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A Review On Clotrimazole Drug

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1. INTRODUCTON

Clotrimazole, sold under the brand name **Canesten** among others, is an antifungal medication. It is used to treat vaginal yeast infections, oral thrush, diaper rash, pityriasis versicolor, and types of ringworm including athlete's foot and jock itch. It can be taken by mouth or applied as a cream to the skin or in the vagina.

Common side effects when taken by mouth include nausea and itchiness. When applied to the skin common side effects include redness and burning. In pregnancy, use on the skin or in the vagina is believed to be safe. There is no evidence of harm when used by mouth during pregnancy but this has been less well studied. When used by mouth, greater care should be taken in those with liver problems. It is in the azole class of medications and works by disrupting the cell membrane.

Clotrimazole was discovered in 1969. It is on the World Health Organization's List of Essential Medicines, the most effective and safe medicines needed in a health system.[3] It is available as a generic medication.[1] The wholesale cost in the developing world as of 2014 is 0.20–0.86 USD per 20gm tube of cream.[4] In the United States a course of treatment typically costs less than 25 USD.

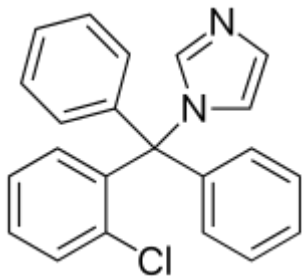

Fig. 6: Structure of Clotrimazole

Clotrimazole is a broad-spectrum antimycotic drug mainly used for the treatment of Candida albicans and other fungal infections. A synthetic, azole antimycotic, clotrimazole is widely used as a topical treatment for

tinea pedis (athlete's foot), as well as vulvovaginal and oropharyngeal candidiasis. It displays fungistatic antimycotic activity by targeting the biosynthesis of ergosterol, thereby inhibiting fungal growth. As well as its antimycotic activity, clotrimazole has become a drug of interest against several other diseases such as sickle cell disease, malaria and some cancers. It has also been combined with other molecules, such as the metals, to produce clotrimazole complexes that show improved pharmacological efficacy. Moreover, several new, modified-release pharmaceutical formulations are also undergoing development. Clotrimazole is a very well-tolerated product with few side effects, although there is some drug resistance appearing among immunocompromised patients. Here, we review the pharmaceutical chemistry, application and pharmacology of clotrimazole and discuss future prospects for its further development as a chemotherapeutic agent.

Therapeutic class and pharmaceutical use-

Clotrimazole is a member of the azole class of synthetic antimycotic agents that were discovered in the 1960s. Azoles comprise the largest class of antimycotic drugs in clinical use and can be further subdivided into two classes on the basis of their chemical structure: imidazoles and triazoles. Clotrimazole falls into the imidazole subclass of azole drugs. Along with econazole and miconazole, clotrimazole is the drug of choice for the topical treatment of tinea pedis (athlete's foot), tinea cruris and tinea corporis caused by isolates of Trichophyton rubrum,Trichophyton mentagrophytes,Epidermophyton floccosum,Microsporum canis and C. albicans (Gelone and O'Donnell 2006). It is also widely used in the topical treatment of vulvovaginal and oropharyngeal candidiasis.

Pharmaceutical dosage forms and administration-

Within the European Union, clotrimazole is available in topical cream and pessary formulations under a variety of trade names. In the USA, additional formulations are available, including clotrimazole lotions, powders, lozenges, topical solutions and vaginal inserts/tablets. Clotrimazole is sometimes formulated with the steroids hydrocortisone or bethamethasone, and in some cases, these compounded preparations may be labelled as coclimasone (Sweetman 2007). Typical excipients in clotrimazole creams include

benzyl alcohol, cetostearyl alcohol, medium-chain triglycerides and tricetearetn-4 phosphate. Although its availability differs slightly from country to country, monopreparations of clotrimazole are generally available over-the-counter, while combined preparations may require a prescription. In products aimed at the treatment of fungal skin infections, clotrimazole is usually formulated as a 1% cream, lotion, spray or solution. In the treatment of vulvovaginal candidiasis, the normal dosage forms are either 100 mg, 200 mg or 500 mg pes- saries which are administered daily for 6, 3 or 1 days, respectively. Similar doses may be obtained by application of 1, 2 or 10% creams to the vaginal area. In the treatment of oropharyngeal candidiasis, clotrimazole lozenges are usually formulated to contain 10 mg of the active drug and these are sucked slowly until dissolved, five times daily for 14 days. In the prophylactic prevention of oropharyngeal candidiasis in immunosuppressed individuals, this dose is reduced to 10 mg, three times daily, for the duration of the immunosuppressive therapy.

Similar drugs-

Antimycotic azole drugs that are closely related to clotrimazole include the imidazole drugs, miconazole,

econazole and ketoconazole, and the triazole drugs fluconazole and itraconazole. They are all broad-spectrum antimycotics and are generally poorly absorbed orally, with the exception of ketoconazole and itraconazole (reviewed in Odds et al. 2003; Gelone and O'Donnell 2006; Lorand and Kocsis 2007). In the

clinical settling, miconazole and econazole are used very similarly to fluconazole in the treatment of topical fungal infections, whereas miconazole is also frequently used intravenously for the treatment

of systemic infections in patients who cannot tolerate amphotericin. Unlike other azoles, itraconazole displays activity against Aspergillus. Because the extent of antifungal activity for each azole drug depends largely on the exact interaction between the drug and cytochrome P450, rational drug design approaches have been employed in the design of a new generation of azole drugs that incorporate triazole structures (reviewed in Odds et al. 2003; Lorand and Kocsis 2007; Weig and Brown 2007; Pasqualotto et al. 2010). These newer drugs include voriconazole and ravuconazole, which are structurally based on fluconazole and posaconazole, which is closely related to itraconazole. In comparison with the first-generation triazole drugs, the newer triazole compounds have extended antimycotic spectrums. These drugs have, in essence, been developed to address the limitations of existing azole compounds, including the emergence of drug-resistant fungal strains. Use of these second-generation drugs is reviewed in the context of paediatric

medicine in Valerio et al. (2013).

