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COSMETOVIGILANCE: A SURVEY AMONG FEMALE EMPLOYEES AND TESTING OF HEAVY METALS IN COSMETICS

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ABSTRACT

Although it is considered that cosmetics do not have adverse effects, studies have revealed that a significant number of consumers experience adverse reactions. Undesirable effects arising from the use of cosmetic products have created the need for a reporting and evaluation, which is responsible for some restrictions on the use of cosmetics components, called cosmetovigilance. However, the new cosmetovigilance concept needs some updates to become more effective for public health. For instance, adverse effects related to cosmetic use have been reported more frequently recently, but this rate is still quite low. These adverse reactions like contact dermatitis, acne pimples, pigmentation, rashes, might be the cause of presence of heavy metals in cosmetic products. Heavy metals contamination in cosmetic products is a serious threat. Present study was conducted to evaluate the concentrations of heavy metals in various brands of cosmetic products with special emphasis on their health risk assessment. Presence of five heavy metals including mercury, lead, arsenic, cadmium and nickel were identified in different brands of lotions, foundations, whitening creams, lipsticks, kajal, mascara and anti-aging creams using qualitative analysis method i.e. limit test.

KEYWORDS: Cosmetovigilance, Limit test, Heavy metals.

1. INTRODUCTION

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

safety. There are concerns regarding the presence of harmful chemicals, including heavy metals, in these products. There has not been many studies on presence of heavy metals in cosmetics in India. The use of cosmetics has been practiced since antiquity as apart from cleansing, cosmetics also beautify and alter the appearance hence making the individual more appealing and attractive. The latter regulation also states clearly what ingredients are prohibited for their presence in cosmetic products. Amongst the prohibit ingredients several heavy metals are also included. Whereas some metals and their salts are completely prohibited (e.g., tin, arsenic, cadmium, nickel and lead), other metals and their salts are either allowed with a specific limit or else only specific salts for such metals are allowed (e.g., cobalt, chromium, gold, mercury and selenium amongst others).

1.1 Heavy metals

Table no.1 Heavy metals limit.

Organization	Lead (Pb)	Cadmium (Cd)	Mercury (Hg)	Arsenic (As)
FDA	5 ppm	0.3 ppm	1 ppm	5 ppm
WHO	10 ppm	0.3 ppm	1 ppm	5 ppm
EU	-	0.5 ppm	-	1 ppm
CA	10 ppm	3 ppm	3 ppm	-

1.2 Metallokinetics and metallodynamics within the body[2]

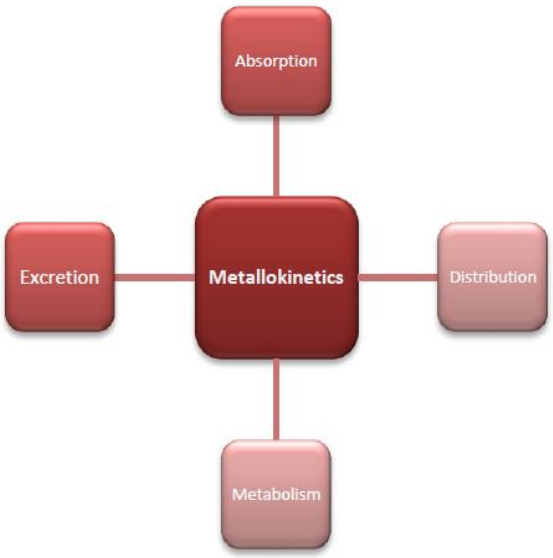


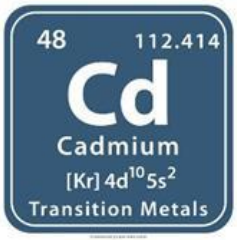
Fig no. 1. Metallokinetics.

- The absorption, distribution, metabolism, excretion and interaction of heavy metals with bodily systems are complex processes that are not yet fully understood. This is even more complex when considering that some cosmetics are applied and rinsed shortly after (such

as toothpastes, shampoos and conditioners and cleansers), others are applied and allowed for a few minutes to hours (such as body creams, lotions and facial makeup) and those that are applied and remain in contact with the skin for several hours (such as nail polish and hair dyes).

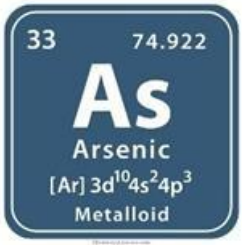
- The kinetics and dynamics of metals present in these cosmetic products, vary significantly in their fate and their extent of effects. With the application of cosmetic products, the mode of entry of heavy metals in the body is via dermal or topical application. These metals may have either topical and/or systemic effects in humans.

