module 7: Dissolution, Permeability and BCS

Dissolution is defined as the process by which a known amount of drug substance goes into solution per unit of time under standardized conditions.

Highly permeable: A drug substance is considered highly permeable when the extent of intestinal absorption is determined to be 85% or higher."

Biopharmaceutical Classification System (BCS), is a drug development tool that allows estimation of the contribution of three fundamental factors including dissolution, solubility and intestinal permeability, which govern the rate and extent of drug absorption from solid oral dosage forms.

Module 8: Polymerization

Bioequivalence is defined in as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." -21CFR 320.1 (US FDA)

Drug targeting is the ability of the drug to accumulate in the target organ or tissue selectively and quantitatively, independent of the site and methods of its administration.

Week 3: Tablets

Module 9: Introduction

Tablets are solid dosage forms each containing a unit dose of one or more medicaments. They are intended for oral administration. (IP) Tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents.

Module 10: Manufacturing Tablets

Tablet formation is one of the most complex processes which involves the volume reduction of a blend of particles/granules (compression) followed by consolidation (into a defined solid dosage form/ tablet).

Mottling: It is an unequal distribution of colours on a tablet with light and dark areas on tablet surface

Picking: Surface materials from a tablet that is sticking to the punch and being removed from the tablet surface is picking.

Module 11: Tablet Coating

Twinning: Two tablets stick together; Most common in capsule shaped tablets

Cracking: Small, fine cracks observed on the upper, lower or side surface of tablets

Blistering: It is local detachment of film from the substrate forming a blister (due to compromised elasticity or adhesive properties.

Chipping: occurs when the film becomes dented and chipped (mostly on the edges of the tablet.)

Cratering: Volcanic-like craters appears exposing the tablet surface

Module 12: QC of Tablets

Dissolution testing is an official test recommended by all pharmacopoeias for evaluating drug release of solid and semisolid dosage forms.

Disintegration test is a measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles which will pass through a 10mesh screen.

Friability Test: The test is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping.

Week 4: Liquid Orals

Module 13: Formulation and manufacturing of solution

Syrup: A viscous concentrated solution of a sugar, such as sucrose, in water or other aqueous liquid combined with other ingredients such a solution is used as a flavored vehicle for medication.

Elixirs: Elixirs are the clear, sweetened, hydro alcoholic liquid intended for oral use. This contain flavoring substances and are used either as a vehicle or for the therapeutic effect of the active medicinal agents.

Solution: A solution is a homogeneous mixture of two or more substances. A solution may exist in any phase. A solution consists of a solute and a solvent.

Module 14: Emulsion –I

Emulsion: An emulsion is a mixture of two or more liquids that are normally immiscible (unmix able or unbendable). Emulsions are part of a more general class of two-phase systems of matter called colloids.

O/W emulsion: An emulsion is called o/w emulsion when water is in continuous phase and oil is dispersed in it.

W/O emulsion: An emulsion is called w/o emulsion when oil is in continuous phase and water is dispersed in it.

Module 15: Emulsion II

Coalescence: Coalescence is fusion of two or more droplets of the disperse phase forming one droplet.

Ostwald ripening: Ostwald ripening is the process whereby larger droplets grow at the expense of smaller ones, because of the transport of dispersed phase molecules from smaller to larger droplets through the intervening continuous phase.

Module 16: Suspension

Deflocculating agents: An agent that prevents fine soil particles in suspension from coalescing to form flocs.

Flocculating agents: A flocculating agent is a chemical that is added to liquids so as to promote the microscopically dispersed insoluble particles, in the liquids, to aggregate and form flocs.

Sedimentation volume: Sedimentation volume of a suspension is expressed by the ratio of the equilibrium volume of the sediment, (Vu) to the total volume (Vo) of the suspension.

Suspending agents: Suspending agents increases the viscosity of the vehicle there by slowing down sedimentation. Most of these agents form thixotropic gels which are semisolid on standing but flow radially after shaking.

Week 5: Parenterals I

Module 1: Introduction: Preformulation of Parenteral:

Parenteral are injectables dosage form administered directly into the blood circulation by the route other than elementary canal.

Sterility: Sterility is defined as freedom from viable and non-viable microorganisms.

Module 18: Formulation of parenterals

Sterile water for injection: It is sterile, hypotonic, nonpyrogenic, and contains no bacteriostatic or antimicrobial agents.

