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STUDY 0F %CONTAIN TINIDAZOLE IN DIFFERENT BRANDS OF ANTIPROTOZOAL DRUG

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Abstract

Antiprotozoal drugs are a class of medication used to treat infection caused by protozoa, which are single cell organisms that belong to the type of parasites. Tinidazole is a drug used to against protozoaninfections. It is widely known throughout Europe and the developing world as a treatment for a variety of amoebic & parasitic infections. Tinidazole is an Antiprotozoal that is used to treat certain types of parasite infection (giardiasis, amebiasis). It works by stopping the growth of certain bacteria &. Parasites, it will not work for viral infection (such as common cold, flu). The main motive of is determination of % assay of Tinidazole in different brands of antiprotozoal tablets. Sold in market and consumed by human beings. For this purpose, I have taken 3 brands of tablets. By this study I have tried to Explore about antiprotozoal drugs & their quality. We have also reported a storage and transportation of pharmaceutical solid doses form. Storage and transportation play an important role in the pharmaceutical industries.

Index Terms: *Antiprotozoal drug, Tinidazole, Protozoa*

1. INTRODUCTION

The group of organisms known as 'protozoa' are defines by a few of their common characteristics. Protozoa are non-photo trophic, unicellular, eukaryotic microorganisms [1] with no cell walls. This diverse group of over 65,000 species commonly shares these basic attributes. The protozoa are often described as the pinnacle of unicellular complexity [2]. Un like the comparatively simple bacteria, protozoa can have many different intracellular organelles performing specific tasks. Some species of protozoa have structure that are analogous to mouths, GI tracts, and an uses. This possibly goes against everything you have been taught about microorganisms being simply bags of protein and enzymes. Many protozoa cause disease in animal & human. Some like plasmodium, which cause malaria. Others like Trichomonas, cause sexually transmitted diseases that are relatively benign and 100% curable. The vast majority of the species, throughout completely harmless. But as is usually the case in microbiology, it is dangerous once that get the most attention.[3]

Antiprotozoal drugs are a class of medication used to treat infection caused by protozoa, which are single cell organisms that belong to the type of parasites. Tinidazole is the most preferred choice of drug for intestinal amoebiasis [4].

The most common disease caused by protozoa are---

1) malaria 2) amoebiasis 3) sleeping sickness 4) toxoplasmosis 5) trichomoniasis 6) Pneumocystis Carini Pneumonia (PCP) [5] etc

1.1 ANTIPROTOZOAL DRUGS

The drug that destroys protozoa or inhibits their growth and ability to reproduce. Any agent that kills or inhibits the growth of organisms known as protozoans. Protozoans cause a variety of diseases, including malaria and Chagas' disease. While protozoans typically are microscopic, they are similar to plants and animals in that they are eukaryotes and thus have a clearly defined cell nucleus. Protozoal infection transmission can be person to person infection of contaminated water, food, direct contact with a parasite, a mosquito and a tick. Anti protozoal agents or antiprotozoal drug is a class of pharmaceutical used in treatment of protozoan infection; the most popular anti protozoal drug are as follows.[6]

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Metronidazole, Furazolidone, Pentamidine, Eflornithine,Ornidazole, Tinidazole, Pyrimethamine,Melarscoprol.

1.2 TINIDAZOLE

Tinidazole is an antibiotic that is used to treat certain types of vaginal infections (bacterial vaginosis, trichomoniasis). It is also used to treat certain types of parasite infections (giardiasis, amebiasis). It works by stopping the growth of certain bacteria and parasites. It was developed in 1972. A derivative of 2-methylimidazole, it is prominent member of the nitro-imidazole antibiotics. Tinidazole is marked by mission pharmacal under the brand name TINIDAMAX, by Pfizer under the names Fasigyn andsimpleton and in some Asian countries as sporinex.

•IUPAC NAME: - 1-(2-(Ethyl sulfonyl) ethyl)-2-methyl-5-nitro-1H-imidazole
•MolecularFormula: - C8H13N3O4S
•Molecularweight: - 247.27152g/mol
•Meltingpoint: -125°to128°
Molecular structure of Tinidazole

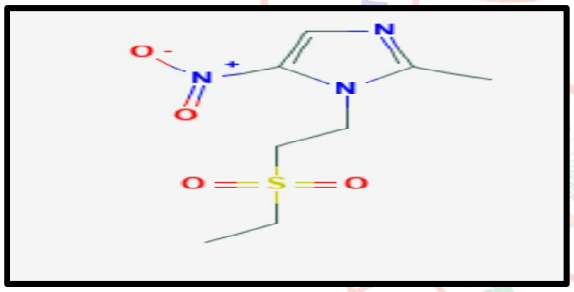

Fig.1: Molecular structure of Tinidazole.