• When a lead comes in contact with vital organs, it is neurotoxic, nephrotoxic and hepatotoxic and may provoke effects also on the reproductive system. It has been reported that the level of Pb in the blood of consumers who use eye cosmetics was threefold higher than that of non- consumers.



• Cadmium is one of the metals that has been used in cosmetics for its colored salts, ranging from deep yellow to orange. It normally binds to the keratin. Systemically, It has been associated with osteoporosis, diabetes, lung cancer and kidney damage.

• Mercury is one of the heavy metals that is widely used in cosmetic formulations. After dermal application, Hg penetrates through the skin via the hair follicles and sweat glands. Hg blocks tyrosinase in situ, inhibiting the melanin-forming enzyme, hence its use in skin-lightening creams.



•Arsenic is a metalloid that is present ubiquitously as a major contaminant in the environment. Although, it is redox inactive, its target functional groups are sulfydryl groups on proteins which may lead to the depletion of glutathione . On long-term dermal exposure, As can cause hyperpigmentation and keratosis in situ, but systemically it may lead to carcinogenesis and vascular diseases.

1.3 Cosmetovigilance[1]

The term “pharmacovigilance” defines the activities related to the collection, detection, assessment, monitoring, and prevention of adverse reactions occurring with medications. Recently, the spectrum of “-vigilance” has broadened to include safety of herbal products and

cosmetic products as well. “Cosmetovigilance” was introduced as a new term used for defining surveillance carried out by industry to address the safety of cosmetic products. It was first used in literature by Vigan (1997) to refer to the monitoring of cosmetic product safety. Today, it is recognized globally as a concept of public health.

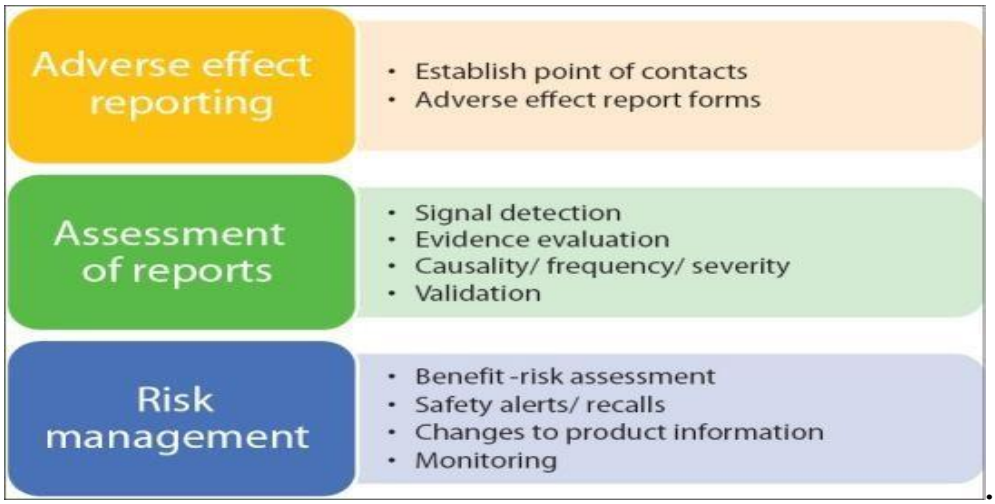


Fig no 2: Pharmacovigilance reporting.

Adverse reactions related to cosmetic ingredients[6]

Several scientific studies have been conducted to determine the frequency of occurrence of side effects related to cosmetics. In a study, it was found that 24% of cosmetic consumers experienced any side effects. Cutaneous side effects constitute 95.9% of total side effects, and 4.1% of systemic side effects. In this study, it was also reported that the most common cutaneous side effects were rash (34.8%), itching (31.5%), eczema (22.8%), and others.

Systemic side effects were stated as headache (1.7%), nausea (1%), dizziness (0.6%), dyspnea (0.3%) and other conditions.

Fig 3: Contact Dermatitis.

Fig 4: Discoloration of skin.

Fig. 5: Acne cosmetic.

2. MATERIALS AND METHOD

1.1 Study design: This study was questionnaire based survey which is undertaken in the Wardha region using general population of female employees and pharmacist and was conducted between February and May. The questionnaire which used is developed by using the earlier reports and knowledge of related topic.

1.2 Study procedure: Questions were asked to the women employees and the pharmacist from questionnaire and forms were filled as per their answer. The data collected through questionnaire was utilized for further analysis.