- Acetyl CoA
- HMG-CoA
- Mevalonate
- Squalene
- 2,3-oxidosqualene
- Lanosterol
- Ergosterol
- Fecosterol
- 4,4-dimenthyl-
- Ergostratrienol
- Eburicol Clotrimazole
- Terbinafine

Ergosterol is a vital component of fungal plasma membranes fulfilling a similarfunction to cholesterol in animal cell membranes. Clotrimazole targets the enzyme lanosterol 14-a-demethylase responsible for the conversion of lanosterol to 4,4-dimenthyl-ergostrienol a common target of azole drugs. Other antifungal drugs, such as terbinafine, target squalene epoxidase.

Mechanism of action-

Clotrimazole works to kill individual *Candida* or fungal cells by altering the permeability of the fungal cell wall. It binds to phospholipids in the cell membrane and inhibits the biosynthesis of ergosterol and other sterols required for cell membrane production. This leads to the cell's death via loss of intracellular elements.

Medical uses-

It is commonly available without a prescription in various dosage forms, such as a cream, vaginal tablet, or as a prescription troche or throat lozenge (prescription only). Topically, clotrimazole is used for vulvovaginal candidiasis (yeast infection) or yeast infections of the skin. For vulvovaginal candidiasis (yeast infection),

clotrimazole tablets and creams are inserted into the vagina. Troche or throat lozenge preparations are used for oropharyngeal candidiasis (oral thrush) or prophylaxis against oral thrush in neutropenic patients.

Clotrimazole is usually used 5 times daily for 14 days for oral thrush, twice daily for 2 to 8 weeks for skin infections, and once daily for 3 or 7 days for vaginal infections.[6]

Clotrimazole may be compounded with a glucocorticoid, such as betamethasone, in a topical cream for the treatment of tinea corporis (ringworm), tinea cruris (jock itch) and tinea pedis (athlete's foot). Although FDA approved, clotrimazole-betamethasone combination cream is not the preferred treatment for dermatophyte infections due to increased side effects from the topical glucocorticoid. Although temporary relief and partial suppression of symptoms may be observed with the combination therapy, glucocorticoids can elicite an immunosuppressive response and rebound effect that results in more severe infection typically requiring systemic antifungal agents to treat the disease. Combination creams are best avoided in order to improve treatment outcome, reduce the possibility of skin atrophy associated with prolonged topical glucocorticoid use, and to limit the cost of treatment. It can be effective in treating chronic paronychia. The preferred treatment of tinea infections is therefore with clotrimazole monotherapy. Topical and oral clotrimazole can be used in both adults and children. Additionally, clotrimazole may be used to treat the sickling of cells (related to sickle cell anemia).

Pregnancy-

Small amounts of clotrimazole may be absorbed systemically following topical and vaginal administration. However, this may still be used to treat yeast infections in pregnant women.

Side effects-

Side effects of the oral formulation include itching, nausea, and vomiting. >10% of patients using the oral formulation may have abnormal liver function tests. Side effects include rash, hives, blisters, burning, itching, peeling, redness, swelling, pain or other signs of skin irritation.[1] For this reason, liver function tests should be monitored periodically when taking the oral clotrimazole (troche). When used to treat vulvovaginal candidiasis (yeast infection), <10% of patient have vulvar or vaginal burning sensation. <1% of patients have the following side effects: Burning or itching of penis of sexual partner; polyuria; vulvar itching, soreness, edema, or discharge. Clotrimazole creams and suppositories contain oil which may weaken latex condoms and diaphragms.

Drug interactions-

There are no known significant drug interactions with topical clotrimazole. However, with oral (troche) clotrimazole, there are multiple interactions as the medication is a CYP450 enzyme inhibitor, primarily CYP3A4. Thus, any medication that is metabolized by the CYP3A4 enzyme will potentially have elevated levels when oral clotrimazole is used. The prescribing physician should be aware of any medication the patient is taking prior to starting oral clotrimazole. Certain medications should not be taken with oral clotrimazole.

Society and culture-

It is available as a generic medication. The wholesale cost in the developing world as of 2014 is 0.20–0.86 USD per 20gm tube of cream. In the United States a course of treatment typically costs less than 25 USD. In

2016 Canesten was one of the biggest selling branded over-the-counter medications sold in Great Britain, with sales of £39.2 million.

Company profiles

Glenmark Pharmaceuticals-

It is a pharmaceutical company headquartered in Mumbai, India. It is a research driven global pharmaceutical organization focused on discovering novel molecules and developing high-quality generics and specialty products for markets across the globe.

Glenmark has 17 manufacturing facilities across 5 countries including US, Argentina, Czech Republic and India. Glenmark has 5 R&D centers around the world engaged in discovery of novel biological and chemical entities.