A large body of clinical data exists to support use of tinidazole for infections from amoebae, giardia, and trichomonas, just like metronidazole. Tinidazole may be a therapeutic alternative in the setting of metronidazole leintolerance. Tinidazole may also be used to treat a variety of other bacterial infections (e.g., as part of combination therapy for Helicobacter pylori eradication protocols). For the treatment of intestinal amebiasis and amoebic liver abscess caused by Histolytic in both adults and paediatric patients older than three years of age[7][8].

Tinidazole is an antiprotozoal, antibacterial agent. The nitro group of tinidazole is reduced by cell extracts of Trichomonas. The free nitro-radical generated as a result of this reduction may be responsible for the antiprotozoal activity. The mechanism by which tinidazole exhibit activity against Giardia and Entamoeba species is not knows through it is probably similar [9]. The sponsor of Tinidazole conducted a Bioavailability/Equivalence (BA/BE)study to establish a bio link between their proposed commercial Tinidazole tablet and the European approved Tinidazole tablet that has been tested in clinical efficacy and safety study.[10]

Tinidazole has been marked in countries other than United states and Canada sincethe1970's.In European countries, tinidazole is approved for use in various anti protozoal and antibacterial indications such as in the treatment of trichomoniasis, giardiasis and amebiasis (intestinal and amoebic liver abscess).In the United states, metronidazole is the only FDA approved nitroimidazole; there appears to be an unmet medical need for infection disease like trichomoniasis and giardiasis.[11]

Oral Tinidazole has been used to treat bacterial vaginosis for over 25 years but in a number of different dosage regimens. There have been a number of published clinical studies but un fortunately there are several problems in trying to compare and evaluate these trials.[12]Deighton R J etal.1987 st G. vaginal is with tinidazole compared to metronidazole. [Comparative in vitro studies showed minor enhanced in vitro activity again] Livengood etal. 2007 published the results of a randomized controlled trials assessing the effectiveness of tinidazole orally1g once daily for 5days and 2g once daily for 2days,compared with placebo, in the treatment of bacterial vaginosis.[13]

In 2020 study on the comparison between metronidazole andtinidazole in cases of Bacterial vaginosis-A clinical study. Vaginitis, Is a polymicrobial disease. Result found that tinidazole was better as compared to metronidazole in cases of Bacterial vaginosis.[14] In 2019 study on controlled delivery of the antiprotozoal agent (tinidazole)from intra vaginal polymer matrices for treatment of the sexually transmitted infection, trichomoniasis. The result of further investigation of PCL matrices as intra vaginal

Devices for controlled delivery of antiprotozoal agents in the Treatment and prevention of sexually transmitted infections.[15] In 2015 reach on formulation and in-vitro evaluation Gastro retentive drug Delivery of tinidazole they concluded that Regulated drug release in Zero order manner attained in the current study indicates that the Optimized gastro-retentive tablet of tinidazole, prepared using Sodium Alginate can successfully be employed as a oral controlled release drug delivery system. High floating ability of the formulation is likely to increase its GI residence time, and eventually, improve the extent of bioavailability.[16]

2. EXPERIMENTAL

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2.1 SAMPLE AND SAMPLING: Sampling is one of the most important operations in a chemical analysis. Chemical analyses use only a small fraction of the available sample. The fractions of the samples that collected for analyses must be representative of the bulk materials. Knowing how much sample to collect and how to further Sub divide the collected sample to obtain a laboratory sample is Vital in the analytical process. All three steps of sampling,standardization, and calibration Require knowledge of statistics.

2.1.1 SAMPLING

We have collected samples of Multivitamins tablets containing Thymine hydrochloride and Pyridoxine hydrochloride of different Brands sold in Vidisha & Ujjain city.

Table No.1

S.No.	Tablets Name	Sample Code
1.	Tinamide	TZ-1
2.	Tin vista	TZ-2
3.	Tz500	TZ-3

Description

Reference standard: Pale yellow crystals or a crystalline Powder, Odour, slight & characteristics.[17]

Table No. 2

S. No	Sample	Observation	Result
1.	TZ-1	Yellow Crystal, crystalline powder	Pass
2	TZ-2	Yellow Crystal crystalline powder	Pass
3	TZ-3	Yellow Crystal crystalline powder	Pass

Identification

- Instrument used: - u v spectroscopy
- Referencestandards: - Absorption maximum at about 310nm.