1.3 Location of study: Wardha

1.4 Wardha district (Maharashtra) is located in the central part of India. Wardha district is located on the north eastern side of Maharashtra state. Wardha districts lies between the 20018’ and 21021’ North latitudes and longitudes 7804’ East to 79015’ East longitudes. It is bound on the west and North by Amravati district on south by Yavatmal district, on the South-East by Chandrapur district and on East by Nagpur district. The boundaries with the Amravati and Yavatmal districts are identified by the river Wardha. Wardha district is a part of Nagpur revenue division. The district covers an area of 6309 sq km, which is 2% area of the Maharashtra state.

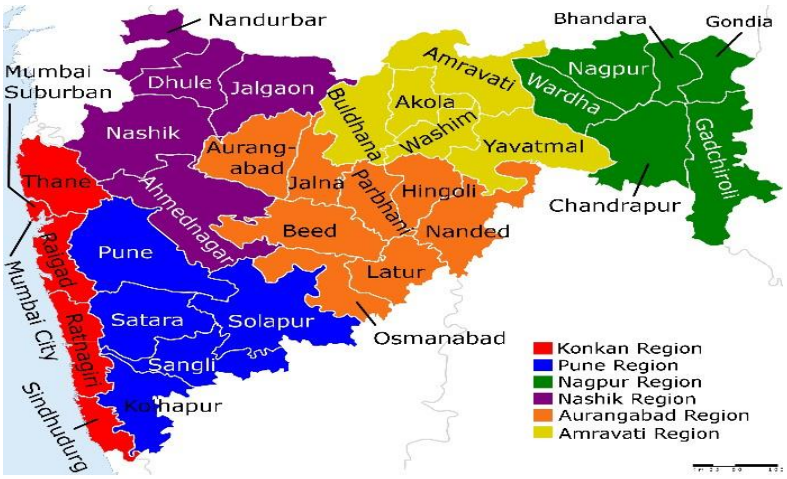


Fig no 6 Maharashtra map.

A) Survey among female employees about the use and Occurance of Adverse drug reaction

- Sample size : 200 female employees.

Survey among female employees about the use and Occurance of Adverse drug reaction in Wardha district. Survey is done via offline and online (google form) both mode.

Googleform:https://docs.google.com/forms/d/e/1FAIpQLScm1rUCtZGA-UDVjvFS2GRfeRYC3wIoiE9CveyW_oz9CE--3A/viewform?usp=sf_link.

Fig no 7: Wardha district.

SURVEY FORM :
Group : Female employees on use and ADRs of cosmetic.

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Questionaries

Employee's detail

1. Name:_____
2. Age:_____
3. Address:_____
   _____
4. Post/ Designation:_____

5. Do you use cosmetic products ?
6. What types of cosmetics use ?
7. How much you spend on cosmetic product monthly ?
8. Are you aware about adverse drug reactions
9. Do you ever experience any kind of adverse drug reaction?
10. If yes, what type of adverse reaction occurs?
11. What measure do you take to treat those reactions ?
12. Do you report those ADRs to anyone ?
13. How frequently you purchase the cosmetic products ?
14. Are there some specific brand you used the most ?
15. Do you ever feel need to change your products brand ?
16. Is brand name more important to you or the content
17. Do you recommend any cosmetic brand depending on your past experience.

B) Survey among the Pharmacists about the brand loyalty of customers.

SURVEY FORM
Group: Pharmacists.

DR. R. G. BHOYAR INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH, WARDHA.

Questionaries.

Pharmacist Details

1. Name:_____
2. Pharmacy Name: _____
3. Address:_____

4. Do you have such customers who mostly purchase cosmetics from your shop only ?
5. If yes, what number of customers you have ?
6. On an average, how much does an average customer spend on cosmetic per visit ?
7. Do they use tester more often before the purchase of cosmetics ?
8. When according to you customers purchase cosmetics ?
9. What role do you play in the cosmetics buying decision of customers ?
10. What, as per your observation are the various including factors in cosmetic buying decision of customers ?
11. How much do the customers compare brands before purchase ?
12. How much time do they invest in buying cosmetics ?
13. What are various brands that are available at your shop ?
14. Have you ever gone through a situation when a customer asks for a brand which is not available at your shop ?
15. What according to you define brand loyalty with respect to cosmetic ?
16. Do you have such customers who are Loyal towards certain brand ?
17. What are the various features of cosmetic product about which the customers generally enquire about ?

C) Determination of heavy metals in the cosmetics

The presence of heavy metals in marketed formulation of cosmetics was determined by limit test.