On a conference call with analysts, Saldanha pointed to the innovative drug development program as one source of new revenue in the next year. He said the coming year could see a licensing deal for one of the company's early-stage discoveries, similar to ones it has signed in the past with the likes of Eli Lilly & Co, Merck KGaA and Sanofi.

The company currently forecasts its leading innovative medicines, a dermatitis treatment and another for cancer, to be ready for a submissio ..

CADILA PHARMACEUTICALS LIMITED

CADILA HEALTH CARE -

An Indian pharmaceutical company headquartered at Ahmadabad in Gujarat state of western India. The company is the fifth largest pharmaceutical company in India, with INR 29.78 Bn in turnover in 2011. It is a significant manufacturer of generic drugs.

HISTORY

Cadila Laboratories was founded in 1952 by RamanbhaiPatel (1952–2001), formerly a lecturer in the L.M. College of Pharmacy, and his business partner Shri IndravadanModi. The company evolved over the next four decades into one of India's established pharmaceutical companies.

In 1995 the Patel and Modi families split, with the Modi family's share being moved into a new company called Cadila Pharmaceuticals Ltd. and Cadila Healthcare became the Patel family's holding company. Cadila

Healthcare did its IPO on the Bombay Stock Exchange in 2000. Its stock code on the Bombay exchange is 532321.

In 2001 the company acquired another Indian pharmaceutical company called German Remedies. On June 25, 2007, the company signed an agreement to acquire 100 per cent stake in Brazil's Quimica e FarmaceuticaNikkho do BrasilLtda (Nikkho) for around 26 million dollars.

In 2010, Cadila Pharmaceuticals received a prestigious Wellcome Trust Award under the new "R&D for Affordable Healthcare in India" initiative.

CORPORATE CONTROL

ZydusCadila's major shareholder remains the Patel family. Pankaj Patel (born 1951), son of the founder, is CEO. In 2004 Pankaj Patel was included by Forbes magazine in its annual List of India's richest people. Forbes estimated Patel's net worth at US$510m, making him India's 26th richest person.[2] However in 2005 Patel dropped off the Forbes list due to a fall in the stock price of Cadila Healthcare. Moreover, there is a team of nine senior level executives, known as the Executive Committee, who are heads of different operations look after the overall management processes. None of the members except Pankaj Patel are on the Board of Directors. The Indian pharmaceutical industry has become the third largest producer in the world and is poised to grow into an industry of $20 billion in 2015 from the current turnover of $12 billion.

Ranbaxy Laboratories Limited

An Indian multinational pharmaceutical company that was incorporated in India in 1961. The company went public in 1973 and Japanese pharmaceutical company Daiichi Sankyo acquired a controlling share in 2008. In 2014, Sun Pharma acquired the entire 63.4% share of Ranbaxy[5] making the conglomerate world's fifth largest specialty generic pharm company. Ranbaxy exports its products to 125 countries with ground operations in 43 and manufacturing facilities in eight countries.[4] In 2011, Ranbaxy Global Consumer Health Care received the OTC Company of the year award. In the Brand Trust Report 2012, Ranbaxy [5] was ranked 161st among India's most trusted brands and subsequently, according to the Brand Trust Report 2013, Ranbaxy was ranked 225th among India's most trusted brands. In 2014 however, Ranbaxy was ranked 184th among India's most trusted brands according to the Brand Trust Report 2014,

HISTORY

Formation

Ranbaxy was started by Ranbir Singh and Gurbax Singh in 1937 as a distributor for a Japanese company Shionogi. The name Ranbaxy is a portmanteau of the names of its first owners **Ran**bir and Gur**bax**. Bhai Mohan Singh bought the company in 1952 from his cousins Ranbir and Gurbax. After Bhai Mohan Singh's son Parvinder Singh joined the company in 1967, the company saw an increase in scale.

Trading

In 1998, Ranbaxy entered the United States, the world's largest pharmaceuticals market and now the biggest market for Ranbaxy [10], accounting for 28% of Ranbaxy's sales in 2005.[For the twelve months ending on 31 December 2005, the company's global sales were at US$1,178 million with overseas markets accounting for 75% of global sales (USA: 28%, Europe: 17%, Brazil, Russia, and China: 29%). For the twelve months ending on 31 December 2006, the company's global sales were at US$1,300 million.

On 1 December 2011, Ranbaxy got the much-awaited approval from the US Food and Drug Administration to launch the generic version of drug Lipitor in the United States of America after its patent expired.

64,000 bottles.

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MANKIND PHARMACEUTICAL

Itis a pharmaceutical company in India based at New Delhi. The company has products in therapeutic areas ranging from antibiotic and antifungal compounds, to gastrointestinal, cardiovascular, dermal, and erectile dysfunction medications. It is the seventh-largest drug maker of India. Also it is No.1 Company of India as per Prescription/Doctor/Month audit of IMS-Health,[5]

HISTORY

Mankind Pharma was founded in 1995 by two brothers, R C Juneja and Rajeev Juneja. The seed capital for establishing the company was 50 Lakh. The company was started with 20 employees and launched in two states in the 1st year of its operation.

BUSINESS CORPORATION

The company has different marketing divisions & a company operating under its umbrella to expand its business operation in India namely Discovery, Future, Special, Vet, &Lifestar. Mankind has also entered the global arena by starting its operation in Srilanka, Vietnam, Philippines, Nepal & Rwanda.

