

COSMETICS –

FORMULATION,
MANUFACTURING &
QUALITY CONTROL

Fifth Edition

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M.Pharm.



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*Dedicated to my wife
who has been
supporting me throughout*

For Preview

For Preview

Preface to Fifth Edition

In the intervening years since the last edition of this book was published, there have been changes in the regulations. The Indian Standard, IS 4707 (Part 2) has been revised and many raw materials have been included in the banned list. New type of cosmetic i.e. cosmetic patches is now also available in the Indian market. All these changes necessitated review and updation of the book.

Animal activists have been demanding ban on animal testing of cosmetics for safety the world over. The European Union is the first region in the world to ban animal testing of cosmetics. India is also in the process of prohibiting animal testing of cosmetics. Therefore, a chapter has been added on *in vitro* testing of cosmetics for safety.

Perfumes and fragrances is a separate industry and so is toilet soaps. Earlier these were covered in chapters. But now these have been covered as separate parts in the book.

Thus the book has much more additional information on different topics. I am sure this revised edition will be more useful to the readers of the book.

I am thankful to all those who have helped me in updating this book. I thank Grato Enterprises for typesetting and designing the book. My sincere thanks to Rakmo Press Pvt. Ltd. who have printed the book.

June 2014

P.P. Sharma

For Preview

Preface to First Edition

The art and science of Cosmetics is as old as recorded history. In the early period, it was associated with religion, medicine and mysticism. For a very long period it remained in the hands of physicians and surgeons. It was Henri de Mondeville who made a move for the first time to separate cosmetics from medicine. Though, in sixteenth century, two French physicians wrote books on cosmetics, but upto seventeenth century, the cosmetic literature was limited to the "books of secrets". These books devoted to body embellishments, medicine and care of home and sundry. Later on, some books appeared on formulations and instructions. Most of the books published during nineteenth century and early twentieth century were in French and German languages. In 1923, Pouchers' book, *Perfumes, Cosmetics & soaps* was published in English. It is only in early 1940s, two cosmetic compendia were published in English which could be taken as scientific and technological compendia of cosmetics. The books by M.G.de Navarre & R.G. Harry furnished upto date and pertinent information to cosmetic chemist and the cosmetic chemist was better informed about the principles and materials employed in cosmetics. In 1957, a team of sixty one persons wrote a comprehensive scientific and technological compendium, known as *Cosmetics – Science & Technology* edited by Sagrain *et al.* The above-mentioned works have been revised and updated. These works are exhaustive in nature.

In India, majority of the cosmetic industry is in small scale. The foreign books are very costly and as such, are beyond their reach. Some of the information given in these books may even be beyond comprehension of the staff working in the small scale cosmetic industry. There are some Indian books on cosmetics, but there is hardly any book which covers quality control of cosmetics, control of microbial contamination in the manufacture of cosmetics, regulatory provisions relating to manufacture of cosmetics. I have made an effort to compile information on the above-mentioned

topics and on the formulation and manufacture of cosmetics to bridge the gap. Soap, though is a cosmetic, but soap industry is distinctly a separate industry, therefore, it has not been included in the book. Thus it is a comprehensive book on formulation, manufacture and quality control of cosmetics. It will be more economic than foreign books to the cosmetic industry.

I can not be complacent with the work as it is my maiden effort in the field of cosmetics. Readers are welcome to send their suggestions, criticism and views to improve upon it.

I am thankful to all those who have helped me in collecting information on various aspects of cosmetics: I am not giving their names as I am afraid I may miss some name and I don't want to be unthankful to him or her. I am grateful to my wife who has given me encouragement time to time to complete the book. I would also like to thank my son, Rajat who has provided me the needed stationery to write manuscript of the book.

Delhi, March 1998

P.P. Sharma

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PART 1

GENERAL

For Preview

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Introduction

All human beings have urge to look beautiful. It is because of this reason that they have been using different types of materials from time immemorial. In early period cosmetics were associated with religious practices. It is almost true for all old civilizations like Indian, Chinese, Egyptian & Greek. Ubtan with flour, turmeric and vegetable oil before marriage is still practised in India. Kum Kum (red in colour) is still applied by Hindu married women whose husbands are alive. During the early period, all cosmetics items were made in the home. Natural materials like aromatic materials, spices, herbs, resins, dyes, fats, oils, perfumes were used by the natives of different countries. Very early in Egypt, some high priests became recognised as medical practitioners and everything related to health and body care was associated with medicine. Although Egyptian physicians were highly specialized in various branches of their art, but their practices were freely adulterated with astrology, magic, mysticism and religion. Egyptians were famous as teachers throughout Middle East. Their knowledge and practices passed successively to the Assyrians, Babylonians, Chaldeans, Hebrews, Persians and Greeks. It can be said that cosmetics unearthed from tombs, temples and other religious places in early period.

In fourth century B.C., after the conquest of Persia by Alexander, a new culture developed in which arts of medicine and cosmetology greatly advanced. Though medical schools had been established in various Greek states, but it was not until Hippocrates (considered Father of Medicine), that all inherited knowledge was systematized into some semblance of scientific principles. It was Hippocrates who dissociated medicine from magic, superstition and religion. He advocated correct diet, exercise, sunlight, special baths and massage for good health and beauty.

The Alexander & his armies carried their healthful living habits eastward into Persia and India and back to Egypt and then to westward to the Italian Peninsula & Sicily. However, to Indians, Hindus in particular, this was no new knowledge as Hindu

literature also advocates correct diet, yoga (including Surya Namaskar), bath & meditation for good health.

The great scientist-philosopher, Aristotle of Stagira supplied valuable information on biology and physical science. Theophrastos of Eresos systematized the study of botany and wrote extensively on plants, minerals and odours among other subjects. Within a century, centre for culture was shifted from Athens to Alexandria. Physicians trained in medical school in Alexandria were in great demand in royal courts of neighbouring countries. But later on, Romans started conquering and Alexandria Empire started disintegrating. In 47 B.C., Julius Caesar occupied Alexandria. The Romans took over everything – art, science, medicine, literature and fused with their already acknowledged skills – architecture, agriculture, engineering, law, literature. In the next three centuries, the arts of cosmetics and cosmetology along with Greek medicine developed very much and reached unprecedented heights. One notable person of this period was Queen Cleopatra. She is believed to be thoroughly skilled in applying cosmetics and also in compounding cosmetics. Some contemporary literature include *Materia Medica* by Pedanios Dioscorides, writings of Galen on anatomy, physiology, pharmacy, therapeutics, philosophy and ethics. Galen's writing remained authority for about 15 centuries. His *ceratum refrigerans* (cooling ointment), a prototype of cold cream emulsion is most direct contribution to cosmetics.

In 529, the famous Academy at Athens which was established by Plato was closed by Emperor Justinian. As a result of this, several of the homeless professors found refuge at the court of Persia. At the court of Persia as well as at great medical school of Jundishapur in India, they introduced latest Greek thought. Within next century this school became an important centre for exchange of ideas by Greek, Christian, Jewish, Syrian, Hindu and Persian scholars. The medical school at Jundishapur brought Persians and others from west in contact with ancient system of medicine. Many substances which are still used in perfumery and cosmetics were given by India to the west. These include myrrh, camphor, musk (now banned), saffron, sandal, aloes, etc. In India, during Gupta Period, cosmetic hygiene was quite advanced. Ladies used many types of creams, oils, pastes before bath. Hair dyes were also used. Men used oils before bath and also used hair oils and perfumes. Almost everything was made in the home.