7.4 SamplingMethodology

Sample of lipstick, fairness creams, lip-balm,antiageing cream, kajal, eyeliner, nail paint were purchased from local market of Wardha. The details of the samples are presented in Table.

Table no. 2: Marketed cosmetics formulation.

Sr. No	Cosmetic	Brand	Batch no.	Use Before	Image
1	Lipstick	AM1L	226J12	Use before 24 months from pkd.	
2	Fairness Cream	AM2C	B33	Use before 24 months from pkd.	
		AM3C	B067		
				Use before 24 months from pkd.	
3	Kajal	AM4E	AB0512	Use before 24 months from pkd.	
4	Eyeliner	AM5B	A310L7	Use before 36 months of manufacturing	
5	Nail paint	AM6N	0066B	Use before 2 years from pkd	
6	Anti-ageing cream	AM7W	B528657C	Use before 2 years from the pkd.	

7.5 Preparation of sample.

- Sample preparation for the determination of Lead, Cadmium, Chromium, mercury and Nickel.

1. About 1.0 g of each sample was digested in 5.0 ml mixture of concentrated acid HNO3:HCLO4 (3:1) for 2-3 hours on a hot plate at 90^0C.
2. Then 3.0 ml of acid mixture was again added and then again heated for 2-3 hours to complete the digestion.
3. The above digested samples were cooled and about 5.0 ml ultra pure water was added mixed well and volume made upto 25 ml in volumetric flask.
4. The solution was then finally filtered through Whatman filter paper (Number 41). The clear solution was used for metal quantification

- Sample preparation for Mercury Determination

1. The samples were weighed (~0.2g) into the beaker. The samples were predigested with 2 ml of H2SO4 and 2 ml HNO3for 1.5 hours at 80 ^{0}C.
2. This initial predigest step dissolved/dispersed the samples and then allowed to cool to room temperature.
3. Then 7.0 ml of 5% KmnO4 and 5 ml 3% HCl were added to each beaker.

- Limit test of heavy metals

Limit test of heavy metals is based on the reaction of metallic impurities with hydrogen sulfide in acidic medium to form brownish color solution. Metals that response to this test are lead, mercury, bismuth, arsenic, antimony, tin, cadmium, silver, copper, and molybdenum. The metallic impurities in substances are expressed as parts of lead per million parts of the substance. The usual limit as per Indian Pharmacopoeia is 20 ppm.

Table no. 3: Limit test of heavy metals.

Test solution	Standard solution
The required quantity of sample is dissolved in 20 ml of water; add 5 ml of sodium hydroxide solution or the sample solution is prepared as per monograph.	The standard solution is prepared by using 1.0 ml of standard lead solution; add 5 ml of sodium hydroxide solution.
Make up to 50 ml with water.	Make up to 50 ml with water.
Add 5 drops of sodium sulphide solution mix well and kept aside for 5 min.	Add 5 drops of sodium sulphide solution mix well and kept aside for 5 min.
View downwards over a white background.	View downwards over a white background.

- Limit test of lead

Limit test of lead is based on the reaction of lead and diphenylthiocabazone (dithizone) in alkaline solution to form lead dithizone complex which is read in color. Dithizone is green in color in chloroform and lead-dithizone complex is violet in color, so the resulting color at the end of process is red.

Table no 4: Limit test of lead.

Standard solution: 20 ppm lead nitrate solution
Test solution: 4 ml test substance + 2 ml acetic acid---- Make up the volume up to 25 ml with distilled water.
Procedure:

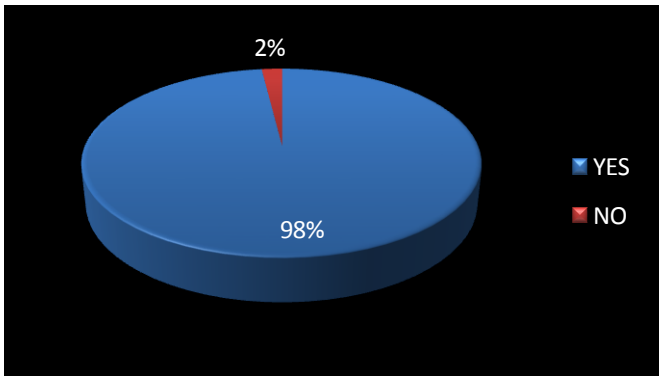
Test solution	Standard solution
Take whole test solution (25 ml)	Take 1 ml lead standard solution
Add 5 ml dilute NaOH solution	Add 5 ml dilute NaOH solution
Make up the volume up to 50 ml with distilled water.	Make up the volume up to 50 ml with distilled water.
Add 5 drops of lead sulfide solution	Add 5 drops of lead sulfide solution
Stir both the solutions and allow both the Nessler cylinders to stand for 5 min. Check intensity of developed color in both the solutions.	