INTAS BIOPHARMACEUTICAL LTD

The Biologics Business Unit (BU) of Intas Pharmaceuticals Limited was formerly an independent biotechnology company and was known as **Intas Biopharmaceuticals Ltd**. [5] Intas Pharmaceuticals limited is an Indian company headquartered in Ahmedabad, India. The Biologics BU is located in Moraiya, Ahmedabad and is one of the leading biosimilar product manufacturers in Asia.

The Biologics BU of Intas Pharmaceuticals has biopharmaceutical operations with R&D facility and an EU-GMP certified bio-pharmaceutical manufacturing facility

HISTORY

Intas Biopharmaceuticals Limited [12] was set up in year 2000, as an independent biotechnology division of Intas Pharmaceuticals Ltd., a mid-sized generic formulation manufacturer located in AhmedabadIntas Biopharmaceuticals Limited was set up in year 2000, as an independent biotechnology division of Intas Pharmaceuticals Ltd., a mid-sized generic formulation manufacturer located in Ahmedabad

The company faced EU-GMP (Good Manufacturing Practice) audit in December 2006, to seek approval of clinical trial of its biosimilar Filgrastim in Europe and was certified as EU-GMP compliant in April 2007, becoming the first company in India to receive such certification for biologics facility.

Apart from EU-GMP certification, the company also has approvals from MCC South Africa, Gulf Cooperation Council(GCC),Syria, Yemen, Belarus and several other national health authorities for its manufacturing facility and product.

CIPLA LIMITED

It is an Indian multinational pharmaceutical[9] and biotechnology company, headquartered in Mumbai, India Belgium, & Surrey in the European Union; and Miami, Florida, in the United States; with manufacturing facilities

in Goa (eight), Bengaluru (one), Baddi (one), Indore (one), Kurkumbh (one), Patalganga (one), and Sikkim(one), along with field stations in Delhi, Pune, and Hyderabad

HISTORY

It was founded by Dr. Khwaja Abdul Hamied as 'The Chemical, Industrial & Pharmaceutical Laboratories' in 1935 in Mumbai.
The name of the Company was changed to 'Cipla Limited' with effect from 20 July 1984, wherein the word Cipla came from the first letters of each word in the old name 'The **C**hemical, **I**ndustrial& **P**harmaceutical **La**boratories'.
In 2012, the company slashed prices of three life-saving cancer drugs by 50-64%.
In 2013, it increased its stake in its South African joint venture CIPLA Medpro from 50% to 100% stake for ₹27 billion (US$420 million) to strengthen its position in the African continent. Cipla Medpro is the third largest South African pharmaceutical company and it was founded in 1993.

SELECTION OF LOCATION

SAHARANPUR

- **JAIN DEGREE COLLEGE ROAD** – Selected because it has a chain of physicians and chemist shops likes' Asha Medical Store, etc it also has a good number of medical shop.

- **Asha Medical Store -** having huge number of medicals and physician shope public crowd is also huge.

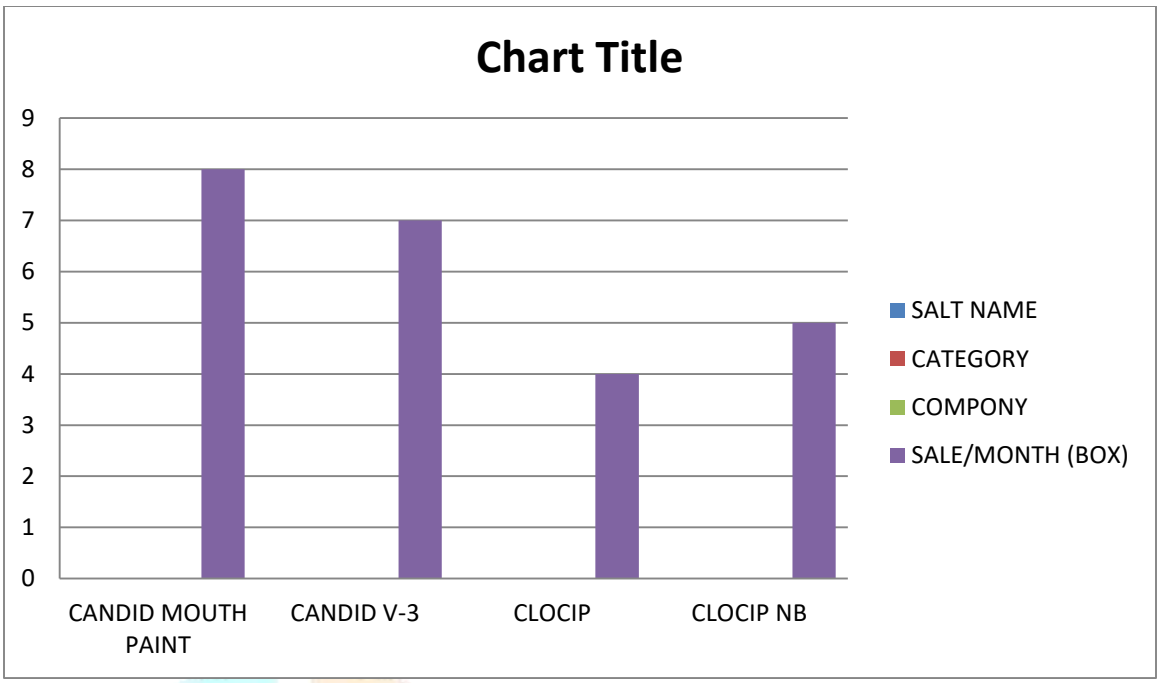
COMPARITIVE STUDY

COMPARITIVE STUDY LOCATION AT SARSAWA :