Rose was introduced into India from China. It was widely

cultivated and was used for rose essence and rose water. India maintained its supremacy in this industry for several centuries.

In the seventh century, Mohammed started religious movement, the Islam. Islam under Mohammed and his successors became scourge of conquest. Within a few years countries like Syria, Persia, Judea, Mesopotamia and Egypt were brought under Muslim control. The original Muslims – mostly Arabs got translated works of Galen, Dioscorides, Paul, Hippocrates, Oribasios, Aristotle, Pliny and others. Arabists advanced a bit the study of physiology and hygiene and gave attention to the therapeutic effects of bathing, proper diet, gymnastics and massage. For about three centuries, Muslim civilization maintained its supremacy. But early in the eleventh century, vast Mohammedan Empire began to crumble. Toledo was lost to Christian Spain & Sicily to the French.

Most of the advances made during Arabian period was due to applications of branches of science particularly chemistry, physics, botany and mathematics. Many products from India were adopted as perfumes and flavours. These include cassia, cloves, nutmeg, musk, myrrh, tamarind and rose. A significant contribution to all branches of science was the introduction of Hindu numerals. Ibn Sina, a Persian physician, scientist and encyclopedist is credited with preparing rose water by distillation. Moses ben Maimon, Spanish-Jewish philosopher and physician classified ideas of Galen and added good commentary. He was one of the first few persons who disputed authority of Galen and denounced astrology and superstition in medicine.

There were not much additions to the list of products which were available before Arabian period. Hindus used betel to darken lips, vermilion and other colours with waxes for their facial designations, almond paste for entire body and also used perfumes and aromatics. Persians paid particular attention to the hair and beard. Use of black dye was common.

Emperor Frederick II Hohenstauffen was a sincere patron of science, art and literature. Therefore, medicine and surgery progressed rapidly in Italian centres of studies. He conferred on Salerno the exclusive right to licence the practice of medicine but the institution was neglected. Teachers & students from Salerno scattered to all parts of Europe. Gilbert, Chancellor of Montpellier wrote a compendium, *Medicinae* containing interesting information on the care of diseases of skin and hair and on hygiene, especially for travellers. During the thirteenth century, new ideas of medicine

& surgery were introduced into France by several Italians.

Sarangdhara, a Hindu physician in mid-thirteenth century in his materia medica mentioned the applications of mercurials and other metallic salts in the treatment of skin conditions.

With the broadening of the field of medicine & surgery there were increased activities that led to reevaluation of both subject matter and practitioners. Surgeons made a guild in Paris which was subdivided into two groups :

- (i) Surgeons of the Long Robe – Surgeons having professional education and status,
- (ii) Surgeons of the Short Robe – Barbers who rendered limited assistance in actual surgery.

The first move to separate cosmetics from medicine was made by a Norman, Henri de Mondeville, a lecturer on anatomy and medicine. He wrote a text book on surgery in which he clearly distinguished pathological conditions of the skin that needed medical treatment and the other conditions which needed cosmetic applications. In his book, *Doctrina decorationis* in 24 chapters. These chapters covered treatment of skin diseases, burns and minor disorders and also several recipes for depilatories, dyes, ointments, pomades, soaps, paints etc. An antidotary in 10 chapters was also included to repair the irreparable outrage of years. Guy de Chauliac, a pupil of Henri, recognised nothing beyond defects of the eyes, ears, nose, mouth and teeth. He also broadened the concept of cosmetic treatment to include amputation of dead and superfluous organs and preserving and embalming of dead bodies. His book, *Inventarium or Chirurgia magna* was translated into eight languages in a short time.

Arabians continued some good work on herbs and plants relating to their use in medicine, perfumery, hygiene and skin care. Abdekar, court physician of Mohammed II, the Ottoman Sultan, in daily conferences instructed his favorite among the beauties of the Sultan's seraglio in the care of skin and hair and virtues of various types of baths. During this period, throughout northern Europe, pharmacy and medicine were becoming more professional. Philippus Aureolus Bombast, called Paracelsus exhorted the alchemists to make medicines and not gold. He also exhorted physicians to study medicine by going out where sick were and not by sitting around and trying to make everything conform to what was in their books. He went to the extent that he burnt the works of Hippocrates, Galen and Ibn Sina. Although his influence was

not immediately effective but he initiated a new period – iatrochemistry. Iatrochemistry gradually succeeded alchemy. He introduced a large number of chemical substances as drugs.

The broadening of knowledge of medicine and surgery resulted in dropping of cosmetics from medicines. It was eliminated from text books of medicine and began to appear in other publications. Two French physicians who actively continued their interest in practice of cosmeticology need mention here. Andre Le Fournier, Dean of Faculty of Medicine at the University of Pans published a comprehensive text on beautification. Jean Liebant, physician and agronomist wrote several books on general health, toxicology, gynaecology and cosmetics. In Italy also, the knowledge of medicine and surgery was enhanced during this period (sixteenth century). This period is called period of Renaissance. With return of crusaders to their homelands – England, France, Germany, the knowledge and understanding of Mediterranean countries and their products like aromatics, spices, beautiful fabrics, jewels and other luxuries spread. Many adventurous travellers acquainted Europe with India and other Eastern countries. The discovery of Western Hemisphere at the end of fifteenth century opened this vast region to exploitation by Spain. During the same period circum navigation of Africa by Vasco da Gama gave Portuguese the advantage of new route for trafficking in coveted spices, medicines, rich fabrics and other luxuries from India. Within 50 years, Portugal and Spain became wealthiest countries of Europe. England was also not slow to adopt the cosmetic innovations from the continent. Both Henry VIII & his daughter Elizabeth were amateur dabblers in pharmacy. Making of pomades and extracts and also medicines became a fad among those who could afford it. During the Elizabethan period, perfumery and cosmetics of all kinds were lavishly used. Face powder consisted of white lead, occasionally mixed with sublimate of mercury & ground orris. Rouge consisted of red ocher, vermilion or cochineal. Extracts of sandalwood or brazilwood were also used. Ingredients of a typical tooth whitener included powdered brick, cuttle bone, red and white coral, egg shells, alum, mustic, sandarac pumice & myrrh. Queen Elizabeth's golden-red hair became fashion. This was acquired by the ladies by soaking the hair first in warm solution of alum and then in decoction of rhubarb, turmeric and bark of barberry. To save time many women wore wigs. One of the notable advances of this period was the knowledge of alcohol and methods of distillation.

When Decoratio was officially dropped from the then considered ethical medical practice, it scattered in different directions and in early seventeenth century two developments became apparent. One, cosmetic treatment was associated with medicine and science, two, cosmetic treatment was considered mere external embellishment. Since the second development was strong, making of cosmetics soon fell into the hands of kitchen-maids, barbers and assorted charlatans. During the seventeenth & eighteenth century, cosmetic products of all kinds were still made principally in the home. Raw materials could be purchased from pharmacists and druggists. There was little change in the composition of cosmetic products. Bismuth subnitrate was introduced for face powder. Cochineal was used for rouge. Composition of creams and lotions were essentially the same. Lard, mutton tallow, white and yellow wax, essential oils were ingredients of pomades and ointments. Perfumery advanced in France during seventeenth and eighteenth century. Progress was also made in England. During this period, there was marked improvement in social condition of middle class everywhere. Personal cleanliness and good grooming lagged considerably behind the greater elegance in dress and surroundings. Soap, though was first manufactured in 1641 in England but its manufacture was hampered by government restrictions. The favourite cleanser for the skin was almond paste. Another cleanser made from cacao butter and vanilla was imported into many European countries from Spain.