Ultrafiltration: Ultrafiltration is a type of membrane filtration in which hydrostatic pressure forces a liquid against semi permeable membrane.

Week 6: Parenterals I

Module 19: Types of parenterals

Lyophilization: The emulsions consist of an oil, an emulsifier and a balanced blend of amino acids in a continuous phase of distilled water SVP: According to USP: “an injection that is packaged in containers labelled as containing 100 ml or less”.

LVP: Large volume parenterals or LVPs (sometimes called large volume injections) are aqueous solutions usually supplied in volumes of at least 100 ml with sizes of 250 ml, 500 ml, 1000 ml, 3000 ml, and 5000 ml most common.

Dry Powder: Dry powders are parenteral products required to be reconstituted before administration.

Module 20: Lay out and production facilities

HEPA filter: HEPA filters are high efficiency particulate air filters. These are highly efficient and can remove 99.7% of all particles 0.3 μm or larger.

Validation: It is the process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages.

Week 7: Parenterals II

Module 21: Pyrogen and pyrogenicity

Gram positive bacteria: Gram-positive bacteria take up the crystal violet stain used in the test, and then appear to be purple-coloured when seen through a microscope. Ex. Streptococcus and Clostridium.

Gram negative bacteria: Gram-negative bacteria are bacteria that do not retain the crystal violet stain used in the gram-staining method of bacterial differentiation. E.g. Vibrio and Salmonella.

Pyrogen: Pyrogens are metabolic products of microorganisms. A substance, typically produced by a bacterium, which produces fever when introduced or released into the blood.

Module 22: Quality control of parenterals

Liquid sterilization: Liquid sterilization is one of the methods for sterilization when low temperature is involved. Liquid sterilization is done by using Para acetic acid and Hydrogen peroxide.

Radiation Sterilization: Radiation Sterilization employs Gamma and UV light the major target for these sterilization is microbial DNA. Radiation Sterilization is done by using radiation. Sterilization: Sterilization refers to any process that eliminates, removes, kills, or deactivates all forms of life and other biological agents.

Week 8: Capsules

Module 23: Introduction

Capsules are solid dosage forms in which the drug or a mixture of drugs is enclosed in Hard Gelatine Capsule Shells, in soft, soluble shells of gelatine, or in hard or soft shells of any other suitable material, of various shapes and capacities. They usually contain a single dose of active ingredient(s) and are intended for oral administration. (IP) Capsules are solid dosage forms in which the drug is enclosed within either a hard or soft soluble container or “shell.” The shells are usually formed from gelatine; however, they also may be made from starch or other suitable substances.

Module 24: Methods of filling soft gelatine capsules

Excessive heat means any temperature above 40℃(104 ). (USP)

Freezer indicates a place in which the temperature is maintained thermostatically between – 25˚and – 10℃(-13˚and 14℉). (USP)

Binder or binding agent is any material or substance that holds or draws other materials together to form a cohesive whole.

Module 25: Production of soft gelatine capsule

Soft Gelatine Capsule: soft gelatine capsules, also called soft gels, are thicker than hard gelatine capsules and are sometimes the gelatine is plasticized by adding glycerine or sorbitol. The thickness of the gelatine is chosen by the manufacturer according to the requirements of the encased material and the environmental conditions outside the capsule.

Modified Release Capsule: In the case of capsules, the capsule body may be coated with a material through which the drug diffuses. Or it may be a slowly dissolving coat that slowly releases the drug over time.

Module 29: Evaluation of commercial capsules

Dissolution testing is an official test recommended by all pharmacopoeias (viz. official books) for evaluating drug release of solid and semisolid dosage forms.

Modified Release Capsule: In the case of capsules, the capsule body may be coated with a material through which the drug diffuses. Or it may be a slowly dissolving coat that slowly releases the drug Finished products quality control test for over time.

Shelf life is the period of time after manufacturing in which the active pharmaceutical ingredient is assured to meet applicable standards of identity, strength, quality, and purity.

Week 09: Opthalmic Preparations

Module 27: Pellets

Periodization is usually associated with spherical units formed by a special process where extrudates or agglomerates are rounded as they tumble on a rotating frictional base plate. Extrusion consists in applying pressure to a wet mass until it passes through the calibrated openings of a screen or die plate of the extruder and further shaped into small extrudate segments. The extrudates must have enough plasticity in order to deform, but an excessive plasticity may lead to extrudates which stick to each other.