1. ASHA MEDICAL STORE SAHARANPUR:

TABLE NO: 1 AREA JAIN DEGREE COLLEGE ROAD

S.NO	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPONY	SALE/MONTH (BOX)
1.	Candid mouth paint	Clotrimazole	Antifungal	Mouth paint	Glenmark	6-8 Box
2.	Candid V-3	Clotrimazole	Antifungal	Tablets	Cipla	7 Box
3.	Clocip	Clotimazole	Antifungal	Powder	Cipla	4 Box
4.	Clocip NB	Clotrimazole	Antifungal	Ointment	Cipla	5 Box

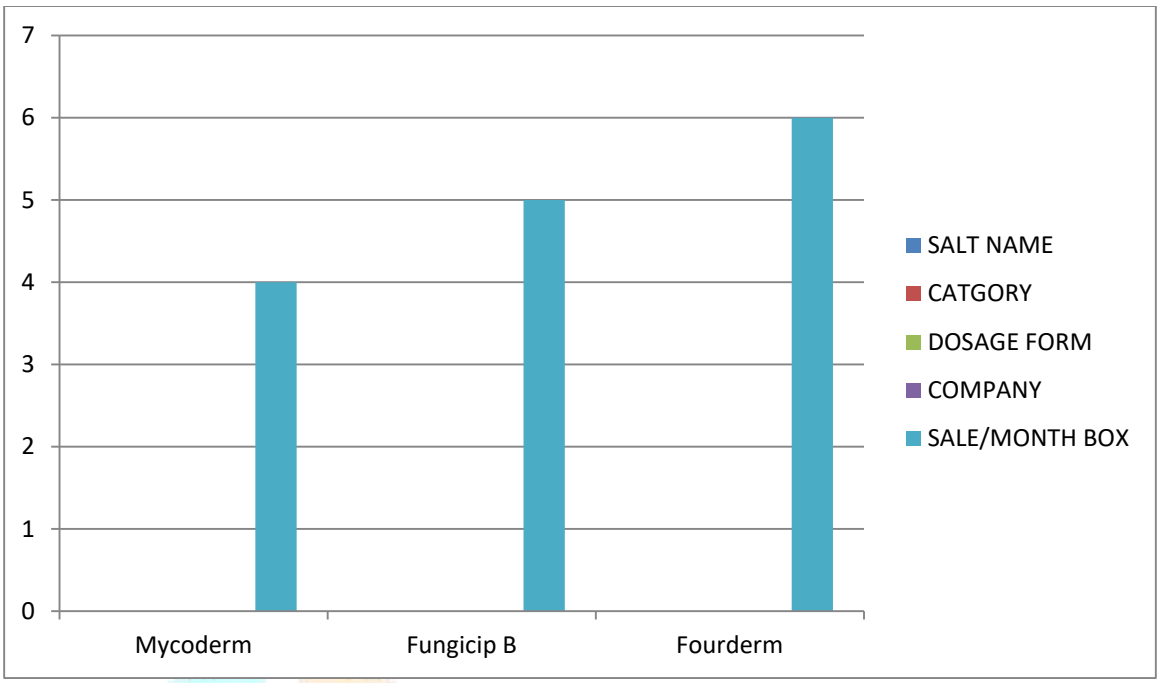


Conclusion: on the basis of above data, it was found that different brands as follows Candid > Candid V-3 > Clocip > Clocip NB the sales of Candid and Candid V-3 was found to be more in comparision of other two.

2. SHUBHAM MEDICAL STORE:

TABLE NO: 2 AREA : MALHIPUR

S.NO	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPANY	SALE/MONTH(Box)
1.	Mycoderm	Clotrimazole	Antifungal	Ointment	FDC	4 Box
2.	Fungicip B	Clotrimazole	Antifungal	Ointment	Cipla	5 Box
3.	Fourderm	Clotimazole	Antifungal	Ointment	Cipla	6 Box