Developments in cosmetics in American colonies followed the trends in parent countries (England, Spain, Portugal, France). Two factors which contributed greatly to the development of cosmetic industry during eighteenth century were the permanent establishment of news papers and that of legitimate pharmacies. Hair dressers and wig-makers started advertising in local newspapers. Pharmacy was largely in the hands of Indians, school masters, old women and clergymen. Drug store of those days stored not only medicines but also plants, spices, perfumery, tanstuffs and dyes. As the demand for "store bought" cosmetics grew, many pharmacists started to make and sell their products. Many of the physicians and pharmacists went to Europe and brought new knowledge of chemistry.

In the years following American and French revolution cosmetics and perfumery suffered a setback. Nineteenth century was a period of extraordinary activity and accomplishment in the

field of science and technology. Many international expositions of products from different countries were organised in nineteenth century at different places (America, England, France, Germany).

After the death of Queen Victoria in 1901, there was remarkable change in the social life in England. The new king, Edward VII was fond of gaiety and high fashion. In London, in 1905, Charles Nessler, a German-born hair dresser invented a mechanical means of putting a permanent curl in the hair. He wound the hair on a narrow rod soaked in borax and heated it by hand between the two halves of cylindrical iron. This invention was taken by him to the America in 1915. About the same time, Eugene Schueller devised a mixture of plant derivative dyes and metallic mordant and called it, "L'Oreal Compound Henna" and offered in a range of shades. The first world war created many problems to the cosmetic industry world over. One of the main problem was availability of perfume grade alcohol. After post war recession, chemical and cosmetic industries started developing. During 1920s beauty saloons flourished all over Europe and America. But 1930s were years of economic slump. When the world was recovering from this slump, Europe was plunged into World War II.

Post World War II period has been the period of growth of chemical and pharmaceutical industry. Availability of synthetic colours and pigments and detergent revolutionized cosmetic industry. Now the cosmetics and cosmetology have moved far into science. Researchers in different branches of science are working on many perennial problems.

In India, perfumery had developed long back and many essential oils known as "attar" were being used in the country and were being exported. Henna has been used traditionally for colouring palms and hair. Except for a few multinational companies like Lakme, Pond's, the cosmetic industry has been a cottage industry in India. Even today majority cosmetic industry is a small scale industry. But all types of cosmetics are being manufactured by this industry.

Prior to nineteen hundred sixties, there was no regulation on manufacture of cosmetics. Recognising the potential of adverse effects of cosmetics not manufactured with safe ingredients, the Government of India amended the Drugs Act, 1940 by bringing the cosmetics also within the purview of the Act and the title of the Act was changed to the Drugs & Cosmetics Act. This amendment was carried out by Act 21 of 1962.

Rules for import and manufacture of cosmetics were introduced under the Drugs & Cosmetics Rules by notification in the Gazette of India vide G.S.R. 1183 dt. 17.8.1964. Thus the regulation of cosmetics was started in the late sixties. For a long time the standards for cosmetics were not prescribed. Later, the Indian Standards were adopted and were prescribed under Schedule S to the Drugs & Cosmetics Rules. Now, the regulatory provisions are in place and these are required to be enforced adequately.

Between 1900 & 1920s many books on cosmetics, perfumery, cosmetology and related subjects were written. Most of them were either in German or French language. *Perfumes, Cosmetics & Soaps* by W.A. Poucher was the first book of its kind in English. Introduced in 1923, it has grown and has been updated time to time. Another good book on cosmetics that was published in mid-fifties is *Harry's cosmeticology. Cosmetics-Science & Technology* by Sagarin *et al.*, a comprehensive book on cosmetics was published in 1957. Since then it has been revised and second edition was published in 1974. Now a reprint edition of 1992 is available. Many other books were published between 1951 to 1972. Now, there is no dearth of books. However, in India, not many books were published on cosmetics. Out of those published books, hardly any one of them has chapter on quality control.

In this book, quality control of cosmetics has been covered extensively in one part. Since manufacture of cosmetics is regulated under the Drugs & Cosmetics Act & rules made thereunder, a chapter has been included on regulatory provisions. Other information which generally is not covered in Indian books include control of microbial contamination in the manufacture of cosmetics, general principles of manufacture of cosmetics and a detailed account of raw materials used in cosmetics. Information on these topics has been compiled in this book. The book has been divided into 11 parts.

Part 1 has general topics. Part 2 to part 6 are devoted to cosmetics for different body parts like the skin, the hair, the teeth. There are age groups which are vulnerable to harmful effects of cosmetics, cosmetics for vulnerable forms part 7. Miscellaneous cosmetic items like aerosol cosmetics, patch cosmetics and herbal cosmetics have been dealt in part 8. Perfumes and fragrances are a different industry and the same have been covered in part 9. Similarly, toilet soaps are again a separate industry and the same have been dealt in part 10. The last and final part 11 deals with quality control and cosmetics.

Chapter 1

Regulatory Provisions

Import, manufacture, sale or distribution of cosmetics were not being regulated in India prior to year 1962. In early sixties, it became necessary to regulate import, manufacture and sale distribution of cosmetics due to prevalence of misbranded and/or spurious cosmetics. Cosmetic was brought within the purview of the Drugs Act and the name of the Act was changed to the Drugs & Cosmetics Act, 1940 (hereinafter referred to as the Act) by Act 21 of 1962. However, the implementation of these provisions came into effect only in mid sixties when rules relating to import and manufacture of cosmetics were framed by the Government of India in 1964. Thereafter, rules have been amended time to time to achieve the intended purpose. Salient regulatory provisions will form the subject matter of this chapter.

Under the Act, Cosmetic has been defined as,

“Cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and includes any article intended for use as a component of cosmetic.

Earlier, soap was excluded from this definition by adding words “but does not include soap” to the definition. But, in 1982, these words were omitted and since then, toilet soaps have been covered under the definition of cosmetic.

1. REGULATORY PROVISIONS RELATING TO IMPORT OF COSMETICS

Chapter III of the Drugs & Cosmetics Act deals with import of drugs & cosmetics. Import of certain cosmetics is prohibited under section 10 of the Act and rules 129F, 134A, 135, 135A of the Drugs & Cosmetics Rules, 1945. These are :

- any cosmetic manufacture, sale or distribution of which is prohibited in the country of origin;

- any cosmetic which is not of standard quality;
- any misbranded or spurious cosmetic;
- any cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;
- any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;
- any cosmetic the import of which is prohibited by rule;
- any cosmetic containing hexachlorophene;
- any cosmetic in which lead or arsenic compound has been used for colouring purpose;
- any cosmetic which contains mercury compounds.

However, small quantities of cosmetics import of which is prohibited under Section 10 of the Act may be imported for personal use subject to two conditions. One, cosmetics should form a part of passenger's baggage and should be the property of and be intended for the bonafide use of passenger. Two, cosmetics should be declared to the custom authorities, if they so direct.

In February 2007, the Government of India, Ministry of Health & Welfare notified draft rules to amend the Drugs & Cosmetics Rules, 1945 to provide for registration of cosmetic products.¹ But these amendments could not be finalized for a long time presumably these did not find favour of the cosmetic trade. Though these amendments were finalized in May, 2010² but their implementation was deferred several times. Finally, their implementation has been made effective from 01.04.2013.