If intensity of color that produced in test solution is less intense than standard then the sample passes the limit test as per IP2018 and If intensity of color that produced in test solution is more intense than standard than the sample fails the limit test as per IP2018 *********

3. RESULT AND DISCUSSION

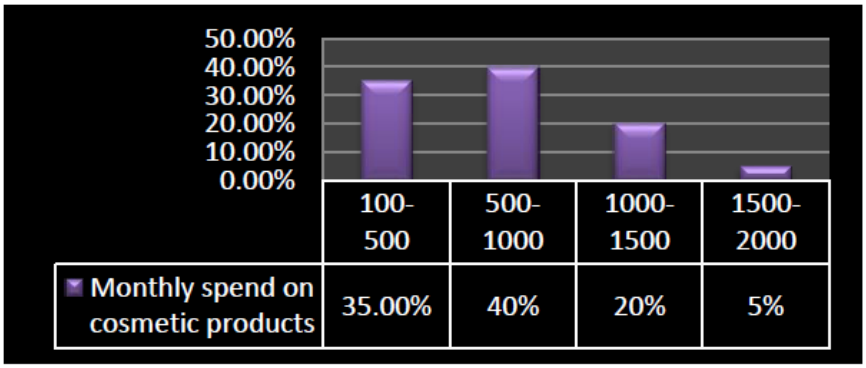
From the survey, the following results was observed,

1. Do you use cosmetic products ?



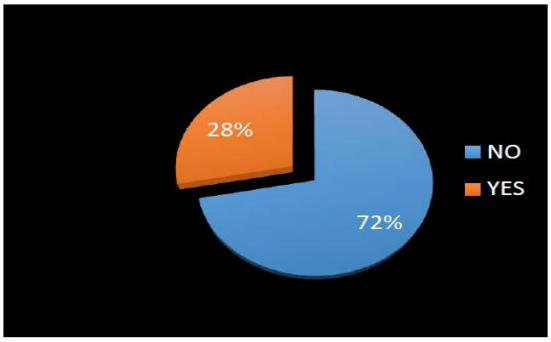
From the above graph it was observed that the 98% of female employees used cosmetic products daily while 2% of female employees do not use cosmetic products.

2. How much you monthly spend on cosmetic products?



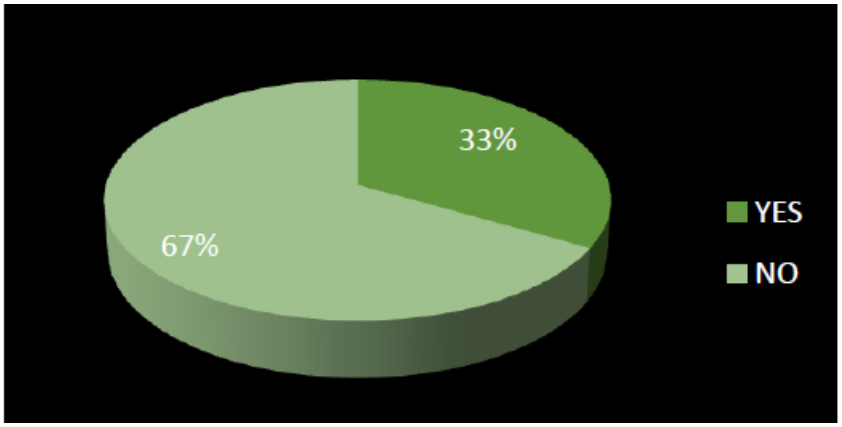
From the above graph it was observed that 35% female employees spend 100-500 rupees, 40% female employees spend 500-1000 rupees, 20% female employees spend 1000-1500 rupees and 5% female employees spend 1500-2000 rupees on cosmetic products.