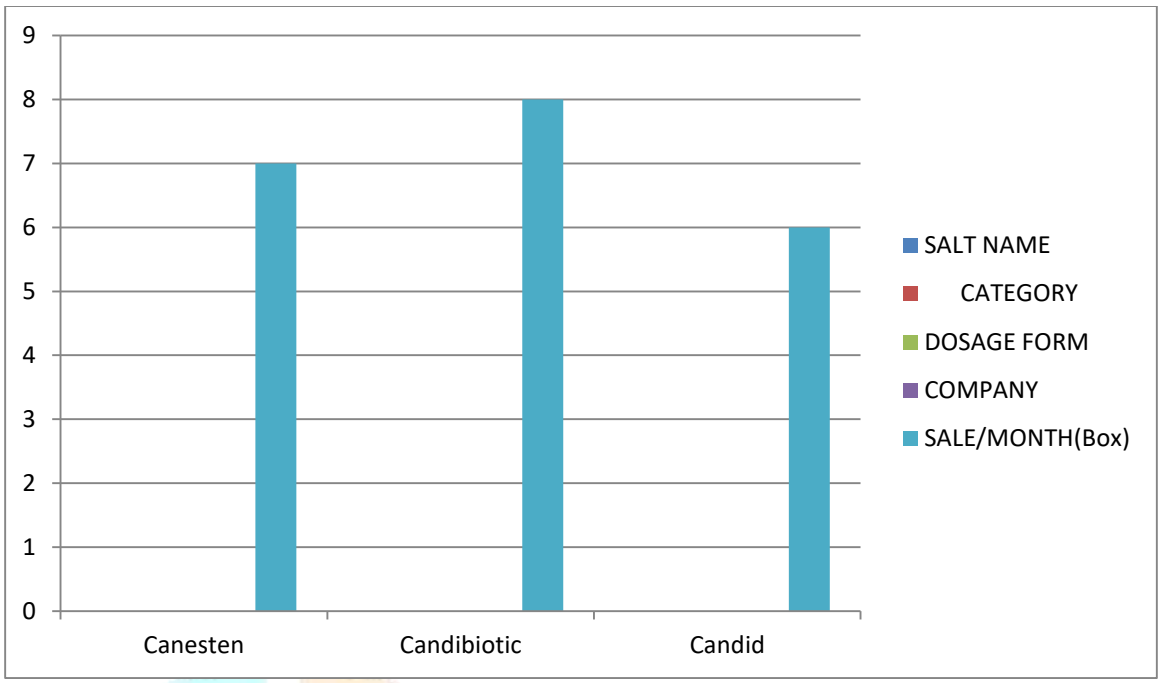


Conclusion: on the basis of above data, it was found that different brands as follows Mycoderm > Fungicip B > Fourderm was present in that medical store and the sales of Mycoderm and Fungicip B was more than other.

3. VIRAT MEDICAL STORE, MALHIPUR:

TABLE NO: 3 AREA: MALHIPUR ROAD

Sr NO.	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPANY	SALE/MONTH(Box)
1.	Canesten	Clotrimazole	Antifungal	Tablet	Bayer	7 Box
2.	Candibiotic	Clotrimazole	Antifungal	Ointment	Glenmark	8 Box
3.	Candid	Clotimazole	Antifungal	Lotion	Glenmark	6 Box

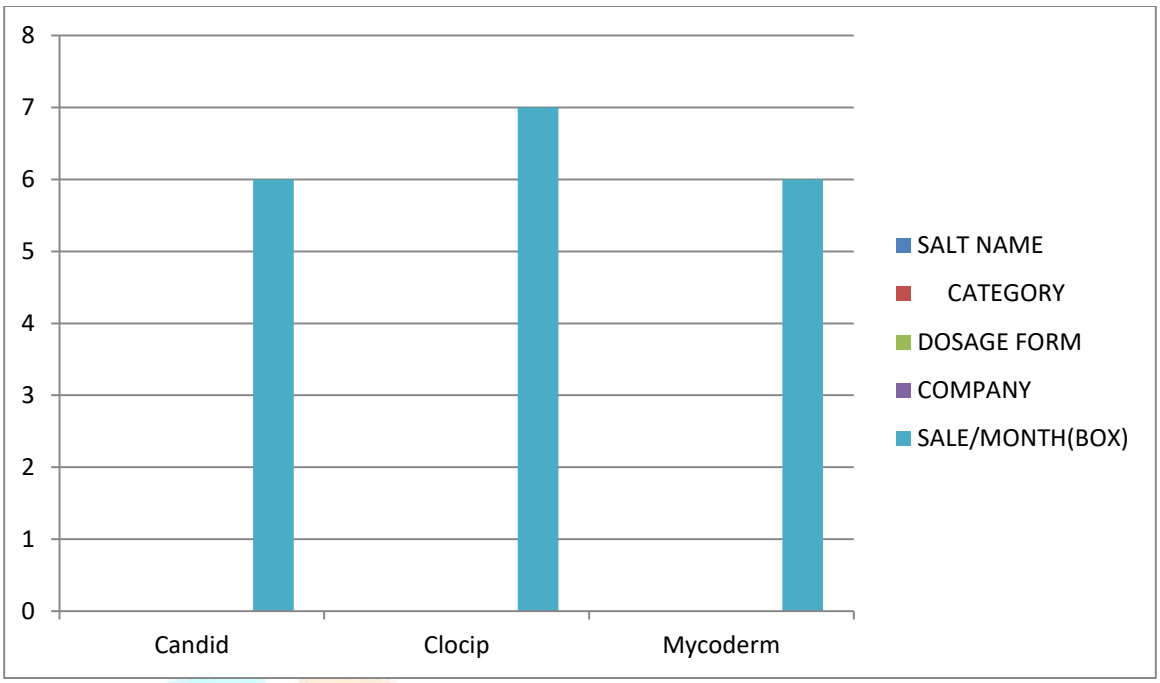


Conclusion: On the basis of above data, that different brands as follows Canestem< Candiboitic< Candid was present in that medical store and the sale of Canesten which contain Candibiotic was more in the comparision of because doctors prescribed Canesten for many problems.

