REVIEW OF LITERATURE

1. Wagstaff *et al.*, (2001) were discussed the Tianeptine as an antidepressant agent with a novel neurochemical profile. The antidepressant efficacy and favourable tolerability and pharmacokinetic profiles of tianeptine in patients with depression, including those with associated anxiety, were proved.

2. Wilde *et al.*, (1988) identified that Tianeptine could be placed in a middle position in the bipolar classification, between the sedative and stimulant antidepressants. Its antidepressant and anxiolytic properties and its action on somatic complaints made the drug particularly suitable for the treatment of the entire range of depressive symptomatology.


4. Nickel *et al.*, (2003) were studied the effects of tianeptine and paroxetine, two drugs with opposite modes of action on 5-HT, with regard to their clinical efficacy and their effects on the HPA system and cognitive functions over 6 weeks when administered to inpatients with major depressive disorder.

5. McEwen *et al.*, (2002) were provided the results on neurochemical targets of adrenal steroid actions that may explain their role in the remodeling process. In studying these actions, we hope to better understand the molecular and cellular targets of action of tianeptine in relation to its role in influencing structural plasticity of the hippocampus.

6. Ahmed *et al.*, (2010) were formulated the orodispersible film(s) of the antidepressant drug tianeptine sodium to enhance the convenience and compliance by the elderly and pediatric patients.
Statistical analysis revealed that there was no significant difference between the bioavailability parameters ($C_{\text{max}}$ (ng/ml), $t_{\text{max}}$ (h), AUC$_{0-t}$ (ng h ml$^{-1}$), and AUC$_{0-\infty}$ (ng h ml$^{-1}$)) of the test film (F1) and the reference product. The mean ratio values (test/reference) of $C_{\text{max}}$ (89.74%), AUC$_{0-t}$ (110.9%), and AUC$_{0-\infty}$ (109.21%) indicated that the two formulae exhibited comparable plasma level-time profiles.

7. Khedr (2007) was developed a sensitive, selective, and validated stability-indicating HPLC assay of tianeptine (TIA) in bulk drug and tablet form. The inter-assay percentage of deviation is not more than 0.03%, and the day-to-day variation is not more than 0.1%.

8. Brink et al., (2006) were patented that the Tianepetine could be given in the therapeutic dosage range as 12.5 to 300 mg per dose, depending on patient age and weight. The preferred salt of tianeptine is specified as the sodium salt.

9. Vuković et al., (2009) they evaluated in their clinical study that tolerability, efficacy and safety of tianeptine in a special population of depressive patients in the region. The study showed that tianeptine had good efficacy in treatment of mild to moderate forms of depression in special populations of depressive patients. The drug was well tolerated.

10. Proença et al., (2007) were detected the absence of other suitable direct causes of death (macroscopic or histological) and the positive results achieved with the toxicological analysis led the pathologist to rule that death was due to an intoxication caused by the suicidal ingestion of tianeptine in combination with alcohol.

11. Bernard et al., (2011) were studied that a single administration of a supratherapeutic dose of tianeptine does not induce psychostimulant effect in young healthy volunteers in contrast to methylphenidate at a therapeutic dose. These findings suggest an absence of psychostimulant liability of tianeptine in a therapeutic situation.
12. Boiret et al., (2011) were developed a method with a near infrared (NIR) for determination of tablet potency of active pharmaceutical ingredient (API) in a complex coated tablet matrix. The calibration set contained samples from laboratory and production scale batches.

13. Ulu et al., (2008) were developed a method that was used for the examined drugs in pharmaceutical formulations and the results demonstrated that the method is equally accurate, precise, and reproducible as the official method. The t-test showed no significant difference at 95% confidence level.

14. Brooks et al., (2004) were discussed about the non-infringement opinions & helps to provide guidelines for attorneys reviewing opinions to determine whether a particular written opinion should withstand scrutiny by the courts. This article only addresses noninfringement opinions. Nonetheless, there may be other reasons why a potential infringer may still be free to manufacture, use, and sell a proposed product or process.

15. Nagori & Mathur (2009) were explained that a competent Non-infringement opinion provides a reasonable basis for determining whether a proposed product, process or technology will infringe third party’s patent or not.

16. Mathur & Nagori (2008) were explained that the Patent opinions are of particular importance in the case of developing generic medicines. This paper provides a brief description of various forms of patent opinions, the reasons for obtaining such opinions and their role in developing generic medicines.