1.1 Application for Registration Certification for Import of Cosmetics

An application in Form 42 prescribed under the Drugs & Cosmetics Rules along with a fee of US \$ 250 or equivalent in Indian currency is required to be submitted in the office of Licensing Authority appointed by the Central Government i.e. office of the Drugs Controller General (India). The application is required to be accompanied by information and undertaking as specified in Schedule D III of the rules (Schedule D III has been reproduced as annex 1 to this chapter) duly signed by or on behalf of the manufacturer or by his authorized agent or importer in India or by the subsidiary in India authorized by the manufacturer. The authorization by the manufacturer to his agent in India should be authenticated either in India before a 1st Class Magistrate or in the

country of origin before such an equivalent authority. A single application can be made for one or more than one item of cosmetics manufactured by the same manufacturer.

1.2 Grant of Registration Certificate

If the application is complete in all respect, and the information specified in Schedule D III is in order, the licensing authority will issue Registration Certificate within six month of receipt of application. Beyond six months, the licensing authority can issue Registration Certificate with additional three months by recording reasons in writing for the delay. The Registration Certificate is issued in Form 43 prescribed under the Drugs & Cosmetics Rules. If the Registration Certificate is not issued within stipulated time, the applicant can make an appeal to Central Government.

This Registration Certificate remains valid for three years from the date of issue, if it is not suspended or cancelled. If an application is made within six months before the expiry of the certificate, it will remain valid till orders are passed on the application.

If the original Registration Certificate is defaced, damaged or lost, a duplicate copy can be obtained from the licensing authority by paying a fee of US \$ 100 or its equivalent amount in Indian currency.

1.3 Suspension or Cancellation of Registration Certificate

If the manufacturer of cosmetics fails to comply with any of the condition of the Registration Certificate, the licensing authority after giving him show cause notice in writing can suspend or cancel Registration Certificate. A person aggrieved by the suspension or cancellation order can make an appeal to the Central Government within thirty days of the receipt of the order.

1.4 Standards for Imported Cosmetics

For a long time, standards for cosmetics in finished form were not laid down under the Act or rules. In early eighties, the standards framed by Indian Standards Institution (now known as Bureau of Indian Standards) were adopted for certain cosmetics. Subsequently Indian Standards for more cosmetics were adopted. Now as many as 29 cosmetics have been placed under Schedule S to the rules and are required to comply with Indian Standards

and these are :

- | | |
|--|-----------------------------|
| 1. Skin powders | 15. Depilatories, chemical |
| 2. Skin powders for infants | 16. Shaving creams |
| 3. Toothpowders | 17. Cosmetic pencils |
| 4. Toothpastes | 18. Lipsticks |
| 5. Skin creams | 19. Toilet soap |
| 6. Hair oils | 20. Liquid toilet soap |
| 7. Shampoos, soap based | 21. Baby toilet soap |
| 8. Shampoos, synthetic detergent based | 22. Transparent toilet soap |
| 9. Hair creams | 23. Shaving soap |
| 10. Oxidation hair dyes, liquid | 24. Lipsalve |
| 11. Cologne | 25. Powder hair dye |
| 12. Nail Polish (Nail Enamel) | 26. Bindi (liquid) |
| 13. Aftershave lotion | 27. Kumkum powder |
| 14. Pomades & brilliantines | 28. Henna powder |
| | 29. Bathing bars |

So any of the 29 cosmetics which is imported into India should conform to the Indian Standards. In case, cosmetic is not included under Schedule S, it should meet the standards of the country of origin.

1.5 Some Prohibited Cosmetics

Misbranded and spurious cosmetics have been defined as under for the purpose of Chapter III of the Act which deals with import of cosmetics.

9-C. Misbranded cosmetics:– For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded –

- (a) if it contains a colour which is not prescribed; or
- (b) if it is not labelled in the prescribed manner; or
- (c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

9-D. Spurious cosmetics:– For the purposes of this Chapter, a cosmetic shall be deemed to be spurious –

- (a) if it is imported under a name which belongs to another cosmetic; or
- (b) if it is an imitation of, or is a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or
- (c) if the label or container bears the name of an individual or a company

- purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or
- (d) if it purports to be the product of a manufacturer of whom it is not truly a product.”³

Rule 134 of the rules stipulates that no cosmetic shall be imported which contains a coal tar colour other than the one prescribed in Schedule Q and Indian Standard (IS: 4707 Part I) to the said rules and coal tar colour used in cosmetic shall not contain more than –

- (i) 2 ppm of arsenic calculated as arsenic trioxide,
- (ii) 20 ppm of lead calculated as lead,
- (iii) 100 ppm of heavy metals other than lead calculated as the total of the respective metals.

Schedule Q to the rules has been reproduced in Chapter 4 Section 7.

So if any cosmetic is to be imported, it should have the colour(s) as stipulated above.

Manner in which a cosmetic should be labelled is given under Rule 148. Some special provisions relating to labelling of hair dyes containing coal tar colours are given under rule 149 and some special provisions relating to tooth paste containing fluoride are given under rule 149A. These will be discussed later in proceeding paragraphs. The cosmetics imported into India should conform to the above mentioned provisions.

After having explained the cosmetics, import of which is prohibited, procedure for import of cosmetics will be given in brief. All consignments which have to be imported, should be accompanied by an invoice or statement showing the name and quantities of cosmetics included in the consignment and name and address of the manufacturer. A declaration either by the manufacturer or by authorized person on his behalf or by importer or authorised person on his behalf should give a signed declaration to the Collector of Customs that cosmetics comply with the provisions of Chapter III of the Act. The officer appointed by the Government of India on port (usually Asstt. Drugs Controller of the Central Government are posted at the ports) may take sample for examination, test or analysis and may advise the Collector of Customs for action in the matter. If the officer on port decides to send the sample for testing, the consignment of cosmetics shall be detained till the report is received from the testing laboratory. However, if the importer gives an undertaking in writing not to

dispose of the cosmetics without the consent of Collector of Customs, the consignment can be handed over to the importer. The importer shall have to return the consignment to the Collector of customs within 10 days of notice given by him. If the sample, on examination, test or analysis, is found contravening any of the provisions of Chapter III and rules made thereunder but the contravention is such that it can be remedied by the importer, the Collector of Customs will forward the report to the importer and may permit release of consignment after obtaining an undertaking in writing not to dispose of the cosmetics without the permission of the officer authorized by Government of India in this behalf. If the contravention is such that it cannot be remedied by the importer, the Collector of Customs will communicate the same to the importer who will either send back the consignment to the country from which it was imported or to the country in which it was manufactured within two months of the receipt of the communication from Collector of Customs or will hand over it to the Central Government. However, the importer can make a representation against the report to the Collector of Customs who shall forward the representation along with a fresh sample of cosmetic to the Drugs Controller General (India) who may send the sample to the Director, Central Drugs Laboratory, Kolkata and obtain a report. Orders passed by the Drugs Controller General (India) shall be final.

2. REGULATORY PROVISIONS RELATING TO MANUFACTURE OF COSMETICS

A licence is required under the Drugs & Cosmetics Rules for manufacture of cosmetics for sale/distribution. This licence is issued by the state regulatory authorities (State Drugs Control Department or State Food and Drug Administration).