1.LAXMI MEDICAL STORE, NAKUR:

TABLE NO: 4 AREA : NAKUR ROAD

S.NO	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPANY	SALE/MONTH (BOX)
1.	Candid	Clotrimazole	Antifungal	Powder	Glenmark	6 Box
2.	Clocip	Clotrimazole	Antifungal	Tablet	Cipla	7 Box
3.	Mycoderm	Clotimazole	Antifungal	Ointment	FDC	6 Box

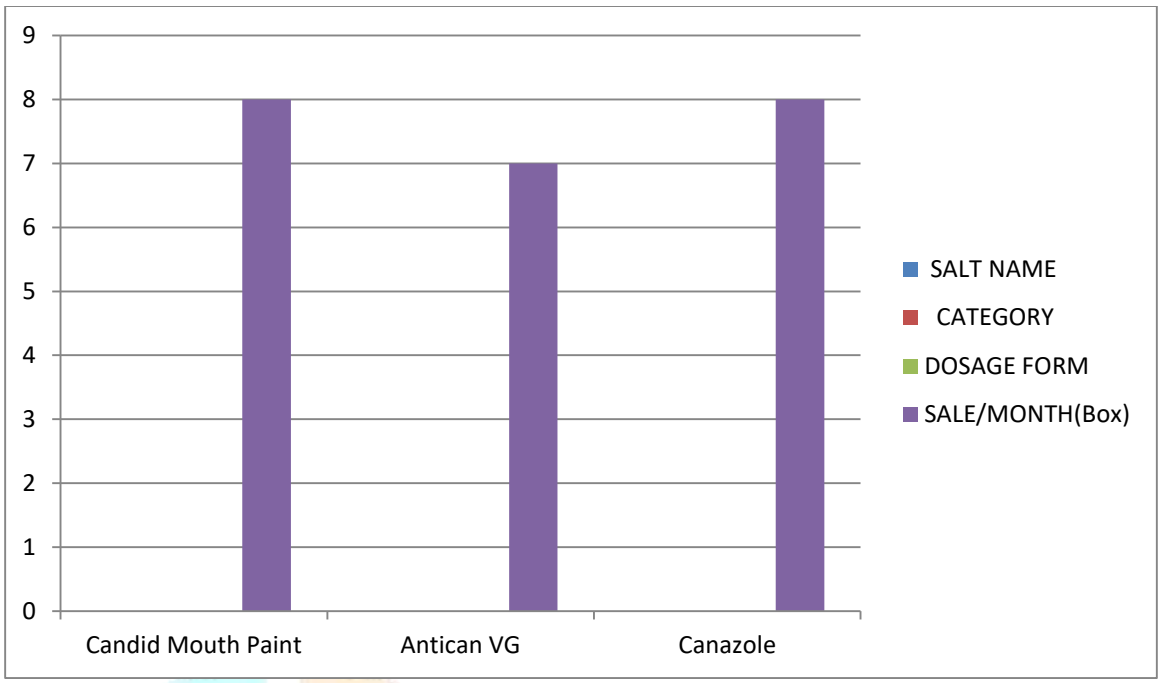


Conclusion: On the basis of above data, it was found that different brands as follows Candid > Clocip > Mycoderm was present in the that shop and and the sale of Candid is more than other brands .

2. SAWAN MEDICAL STORE

TABLE NO. 5 AREA: SABJI MANDI SARSAWA

S NO.	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPANY	SALE/MONTH(Box)
1.	Candid Mouth Paint	Clotrimazole	Antifungal	Mouth Paint	Glenmark	8 Box
2.	Antican VG	Clotrimazole	Antifungal	Tablet	Baroda Pharma	7 Box
3.	Canazole	Clotimazole	Antifungal	Ointment	Lupin	8 Box

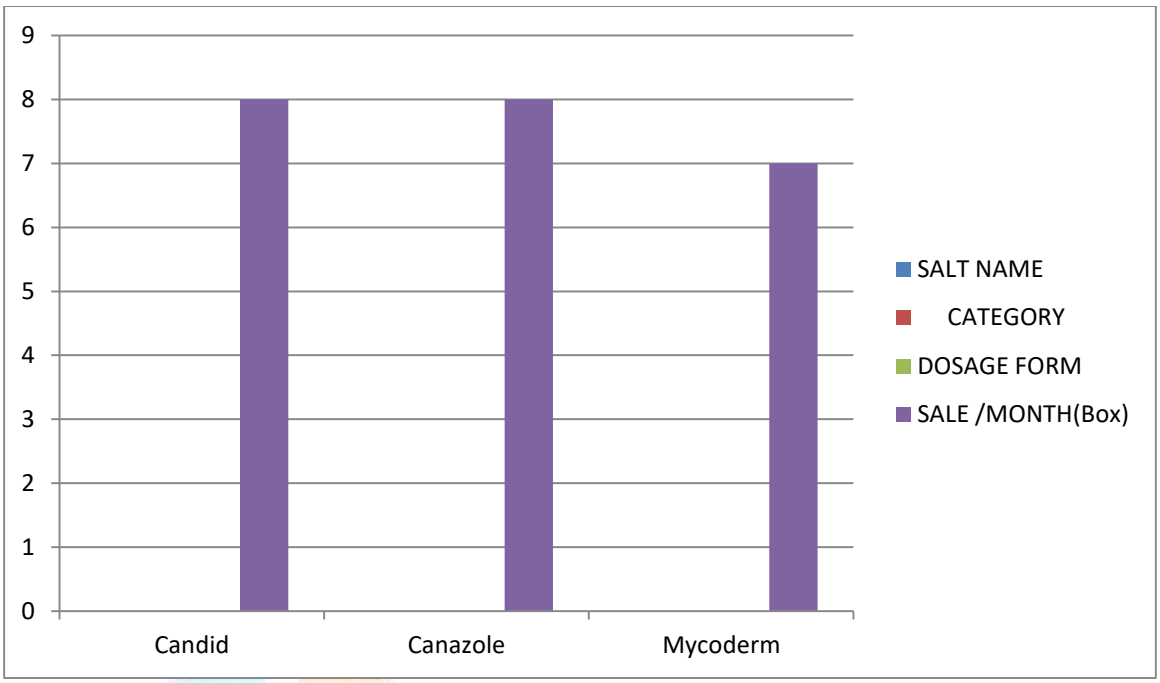


Conclusion: On the basis of above data , it is clear that the sale of Candid Mouth Paint is more in the Canazole of other brands , because doctors prescribe Candid mouth paint to more patient for, because it has a great effect for this type of conditions .