17. Molzon (2003) studied that the regulatory authorities working under the umbrella of the International Conference on Harmonisation are hoping that the development of the Common Technical Document will soon harmonize the application procedure, and make this process simpler for applicants.

18. Suchanek & Ostermann (2012) were discussed that more than three-quarters of individuals with eCTD experience were able to shorten their total time to approval, and more than 90% of this group was able to demonstrate cost savings
relative to paper submissions, regardless of their company kind, size, or number of submissions.

19. **Cartwright & Anthony (2006)** were discussed that the Common technical document (CTD) format has now become the obligatory format for the EU, Japan, Canada, Switzerland & Australia, & the recommended format in the US. Derivatives of the CTD are becoming widely adopted in other regions, including the ASEAN countries. An electronic CTD (eCTD) was developed in parallel with the CTD & the three ICH regions now accept eCTD filings.

20. **Sharma et al., (2009)** were discussed that the Generics are similar to branded drugs in terms of purity, efficacy and are perceived to be safer as compared to new drug molecules, as they tend to be older and time tested. Indian pharmaceutical market of generic drugs is increasing day by day.

21. **Blackett (1992)** studied that the British companies were the most innovative companies in the world and pharmaceutical was the only area of science where the UK could claim to match, and frequently outperform, the Americans, Japanese and Germans.

22. **Bruno & Patrick (1997)** patented the Tablet matrix in which sustained release of sodium tianeptine (I) is controlled using a polymeric cellulose derivative and a calcium salt is new.

23. **Piero Del Soldato et al., (2007)** were patented the Nitro-oxyderivative compounds or salts thereof having the following general formula (I): A-(B) b0-(C) c0-NO2 wherein: c0 is an integer and is 0 or 1, b0 is an integer and is 0 or 1, AR-T1-, wherein R is the radical of an analgesic drug for the chronic pain, in particular for the neuropathic pain.

24. **Blanchard et al., (2002)** were patented a process for the industrial synthesis of 11-amino-3-chloro-6,11-dihydro-5,5dioxo- 6-methyl-dibenzoc,f1,2thiazepine of Formula (I): and its addition salts, wherein the ketone of Formula (III): is reacted with sodium borohydride, in a two-phase medium.
25. **Kucharik & Harris (2004)** were patented a method of treating irritable bowel syndrome or nonulcer dyspepsia in a subject in need of such treatment, comprising administering to the subject an effective amount of at least one compound of formula I.

26. **Guzman et al, (2010)** were patented a novel sulfate salt of tianeptine with improved properties. Also described herein are novel pharmaceutical compositions comprising tianeptine sulfate salt, methods of making, and related methods of treatment.

27. **Roegel & Eftekhari (2009)** were patented the novel therapeutic use of other glutamine synthetase (GS) ligands and to the use of these ligands in obtaining methods for screening and developing drugs.

28. **Hardman JG, & Limbird LE (eds) (2001)** explained the Drugs acting on the Central Nervous System. Several groups of depressed patients continue to be particularly inadequately treated or studied. They include children & elderly, those with bipolar depression & those with severe, chronic or Psychotic forms of depression.

29. **Nally, J.D (1998)** explained the Dosage units (e.g., tablets or capsules) were individually sealed in clear plastic or plastic compartments with foil or paper backing. The individual compartment must be torn or broken to obtain the product. The backing Materials cannot be separated from the blisters or replaced without leaving visible evidence often try.

30. **Banker, G.S & Rhodes, C.T (2002)** explained that Hard shell capsule have often being assumed to have better bioavailability than Tablets. Most likely this assumption derives from the fact the gelatin shell rapidly dissolves & ruptures which afford at least the potential for rapid release of drugs & easily formulated as tablets.
31. **Aulton, M.E (2007)** explained that Empty capsules contain significant amount of water that acts as a plasticizer for the gelatin film & is essential for their function.

32. **Lachman, L., Liberman, H.A., & Kanig, J.L. (1990)** were explained the process for manufacturing gelatin used in capsules.

33. **Tripathi, K.D. (December 1, 2004)** explained the Antidepressant drugs, its Classification, & that the Tianeptine is reported to increase rather than inhibit 5-HT uptake, & is neither sedative nor stimulant.