2.1 How to Obtain Licence

Application form has been prescribed under the rules. Application is required to be made in Form 31. The application should be accompanied by a licence fee of Rs.2500.00 and inspection fee of Rs. 1000.00. Additional fee will be required to be deposited, if number of items in any category exceeds ten. The categories of cosmetics have been specified under schedule M-II to the rules. Schedule M-II has been reproduced in the proceeding paragraphs of this chapter. The application should be accompanied

by the following documents:

- layout plan of the factory premises;
- a list of equipment and machinery installed;
- a document about the constitution of the firm i.e., an affidavit of proprietorship in case of sole-proprietorship, a copy of partnership deed, in case of partnership firm, a copy of memorandum and articles of association in case of a private limited or public limited company;
- a document showing possession of the applicant on the proposed premises for factory e.g. rent agreement/rent receipt etc.

Usually the application forms are got printed by the State Drugs Control Dept./FDA and are available from their office. Apart from the documents mentioned above State Drugs Control Department/FDA may also require certain affidavits or some other relevant information. Before grant of licence (which is issued in Form 32) the factory premises are inspected by the officer(s) of the State regulatory agency. During inspection, the officer finds out whether :

- The applicant has provided adequate space for manufacturing operations, quality control and storage of raw materials, packaging materials and finished products.
- The applicant has provided adequate equipment and machinery for manufacture of cosmetics which he intends to manufacture.*
- The applicant has provided adequate testing facilities for raw materials & finished form of cosmetics or has made arrangements for testing with an approved testing laboratory. State regulatory agency together with central agency approves testing laboratories where manufacturers of drugs and or cosmetics can get their products and raw materials tested.
- The applicant has whole time services of a person who has either of the qualifications :
 - Diploma in Pharmacy (D.Pharm.),
 - Registered Pharmacist,
 - Intermediate in science with chemistry as one of the subjects.

* Lists of equipment required for different categories of cosmetics are given under Schedule M (II) (see pages 18-23). For the benefit of readers, name and address of some machinery and equipment manufacturers are given in Appendix I.

Minimum requirements of space, equipment and machinery for manufacture of cosmetics have been prescribed under Schedule M-II to the Drugs & Cosmetics Rules. For convenience of the readers Schedule M-II is reproduced here.

SCHEDULE M (II)⁴

[See Rule 139]

REQUIREMENTS OF FACTORY PREMISES FOR MANUFACTURE OF COSMETICS

I. GENERAL REQUIREMENTS

A. Location and surroundings:– The factory shall be located in a sanitary place and hygienic conditions shall be maintained in the premises. Premises shall not be used for residence or be interconnected with residential areas. It shall be well ventilated and clean.

B. Buildings:– The buildings used for the factory shall be constructed so as to permit production under hygienic conditions and not to permit entry of insects, rodents, flies etc.

The walls of the room in which manufacturing operations are carried out, shall be up to a height of six feet from the floor, be smooth, water-proof and capable of being kept clean. The flooring shall be smooth, even and washable and shall be such as not to permit retention or accumulation of dust.

C. Water supply:– The water used in manufacture shall be of potable quality.

D. Disposal of water:– Suitable arrangements shall be made for disposal of waste water.

E. Health, clothing and sanitary requirements of the staff:– All workers shall be free from contagious or infectious diseases. They shall be provided with clean uniforms, masks, headgears and gloves wherever required. Washing facilities shall also be provided.

F. Medical services:– Adequate facilities for first-aid shall be provided.

G. Working benches shall be provided for carrying out operations such as filling, labelling, packing etc.

Such benches shall be fitted with smooth, impervious tops capable of being washed.

H. Adequate facilities shall be provided for washing and drying of glass containers, if the same are to be used for packing the products.

II. REQUIREMENTS OF PLANT AND EQUIPMENT

The following equipment, area and other requirements are recommended for the manufacture of –

A. Powders:– Face powder, cake make-up, compacts, face packs, masks and rouges etc.

1. **EQUIPMENT:**

(a) Powder mixer of suitable type provided with a dust collector.

- (b) Perfume and colour blender.
- (c) Sifter with sieves of suitable mesh size.
- (d) Ball mill or suitable grinder.
- (e) Filling and sealing equipment provided with dust extractor.
- (g) For compacts :-
 - (i) a separate mixer,
 - (ii) compact pressing machine.
- (h) Weighing and measuring devices.
- (i) Storage tanks.

An area of 15 square metres is recommended. The section is to be provided with adequate exhaust fans.

B. Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving creams and hair oils etc.

- (a) Mixing and storage tanks of suitable materials.
- (b) Heating kettle – steam, gas or electrically heated.
- (c) Suitable agitator.
- (d) Colloidal mill or homogeniser (wherever necessary).
- (e) Triple roller mill (wherever necessary).
- (f) Filling and sealing equipment.
- (g) Weighing and measuring devices.

An area of 25 square metres is recommended.

C. Nail Polishes and Nail Lacquers :

1. *EQUIPMENT :*

- (a) A suitable mixer.
- (b) Storage tanks.
- (c) Filling machine – hand operated or power driven.
- (d) Weighing and Measuring devices.

An area of 15 square metres is recommended. The section shall be provided with flame proof exhaust system.

2. *PREMISES :*

The following are the special requirements related to Nail Polishes and Nail Lacquers :

- (a) It shall be situated in an industrial area.
- (b) It shall be separate from other cosmetic manufacturing areas by metal/brick partition upto ceiling.
- (c) Floors, walls, ceilings and doors shall be fire proof.
- (d) Smoking, cooking and dwelling shall not be permitted and no naked flame shall be brought in the premises.
- (e) All electrical wiring and connections shall be concealed and main electric switch shall be outside the manufacturing area.
- (f) All equipment, furniture and light fittings in the section shall be flame proof.
- (g) Fire extinguisher like foam and dry powder and sufficient number of buckets containing sand shall be provided.

(h) All doors of the section shall open outwards.

3. *STORAGE* :

All explosive solvents and ingredients shall be stored in metal cupboards or in a separate enclosed area.

4. *MANUFACTURE* :

(a) Manufacture of lacquer shall not be undertaken unless the above conditions are complied with.

(b) Workers shall be asked to wear shoes with rubber sole in the section.

5. *OTHER REQUIREMENTS* :

No objection certificate from the local Fire Brigade Authorities shall be furnished.

D. Lipsticks and Lipgloss, etc.

1. *EQUIPMENT* :

- (a) Vertical mixer.
- (b) Jacketed kettle – steam, gas or electrically heated.
- (c) Mixing vessel (stainless steel).
- (d) Triple roller mill/Ball mill.
- (e) Moulds with refrigeration facility.
- (f) Weighing and measuring devices.

An area of 15 square metres is recommended.

E. Depilatories :

1. *EQUIPMENT* :

- (a) Mixing tanks.
- (b) Mixer.
- (c) Triple roller mill or homogeniser (where necessary).
- (d) Filling and sealing equipment.
- (e) Weighing and measuring devices.
- (f) Moulds (where necessary).

An area of 10 square metres is recommended.

F. Preparations used for Eyes :

Such preparations shall be manufactured under strict hygienic conditions to ensure that these are safe for use.

1. *Eyebrows, Eyelashes, Eyeliners etc.*

1. *EQUIPMENT* :

- (a) Mixing tanks.
- (b) A suitable mixer.
- (c) Homogeniser (where necessary).
- (d) Filling and sealing equipment.
- (e) Weighing and measuring devices.

An area of 10 square metres is recommended.

2. *Kajal and Surma* :

1. *EQUIPMENT* :

- (a) Base steriliser.
- (b) Powder steriliser (dry heat oven).
- (c) Stainless steel tanks.
- (d) A suitable Mixer.
- (e) Stainless steel sieves.
- (f) Filling and sealing arrangements.
- (g) Weighing and measuring devices.
- (h) Homogeniser (where necessary).
- (i) Pestle and Mortar (for Surma).