Procedure: Weight accurately a quantity of the powder containing about 0.15g of Tinidazole, add 20 ml of methanol, shake well and add sufficient methanol to produce100.0ml, mix Well and filter. Dilute 10.0mlofthe solution to 100.0 ml with Methanol and further dilute10.0mlofthesolutionto100.0ml with methanol. Measure the absorbance of the resulting solution when examined in the range 230nm to 360nm.Shown an absorption maximum atabout310nm.[17]

Table No. 3

S. No	Sample	Observation	Result
1	TZ-1	Shows an absorption maximum at 310nm.	Pass
2	TZ-2	Shows an absorption maximum at 310nm.	Pass
3	TZ-3	Shows an absorption maximum at 310nm.	Pass

Solubility

Reference standards: - Soluble in acetone and in dichloromethane, sparingly soluble in methanol. Slightly soluble in ethanol (95%) and in chloroform, practically insoluble in water.[18]

Table No. 4

S. No	Sample	Observation	Result
1.	TZ-1	Soluble in acetone and in dichloromethane, sparingly Soluble in ethanol	Pass
2.	TZ-2	Soluble in acetone and in dichloromethane, sparingly Soluble in ethanol	Pass
3.	TZ-3	Soluble in acetone and in dichloromethane, sparingly Soluble in ethanol	Pass

2.1.2 % ASSAY BY UV

Reference standard: -95.0-105.0 percent

Procedure: -Weight accurately a quantity of the powder containing about 0.15g of Tinidazole, add 20 ml of methanol, shake well and add sufficient methanol to produce100.0ml, mix well and filter. Dilute10.0 ml of the solutionto100.0ml with methanol and further dilute10.0ml of the solution to 100.0 ml with methanol. Measure the absorbance of the resulting solution when examined in the range 230nm to 360nm shownan absorption maximum at about 310nm [14].

Table No.5

Sample Code	Total weight	Average weigh	Absorbance
TZ-1	11.336	0.5668	0.474
TZ-2	11.403	0.5701	0.428
TZ-3	11.5116	0.5755	0.564

Table No.6

S.N0.	Sample Code	Description	Identification	Solubility	%Assay
01	TZ1	Pass	Pass	Pass	99.95%
02	TZ-2	Pass	Pass	Pass	95.49%
03	TZ-3	Pass	Pass	Pass	98.73%

3. RESULTS AND DISCUSSION

All sample had found pale yellow crystal, crystalline powder.as per IP Tinidazole are pale yellow crystal, crystalline powder. All sample are pass in description test. solubility of sample in the specific solvent. The test is carried out at the temperature 20-30□. As per IP Tinidazole is soluble in acetone &dichloromethane, sparingly soluble in methanol. When solubility tested the sample were found soluble in acetone &dichloromethane, sparingly soluble in methanol. All sample were pass in the test.

Identification: -In this qualitative analysis identification test is carried out for confirming the presence of TINIDAZOLE in samples. Tablets shows an absorption maximum at310nm.We found that all samples were passed in the test. According to the Indian Pharmacopeia Tinidazole tablets shows an absorption maximum at 310nm. & We found that all samples were pass in the test

% Assay is the percentage of the material which is the actually desired chemical in a sample of it. The% assay wasdetermined byUVSpectroscopy.We havetaken three differenttypesofsamples with same API (tinidazole)and perform the analysis as per IP tinidazole tablet contain not less than 95.0% and not more than 105.0% of the stand amount of tinidazole. Result of the samples were found within the limit per IP tinidazole tablet contain not less than 95.0% and not more than 105.0% of the stand amount of tinidazole. Result of the samples were found within the limit.

4. CONCLUSION

The chemical analysis (comparative study) of antiprotozoal drug i.e. Tinidazole on various parameters description, Solubility and % assay indetermined. Description, solubility, test was carried out. For gaining knowledge of purity & presence of API in tablets. All Sample were pass in the test. And the %assay of all samples TZ-1,TZ-2,&TZ-3 is found within limit.

Chemical plant uses chemical process, which are detailed Industrial scale methods to transform feed stock chemical in to products. Chemical plant at a site may be construed to utilize more than One chemical process, for instance to produce multiple products.

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