3. Do you ever experience ADRs ?



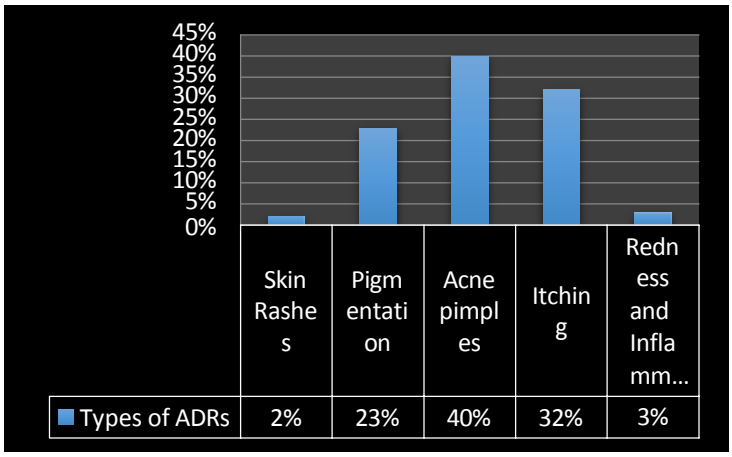
From the above graph it was observed that adverse drug reactions were occur to 72% of female employees while 28% do not experience any adver drug reactions of cosmetic products.

4. Do you report those ADRs?



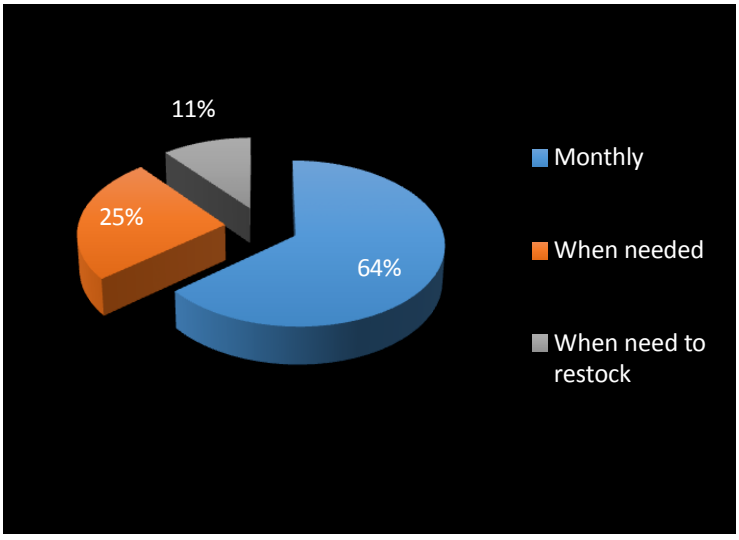
From the above graph it was observed that 67% female employees report the ADR while 33% do not report the ADR.

5. What type of adverse reaction do you experience?



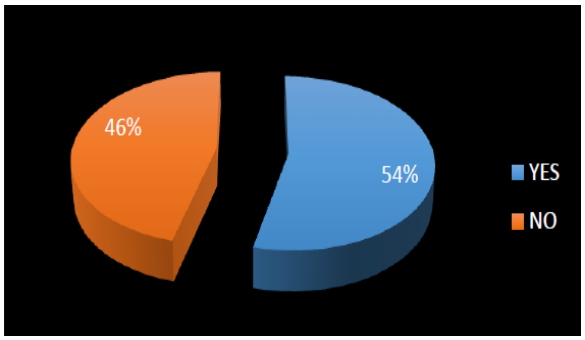
From the above graph it was observed that 2% of female employees. 23% female employees, 40% female employees, 32% female employees and 3% female employees occur skin rashes, pigmentation, acne and pimples, itching and redness inflammation respectively.

6. How frequently you purchase the cosmetic products ?



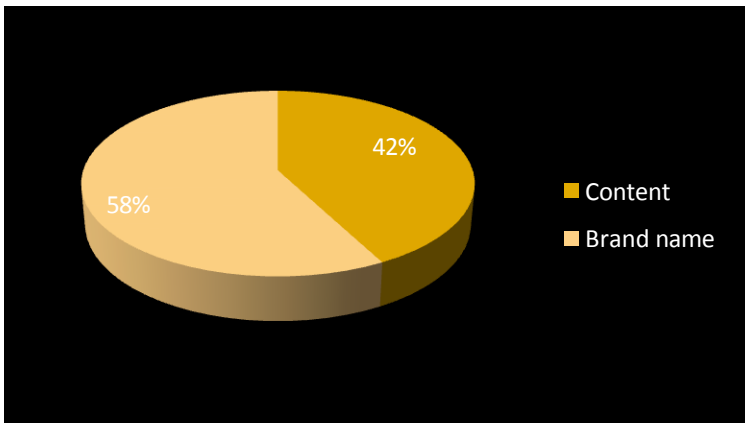
From the above graph it was observed that 64% female employees purchase the product monthly, 25% purchase the product when needed, 11% female employees purchase the product when they need to restock.