An area of 10 square metres with a separate area of 5 square metres for base sterilization is recommended.

OTHER REQUIREMENTS FOR 1 AND 2 :

- (a) False ceiling shall be provided wherever required.
- (b) Manufacturing area shall be made fly proof. An airlock or an aircurtain shall be provided.
- (c) Base used for Kajal shall be sterilised by heating the base at 150 degree C for required time in a separate enclosed area.
- (d) The vegetable carbon black powder shall be sterilised in a drying oven at 120 degree C for required time.
- (e) All utensils used for manufacture shall be of stainless steel and shall be washed with detergent water, antiseptic liquid and again with distilled water.
- (f) Containers employed for 'Kajal' shall be cleaned properly with bactericidal solution and dried.
- (g) Workers shall put on clean overalls and use handgloves wherever necessary.

G. Aerosol :

1. *EQUIPMENT :*

- (a) Air compressor (wherever necessary).
- (b) Mixing tanks.
- (c) Suitable propellant filling and crimping equipments.
- (d) Liquid filling unit.
- (e) Leak testing equipment.
- (f) Fire extinguisher (wherever necessary).
- (g) Suitable filtration equipment.
- (h) Weighing and measuring devices.

An area of 15 square metres is recommended.

2. *OTHER REQUIREMENTS :*

No objection certificate from the Local Fire Brigade Authorities shall be furnished.

H. Alcoholic Fragrance Solutions :

1. *EQUIPMENT :*

- (a) Mixing tanks with stirrer.
- (b) Filtering equipment.

- (c) Filling and sealing equipment.
 - (d) Weighing and measuring devices.
- An area of 15 square metres is recommended.

I. Hair Dyes :

1. *EQUIPMENT :*

- (a) Stainless steel tanks.
- (b) Mixer.
- (c) Filling Unit.
- (d) Weighing and measuring devices.
- (e) Masks, gloves and goggles.

An area of 15 square metres with proper exhaust is recommended.

J. Tooth Powders and Tooth Pastes etc.

1. *TOOTH POWDER IN GENERAL :*

Equipment :

- (a) Weighing and measuring devices.
- (b) Dry mixer (powder blender).
- (c) Stainless steel sieves.
- (d) Powder filling and sealing equipments.

An area of 15 square metres with proper exhaust is recommended.

2. *TOOTH PASTES :*

Equipment :

- (a) Weighing and measuring devices.
- (b) Kettle – steam, gas or electrically heated (where necessary).
- (c) Planetary mixer with deaerator system.
- (d) Stainless steel tanks.
- (e) Tube filling equipment.
- (f) Crimping machine.

An additional area of 15 square metres with proper exhaust is recommended.

3. *TOOTH POWDER (BLACK) :*

Equipment :

- (a) Weighing and measuring devices.
- (b) Dry mixer / powder blender.
- (c) Stainless steel sieves.
- (d) Powder filling arrangements.

An area of 15 square metres with proper exhaust is recommended.
Areas for manufacturing “Black” and “White” tooth powders should be separate.

K. Toilet Soaps :

1. *EQUIPMENT :*

- (a) Kettles/pans for saponification.
- (b) Boiler or any other suitable heating arrangement.
- (c) Suitable stirring arrangement.
- (d) Storage tanks or trays.

- (e) Driers.
- (f) Amalgamator/chipping machine.
- (g) Mixer.
- (h) Triple roller mill.
- (i) Granulator.
- (j) Plodder.
- (k) Cutter.
- (l) Pressing, stamping and embossing machine.
- (m) Weighing and measuring devices.

A minimum area of 100 square metres is recommended for the small scale manufacture of toilet soaps.

The areas recommended above are for basic manufacturing of different categories of cosmetics. In addition to that separate adequate space for storage of raw materials, finished products, packing materials shall be provided in factory premises.

Note No.-I: The above requirements of Schedule are made subject to the modification at the discretion of the Licensing Authority, if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

Note No.-II : The above requirements do not include requirements of machinery, equipments and premises required for preparation of containers and closers of different categories of cosmetics. The Licensing Authority shall have the discretion to examine the suitability and adequacy of the machinery, equipments and premises for the purpose taking into consideration of the requirements of the licensee.

Note No.-III : Schedule M-II specifies equipments and space required for certain categories of cosmetics only. There are other cosmetics items viz. Attars, perfumes etc. which are not covered in the above categories. The Licensing Authority shall, in respect of such items or categories of cosmetics, have the discretion to examine the adequacy of factory premises, space, plant and machinery and other requisites having regard to the nature and extent of the manufacturing operations involved and direct the licensee to carry on necessary modification in them.

Though the Schedule M-II stipulates that the walls of the room when manufacturing operations are carried out, shall be upto a height of six feet from the floor, be smooth, water proof and capable of being kept clean, the author recommends that the entire walls should be smooth impervious free from cracks and capable of being kept clean.

The Schedule M-II stipulates air-lock or air curtain only in case of eye preparations. Author recommends that entry to manufacturing areas of all categories should be through an air-

lock, as bacterial contamination is a serious issue and should be addressed. It will be discussed in Chapter 5 of this book.

On submission of satisfactory inspection report, Licensing Authority of the State grants the applicant licence in Form 32 for manufacture of cosmetics for sale/distribution. This licence remains valid for five years unless suspended or cancelled by the licensing authority under the rules. An application for renewal in prescribed form (Form 31) along with fee (Rs. 3500.00) is required to be made to the Licensing Authority before the date of validity of the licence. Once the application for renewal has been made, the licence is deemed valid till orders on renewal application are communicated by the Licensing Authority to the applicant. If it has not been possible for a licensee to apply for renewal of licence before its validity, he can apply for renewal of licence within a maximum period of six months with penalty fee of Rs. 400 per month or part thereof.

2.2 Conditions of Licence

Licensed cosmetics manufacturer has to comply with certain conditions. These conditions in brief are :

- Manufacturer should continue to provide and maintain the premises, equipment and staff as at the time of grant of licence.
- Manufacturer should test each batch or lot of raw materials before its use in the manufacture of cosmetics.
- Manufacturer should test each batch of finished cosmetics. Cosmetics appearing under Schedule S should conform to the Indian Standards framed by the Bureau of Indian Standards (BIS).
- Manufacturer should maintain records of raw materials, manufacture of each batch of cosmetic(s) and their testing. In the raw material and manufacturing records, at least the particulars those given under Schedule U(I) to the Drugs and Cosmetics Rules should be shown. For convenience of the readers Schedule U(I) is reproduced here.

SCHEDULE U(I)

[See Rules 142 and 142-B]

I. PARTICULARS TO BE SHOWN IN THE MANUFACTURING RECORDS

1. Serial number.
2. Name of the product.

3. Lot/Batch size.
4. Lot/Batch number.
5. Date of commencement of manufacture and date when manufacture was completed.
6. Names of all ingredients, quantities required for the lot/batch size, quantities actually used.
7. Control reference numbers in respect of raw materials used in formulation.
8. Reference to analytical report numbers.
9. Actual production and packing particulars indicating the size and quantity of finished packings.
10. Date of release of finished packing for distribution or sale.
11. Signature of the expert staff responsible for the manufacture.

