

(54) Title of the invention : "ORAL DISINTEGRATING FILM COMPOSITION OF WITHANIA SOMNIFERA EXTRACT FOR THE TREATMENT OF ANXIETY"

<p>(51) International classification :A61K36/48, A61K9/70, A6147/38, A61K47/26, A61K47/12, A61K47/10</p> <p>(86) International Application No :NA Filing Date :NA</p> <p>(87) International Publication No: NA</p> <p>(61) Patent of Addition to Application Number :NA Filing Date :NA</p> <p>(62) Divisional to Application Number :NA Filing Date :NA</p>	<p>(71)Name of Applicant :</p> <p>1)Gargee Vivek Dhaneshwar Address of Applicant :Dr. D Y Patil College of Pharmacy, Akurdi, Pune 411044 Maharashtra, India -----</p> <p>2)Pallavi M. Chaudhari Name of Applicant : NA Address of Applicant : NA</p> <p>(72)Name of Inventor :</p> <p>1)Gargee Vivek Dhaneshwar Address of Applicant :Dr. D Y Patil College of Pharmacy, Akurdi, Pune 411044 Maharashtra, India -----</p> <p>2)Pallavi M. Chaudhari Address of Applicant :Dr. D Y Patil College of Pharmacy, Akurdi, Pune 411044 Maharashtra, India -----</p>
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(57) Abstract :

Orally disintegrating films are formulations that when placed inside the oral cavity, disintegrate rapidly facilitating drug release. They are beneficial over conventional dosage forms to enable quick drug release, increase patient compliance and protect drugs from first pass metabolism. Withania Somnifera, also known as Ashwagandha, is known to help with mood regulation, insomnia and anxiety. Films were prepared by solvent casting method using HPMC E5 polymer as film forming agent, croscarmellose sodium as super-disintegrant, propylene glycol as plasticizer, citric acid as saliva stimulating agent and aspartame as sweetener. Box-Behnken design was used for optimization of formulation. The films prepared were characterized for disintegration time, film forming capacity, pH, folding endurance, thickness, mouth dissolution time, tensile strength, weight variation, content uniformity and drug release. The effect of varying concentrations of film forming agent, plasticizer and super-disintegrant were studied. All batches displayed satisfactory results for drug content and percentage of drug released. Maximum drug release was observed for batch F13 which was 95.19±3.22% and disintegration time was found to be 33.51±2.84 seconds. The findings suggested that an effective formulation of Withania Somnifera extract can be prepared for the treatment of anxiety.

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