1. SAINI MEDICAL STORE:

TABLE NO. 6 AREA: MALHIPUR ROAD SAHARANPUR:

S NO.	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPANY	SALE/MONTH(Box)
1.	Candid	Clotrimazole	Antifungal	Tablet	Glenmark	8 Box
2.	Canazole	Clotrimazole	Antifungal	Ointment	Lupin	8 Box
3.	Mycoderm	Clotimazole	Antifungal	Ointment	FDC	7 Box

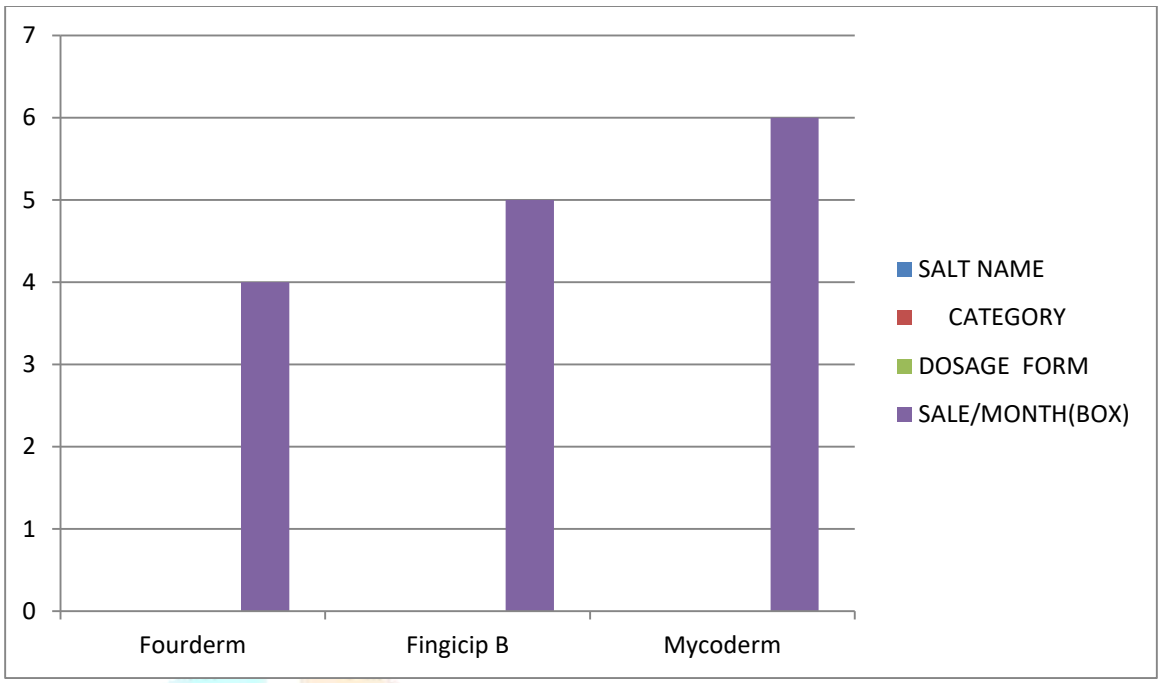


Conclusion: On the basis of above data, it was found to be that different brands of aceclofenac are as follows, Dolokind > Voltenac > Altraflam was present and the sale of Dolokind was found to be more in comparision of other two brands.

2. MAHALAXMI MEDICAL STORE:

TABLE NO.7 AREA: COURT ROAD SAHARANPUR

S NO.	BRAND NAME	SALT NAME	CATEGORY	DOSAGE FORM	COMPANY	SALE/MONTH(BOX)
1.	Fourderm	Clotrimazole	Antifungal	Ointment	FDC	4 Box
2.	Fingicip B	Clotrimazole	Antifungal	Ointment	Cipla	5 Box
3.	Mycoderm	Clotimazole	Antifungal	Ointment	Cipla	6 Box



Conclusion: On the basis of above data, it was found to be that doctors prescribed frequently Do mycoderm to more patient for their arthritic problems, because it has the better effect in comparision of the fourderm and fingicip-B.

CONCLUSION

From the above report and analysis, it was confirmed that sale of particular brand is based on various factors that includes market forces, planning, demand and market trend, new development and how convinced are doctor on safe use of product.

I have surveyed different types of population, in some living standard of people was very good, and while in some locality was very poor. In area where the locality was rich the people and doctors preferred Candid.

Somewhere other brand are also use by other locality but the overall sale of Candid V-3 was high as compared to Candid V-3.

Apart from this market availability also affects the sale of any brands. The market availability and approach of Clocip is very good as compared to Clocip NBR and Clocip Powder.

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