7. Do you ever feel need to change the brand?



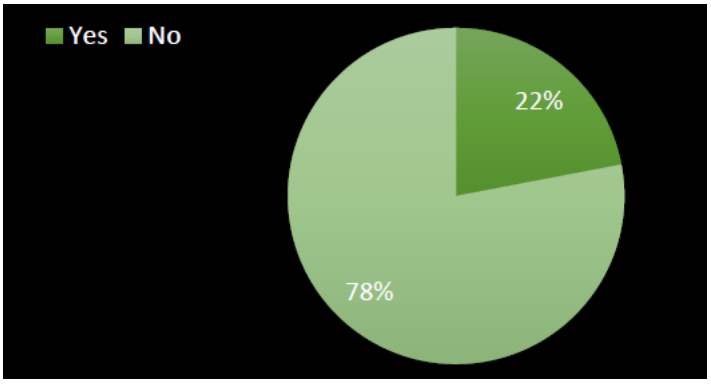
From the above graph it was observed that 54% female employees feel need to change the brand they use while 46% female employees do not feel need to change the brand.

8. What is more important to you content or the brand name?



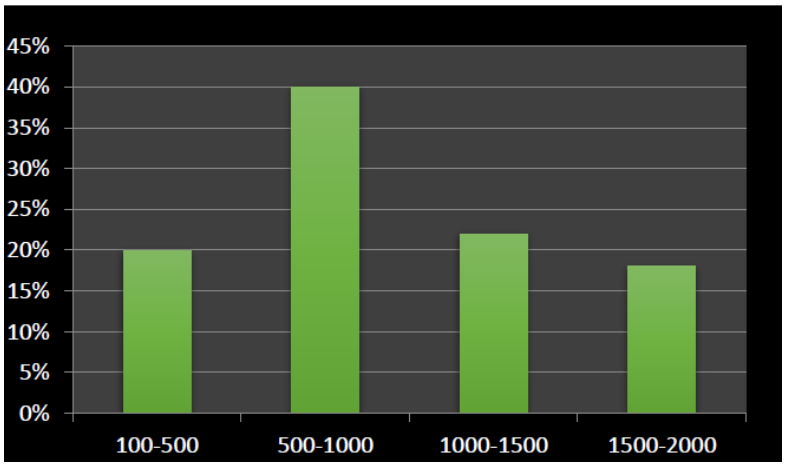
From the above graph it was observed that according to 58% female employees brand name is more important than content while for 42% of female employees content is more important than the brand name.

9. Do you have such customers who mostly purchase cosmetic from your shop only?



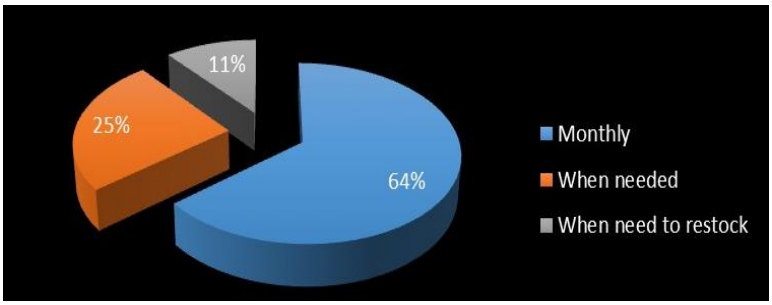
From the above graph it was observed that 22% customers purchase products from a dedicated pharmacy.

10. On an average, how much does an average customer spend on cosmetic per visit?



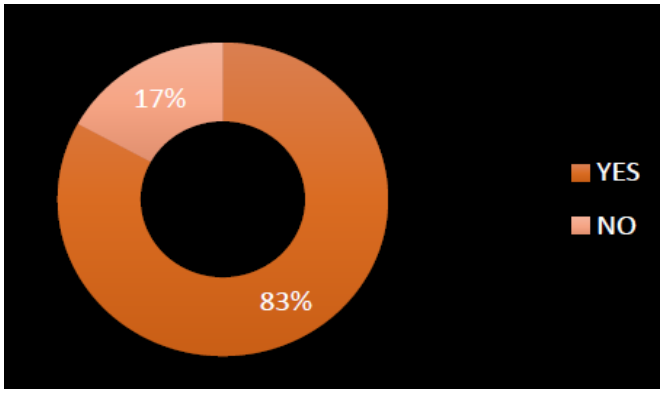
From the above graph it was observed that 20% customers spend 100-500 rupees, 40% customers spend 500-1000 rupees, 22% customers spend 1000-1500 rupees while 18% customers spend 1500-2000 rupees on cosmetic products.