II. RECORDS OF RAW MATERIALS

Records in respect of each raw material shall be maintained indicating the quantity received, control reference number, the quantity issued from time to time, the names and batch numbers of the products for the manufacture of which the said quantity of raw material has been issued and the particulars relating to the proper disposal of the stocks.

Notes:- (1) The Licensing Authority may permit the licensee to maintain records in such manner as is considered satisfactory, provided the basic requirements laid down above are complied with.

(2) The Licensing Authority may direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.

During manufacture of cosmetics only prescribed coal tar colours should be used. These colours have been prescribed under Schedule Q to the Rules and the same has been reproduced in Chapter 4 Section 7. The coal tar colour used in the manufacture of cosmetics should not contain more than

- 2 ppm of arsenic calculated as arsenic trioxide;
- 20 ppm of lead calculated as lead;
- 100 ppm of heavy metals other than lead calculated as the total of the respective heavy metals.

Finished cosmetics should be labelled in the manner laid down under rule 148 of the Drugs & Cosmetics Rules. Special provisions relating to labelling hair dye containing coal tar colours and tooth paste containing fluoride are given under rules 149 and 149A. These rules are reproduced here for the convenience of the readers.

148. Manner of Labelling:- Subject to other provisions of the rules, a cosmetic shall carry –

- (1) on both the inner and outer labels :
 - (a) the name of the cosmetics,
 - (b) the name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured;
Provided that if the cosmetic is contained in a very small size container where the address of the manufacturer can not be given, the name of the manufacturer and his principal place of manufacture shall be given along with pin code.
 - (c) use before (month and year)
- (2) on the outer label :
 - (a) A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semi-solids, combined with numerical count if the content is sub-divided :
Provided that this statement need not appear in case of a package of perfume, toilet water or the like, the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.
- (3) on the inner label; where a hazard exists :
 - (a) Adequate direction for safe use,
 - (b) Any warning, caution or special direction required to be observed by the consumer,
 - (c) A statement of the names and quantities of the ingredients that are hazardous or poisonous.
- (4) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the letter "B":
Provided that this clause shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semi-solid state, and 25 millilitres or less if the cosmetic is in a liquid state :
Provided further that in the case of soaps, instead of the batch number, the month & year of manufacture of soap shall be given on the label.
- (5) Manufacturing licence number, the number being preceded by the letter 'M'.
- (6) Where a package of a cosmetic has only one label such label shall contain all the information required to be shown on both the inner and the outer labels, under these rules.
- (7) The list of ingredients, present in concentration more than one per cent shall be listed in the descending order of weight or

volume at the time they are added, followed by those in concentration of less than one per cent, in any order and preceded by words "ingredients"

Provided that this statement need not appear for packs of less than 60 ml of liquids and 30 gm of solid or semi solids.

(8) Labelling requirements, if any, specified in the relevant Indian Standards for the cosmetics covered under Schedule S.

149. Labelling of hair dyes containing coal tar colours:— Hair dyes containing para-phenylene-diamine or other coal tar dye base or coal tar dye intermediate shall be labelled with the following legend in English and local languages and these shall appear on both the inner and the outer labels :

"Caution:— This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying directions should first be made. This product should not be used for dyeing the eyelashes or eyebrows; as such a use may cause blindness."

Each package shall also contain instructions in English and local language on the following lines for carrying out the test :

"This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty-four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eyebrows or eye lashes as severe inflammation of the eye or even blindness may result."

149-A. Special provisions relating to toothpaste containing fluoride :

- (i) Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.
- (ii) Date of expiry should be mentioned on tube and carton.

Licence of the manufacturer can be suspended or cancelled by the Licensing Authority if he is found not complying with the conditions of the licences mentioned above or if he is found contravening any other provisions of the Act or rules made thereunder.

2.3 Prohibition of Manufacture/Sale of Certain Cosmetics

Manufacture and/or sale of certain cosmetics is prohibited under the Act and rules made thereunder. These are :

- any cosmetic which is not of standard quality or is misbranded or spurious;
- any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;
- any cosmetic manufactured in contravention of the provisions of the Act or rules made thereunder;
- any cosmetic except toilet soap containing hexachlorophene;
- any cosmetic containing lead and arsenic compounds for colouring purpose;
- any cosmetic containing mercury compounds;
- any cosmetic containing colours other than prescribed ones.
- tooth paste/powder containing tobacco.

Some of the prohibited cosmetics will need explanation. These are given in proceeding paragraphs.

As mentioned in Section 1 of this Chapter, standards for cosmetics were not prescribed under the rules for a long time. Now 29 types of cosmetics mentioned in Schedule S are required to conform to the Indian Standards laid down by the Bureau of Indian Standards. So, a cosmetic not conforming to these standards will be considered as not of standard quality.

Misbranded and spurious cosmetics have been defined under Section 17-C and 17-D respectively and are as under,

17-C. Misbranded cosmetics:– For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded –

- (a) if it contains a colour which is not prescribed; or
- (b) if it is not labelled in the prescribed manner; or
- (c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

17-D. Spurious cosmetics:– For the purposes of this Chapter, a cosmetic shall be deemed to be spurious, –

- (a) if it is manufactured under a name which belongs to another cosmetic; or
- (b) it is an imitation of, or a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic unless it is plainly and conspicuously marked so as to reveal its

- true character and its lack of identity with such other cosmetic;
or
- (c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or
 - (d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Manufacturer should pay special attention to ingredients which he is going to use for manufacture of cosmetics as an ingredient which is not safe may render cosmetic harmful. Thus he may manufacture prohibited cosmetic. He should collect all relevant information on the ingredients which are to be used in the manufacture of cosmetics. Bureau of Indian Standards, based on information available within the country and overseas has classified raw materials of cosmetics in two categories, namely,

- generally recognised as safe (GRAS)
- generally not recognised as safe (GNRAS)

For details of materials which have been classified as GRAS and GNRAS, the readers are advised to refer to IS:4707 (Part I) and IS:4707 (Part II). These publications are very useful and should be referred to while developing formulation of cosmetics.

2.4 Loan Licence

A person not having his own manufacturing facilities can get cosmetics manufactured from a licensed cosmetic manufacturer under loan licence system. Application for loan licence in prescribed form (Form 31-A) along with a fee of Rs. 3500.00 (at present, may be revised) together with other requisite documents should be submitted to the state regulatory authorities. The Licensing Authority of the State, after examining that the licensed manufacturer has spare capacity and has agreed to manufacture cosmetics for applicant, will grant loan licence.

3. OFFENCES AND PENALTIES

Different offences relating to import, manufacture for sale/ distribution & sale of cosmetics have been laid down under the Drugs & Cosmetics Act. Penalties for different offences have also been laid down under the Act. For details, the readers are advised to refer to Sections 13, 18 and 27A of the Act. Offences relating to cosmetics and penalties in brief have been tabulated in the table printed hereafter.

Only salient provisions of the Drugs & Cosmetics Act & Rules made thereunder have been mentioned in this Chapter. For detailed information on the various provisions relating to import and manufacture of cosmetics for sale/distribution readers are advised to refer to the following parts of the Drugs & Cosmetics Act and the Drugs & Cosmetics Rules.

- Chapter III of the Drugs & Cosmetics Act, Import of Drugs & Cosmetics (Section 8 to Section 15)
- Chapter IV of the Drugs & Cosmetics Act, Manufacture, Sale and Distribution of Drugs & Cosmetics (Section 16 to Section 33-A)
- Part XIII of the Drugs & Cosmetics Rules, Import of Cosmetics (rule 129 to rule 136)
- Part XIV of the Drugs & Cosmetics Rules, Manufacture of Cosmetics for Sale or Distribution (rule 137 to rule 150-A).