Module 28: Ophthalmic 1

Eye Drops can be defined as a solution or suspension in Purified Water does not preclude the inclusion of suitable additional substances where necessary for the purposes referred to above under the requirements of the European Pharmacopoeia. However, if buffering agents are used in preparations intended for use in surgical procedures great care should be taken to ensure that the nature and concentration of the chosen agent are suitable. (BP)

Module 29: Ophthalmic 2

Preparation: In preparing Eye Ointments in tropical or subtropical countries where the prevailing high temperatures otherwise make the basis too soft for convenient use, the proportions of Yellow Soft Paraffin

And Liquid Paraffin specified in the individual monograph may be varied, or Hard Paraffin may be added but the proportions of active ingredients must not be changed. Multidose preparations are supplied in containers that allow successive drops of the preparation to be administered. The containers contain at most 10 ml of the preparation, unless otherwise justified and authorised.

Module 30: Ophthalmic 3

Eye Ointments should be packed in small, sterilised collapsible tubes of metal or of suitable plastic fitted or provided with a nozzle of suitable shape to facilitate the application of the product without contamination and with a cap. The content of such containers is not more than 5 g of the preparation. Finished products quality control test for Parenterals: Review Srinath College of Pharmacy, Aurangabad Page 18 Ophthalmic inserts are sterile, solid or semi-solid preparations of suitable size and shape, designed to be inserted in the conjunctival sac, to produce an ocular effect. They generally consist of a reservoir of active substance embedded in a matrix or bounded by a rate controlling membrane. The active substance, which is more or less soluble in lachrymal liquid, is released over a determined period of time.

Week 10: Pharmaceutical Aerosols

Module 31: Pharmaceutical Aerosols I

Pharmaceutical aerosols are products that are packaged under pressure and contain therapeutically active ingredients that are released upon activation of an appropriate valve system. They are intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).

These

Aerosols are a suspension of small solid particles or droplets suspended in a gas or vapor. Aerosols are the products that depend on the power of a compressed or liquefied gas to expel the contents from the container.

Propellants provide the driving force to expel product from its container. Propellants provide dispersion medium.

Module 33: Pharmaceutical Aerosols III (Components and systems of aerosols)

Actuator: It provides rapid and convenient means for releasing the contents from a pressurized container. An actuator fits onto the valve stem

Propellants: It is a dispersion medium as well as the driving force provider for dispensing/discharge of product from aerosol container.

Module 34: Pharmaceutical Aerosols IV (Inhalers and Evaluation of Aerosols)

Dry Powder Inhalers (DPIs): Small portable, propellant free, breath-actuated inhalers.

Flame project test: In this test effect of an aerosol on the extension of an open flame after exposure of spray for 4 sec in flame is recorded.

Mesh nebulizers: It involves use of a mesh or plate with multiple apertures to produce a liquid aerosol.

Metered Dose Inhalers (MDIs): The aerosols which can deliver a dose from 25 µL to 100 µL of fixed volume range filled in metering chamber.

Week 11: Cosmetics

Module 35: Cosmetics – I

Cold cream: Cold cream is water in oil emulsion used for cleansing and softening of the skin. Cosmetics: Cosmetics are any substance or preparation intended to be put in contact with the different superficial part of human body or with the teeth and the mucous membrane of mouth in order to exclusively or generally clean, perfume, modify their appearance and/or correct body odours and/or protect or keep them in good condition.

Module 36: Cosmetics II

Formulation of Lipsticks, Shampoos, Hair Dyes

Shampoo: Shampoo are cosmetic preparation used for cleansing of hairs. It includes dust, oil, sebum and other debris it gives clean, soft, shining and strong hair.

Lipstick: Lipstick is a cosmetic product containing pigments, oils, waxes, and emollients that apply colour, texture, and protection to the lip

## Conclusion

It is obvious that management of IP and IPR is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices. It is no longer driven purely by a national perspective. IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on. In other words, trade and commerce considerations are important in the management of IPR. Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics. Each industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty. Pharmaceutical industry currently has an evolving IP strategy. Since there exists the increased possibility that some IPR are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the pharmaceutical industry. Still many things remain to be resolved in this context.

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