11. When according to you customers purchase cosmetics?



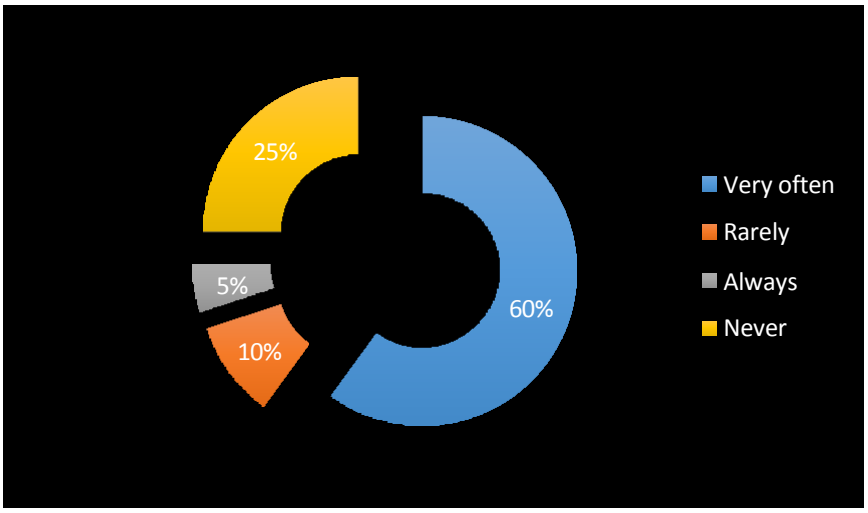
From the above graph it was observed that 64% female employees purchase the product monthly, 25% purchase the product when needed, 11% female employees purchase the product when they need to restock.

12. Do you have such customers who are loyal towards certain brand?



From the above graph it was observed that only 83% customers are loyal towards a certain brand.

13. How much do the customers compare brands before purchase?



From the above graph it was observed that 60% customers compare brands before purchase very often, 10% rarely, 5% always and 25% never.

DETERMINATION OF HEAVY METALS

Table no.5: Limit test results.

PRODUCT	RESULT
Lipstick (AM1L)	Shows presence of lead
Fairness cream (AM2C)	Shows presence of mercury
Kajal (AM4E)	Shows presence of lead
Eyeliner (AM5B)	Shows presence of lead
Nail Paint (AM6N)	Shows presence of mercury
Anti-aging cream (AM7W)	Shows presence of mercury

From the above study it was found that almost every marketed cosmetic product contains heavy metals. It's product label claims dose not confirmed the type of heavy metal and percentage use. Hence, the ADR with cosmetics may be by the presence of heavy metals in higher concentration or above the prescribed limit value given by standard organization.

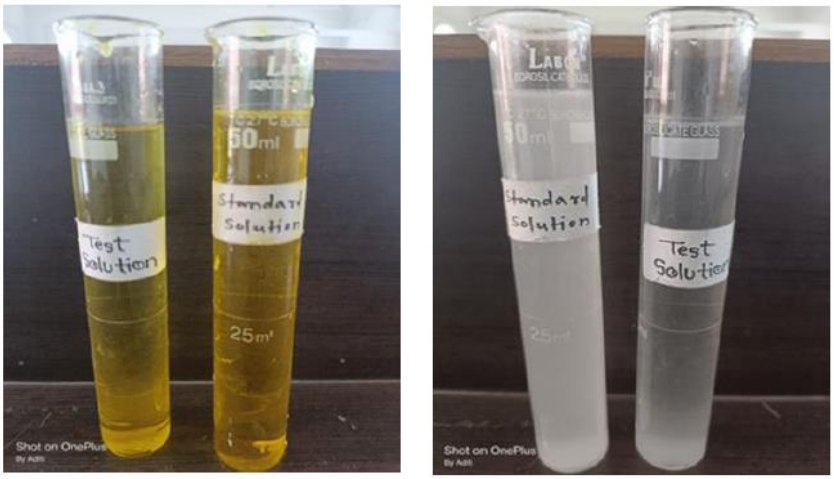


Fig no.8: Limit test.

4. CONCLUSION

About 98% female employees used cosmetic products on daily basis from that 28% experience adverse reactions due to certain cosmetic products. Mainly the ADR include acne, pimples, itching and pigmentation. The brands which causes the adverse reactions in majority of participants of survey were Brand AM1L, AM2C, AM3C, AM4E, AM5B, AM6N, AM7W. Customers (female employees) are loyal to brand name. Majority of participants i.e. 58% believe that brand name is more important than the content of the product. The ADR with cosmetics may be by the presence of heavy metals in higher concentration or above the prescribed limit value given by standard organization.

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