References

1. G.S.R. 63(E) dated 02.02.2007, Gazette of India (E).
2. G.S.R. 426(E) dated 19.05.2010 (w.e.f. 01.04.2013).
3. Drugs & Cosmetics Act, 1940.
4. Drugs & Cosmetics Rules, 1945.

For Preview

Table 1.1: Offences and Penalties

S.No.	Contravention in brief	Offence Under Section	Penalty
1.	Import of spurious cosmetic or a cosmetic containing any ingredient which may render it unsafe/harmful under indicated directions.	13 (1) (a)	Imprisonment for a term which may extend to three years and fine which may extend to five thousand rupees.
2.	Import of cosmetic, other than the one mentioned at S. No. 1, import of which is prohibited.	13 (1) (b)	Imprisonment for a term which may extend to six months or fine which may extend to five hundred rupees or with both.
3.	Import of cosmetic, import of which has been prohibited under Section 10-A.	13 (1) (c)	Imprisonment for a term which may extend to three years or fine which may extend to five thousand rupees or with both.
4.	Repeated offence under S. No. 1 or 3.	13 (2) (a)	Imprisonment for a term which may extend to five years or fine which may extend to ten thousand rupees or with both.
5.	Repeated offence under S. No. 2.	13 (2) (b)	Imprisonment for a term which may extend to one year or fine which may extend to one thousand rupees or with both.
6.	Manufacture for sale/distribution or stock/exhibit for sale/distribution or sale of a cosmetic not of standard quality or misbranded.	18 (a) (ii)	Imprisonment for a term which may extend to one year or fine which may extend to one thousand rupees or with both.
7.	Manufacture for sale/distribution or stock/exhibit for sale/distribution or sale of a cosmetic containing any ingredient which may render it unsafe/harmful for use under indicated direction.	18 (a) (v)	Imprisonment for a term which may extend to one year or fine which may extend to one thousand rupees or with both.

Table 1.1: (Contd.)

S.No.	Contravention in brief	Offence Under Section	Penalty
8.	Manufacture for sale/distribution or stock/exhibit for sale/distribution or sale of a cosmetic in contravention with provisions of Chapter IV of the Act or any rule made thereunder.	18 (a) (vi)	Imprisonment for a term which may extend to one year or fine which may extend to one thousand rupees or with both.
9.	Sale or stock/exhibit for sale/distribution of a cosmetic imported or manufactured in contravention with provisions of the Act or any rule made thereunder.	18 (b)	Imprisonment for a term which may extend to one year or fine which may extend to one thousand rupees or with both.
10.	Manufacture for sale/distribution of a cosmetic except under, and in accordance with a license issued for the purpose.	18 (c)	Imprisonment for a term which may extend to one year or fine which may extend to one thousand rupees or with both.
11.	Manufacture for sale/distribution or stock/exhibit for sale/distribution or sale of a spurious cosmetic.	18 (a) (ii)	Imprisonment for a term which may extend to three years and fine.
12.	Repeated offence under S. No. 6 to 11.	Respective section	Imprisonment for a term which may extend to two years or fine which may extend to two thousand rupees or with both.

Annex 1***[SCHEDULE D-III**

[See Rule 129-A]

**INFORMATION AND UNDERTAKING REQUIRED TO
BE SUBMITTED BY THE MANUFACTURER OR HIS
AUTHORISED IMPORTER/DISTRIBUTOR/AGENT
WITH THE APPLICATION FORM FOR A REGISTRATION
CERTIFICATE. THE FORMAT SHALL BE PROPERLY
FILLED IN FOR EACH APPLICATION IN FORM 42**

1. Particulars of the Manufacturer and Manufacturing Premises.–
 - (a) Name and address of the manufacturer and manufacturing premises to be registered along with telephone numbers, Fax numbers and e-mail address.
 - (b) Name(s) and address of the Partners/Directors.
 - (c) Name and address of the authorised importer/distributor/agent in India, responsible for the business of the manufacturer.
 - (d) A brief profile of the manufacturer's business activity, in domestic as well as global market.
2. Particulars of the Cosmetics to be Registered under Registration Certificate.–
 - (a) Names of cosmetics along with their brands name, category, pack sizes and variants to be registered and meant for import into and use in India.
 - (b) Particulars of the manufacturing licenses/registration/marketing authorizations (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses/ marketing authorization/registration issued by the Regulatory Authority of that country.
 - (c) List of countries where marketing authorization or import permission for the said cosmetic has been granted.
3. Chemical Information of Cosmetics.–
 - (a) Name(s) of ingredients in the nomenclature of standard references, along with percentages contained in the cosmetic.
 - (b) Specification and testing method for testing of the cosmetic(s).
 - (c) Manner of labeling as per Drugs and Cosmetics Rules, 1945.
 - (d) Package insert (if any).

* *Ins.* by GSR 426(E), dt. 19-5-2010 (w.e.f. 1-4-2013) as corrected by GSR 733(E), dt. 29-9-2012.

4. Undertaking to declare that.–

- (a) We shall comply with all the conditions imposed on the Registration Certificate for the import of cosmetics as required under the provisions of Drugs and Cosmetics rules, 1945.
- (b) We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.
- (c) We shall comply with the provisions of Part XIII of the Drugs and Cosmetics Rules, 1945.
- (d) Every cosmetic manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time.
- (e) We shall inform to the licensing authority, within 30 days in the event of any change in variants or in category or in manufacturing location or in labeling or in documentation of any of the cosmetic pertaining to the certificate to be granted to us.
- (f) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawals/regulatory restriction, or cancellation of authorisation and/or “not of standard quality report” of any cosmetic pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the cosmetic is marketed/sold or distributed. The despatch and marketing of the cosmetic in such cases, shall be stopped and the licensing authority shall be informed immediately.
- (g) We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made thereunder.
- (h) We shall allow the licensing authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the licensing authority.

The information submitted above is true to the best of my/our knowledge and belief.

Place:

Date: Signature of the manufacturer or his authorized agent
Seal/ Stamp]

Chapter 2

Plant Layout and Other Factory Requirements

Plant layout will depend on factors like type of cosmetics to be manufactured, scale of operation, type of equipment to be used, total space available etc. Schedule M-II to the Drugs & Cosmetics Rules lays down minimum requirements for space for different types of cosmetics, e.g., powders, creams/lotions, lipsticks, nail enamel etc. These requirements are for manufacturing operations only. Equipment for a particular type of cosmetics have also been specified. The schedule also prescribes general requirements like location and surroundings, buildings, water supply, disposal of water, health, clothing and sanitary requirements of staff, medical services. Readers may refer to chapter 1 of this book where Schedule M (II) has been reproduced.

It will be appropriate to deal with general requirements also when dealing with plant layout.

1. LOCATION AND SURROUNDINGS

Selection of site for constructing a cosmetics factory is an important decision. It should be made after careful consideration of various factors. Site, once selected is forever until the factory is shifted to another location. Ideally, location should be hygienic. Surroundings should be such that sources of pollution are minimum. The site should be away from sewage drain, public lavatory or other potential pollution source. Other points which are important from the point of view of commerce include:

- Transportation facilities for transportation of men, materials and equipments to and fro.
- Availability of suitable quality of water.
- Availability of electricity.
- Availability of skilled and unskilled personnel.