

(54) Title of the invention : FAST DISSOLVING ORAL THIN FILMS OF CETIRIZINE HYDROCHLORIDE AND PREPARATION METHOD THEREOF

(51) International classification :A61K 090000, A61K 314950, A61P 110000, A61P 110200, A61P 370800  
 (86) International Application No :PCT//  
 Filing Date :01/01/1900  
 (87) International Publication No : NA  
 (61) Patent of Addition to Application Number :NA  
 Filing Date :NA  
 (62) Divisional to Application Number :NA  
 Filing Date :NA

## (71)Name of Applicant :

1)Dr. M. Kishore Babu

Address of Applicant :Professor &amp; Principal, Krishna Teja Pharmacy College, Chadalawada Nagar, Renigunta Rd, Tirupati, Andhra Pradesh 517506 -----

2)SK Rubina

3)Mr. Bharadhan Bose

4)Dr N M Vageesh

5)Dr. Kalirajan Rajagopal

6)Shabana Parveen

7)Dr. Karthickeyan Krishnan

8)Katroju Neelima Santhoshi

9)Dr. Prakash Srichand Sukhramani

10)Mekala Sumathi

Name of Applicant : NA

Address of Applicant : NA

## (72)Name of Inventor :

1)Dr. M. Kishore Babu

Address of Applicant :Professor &amp; Principal, Krishna Teja Pharmacy College, Chadalawada Nagar, Renigunta Rd, Tirupati, Andhra Pradesh 517506 -----

2)SK Rubina

Address of Applicant :Associate Professor, Dr K V Subba Reddy Institute of Pharmacy, Opp Doopadu R.S.NH.44, Kurnool Dist, Andhra Pradesh, India-518218 -----

3)Mr. Bharadhan Bose

Address of Applicant :Associate Professor, Department of Pharmacognosy, Karpagam College of Pharmacy, Coimbatore-641032, Tamil Nadu, India -----

4)Dr N M Vageesh

Address of Applicant :Professor, Department of Pharmaceutics, St John's College of Pharmaceutical Sciences, Yerrakota, Yemmiganur, Kurnool, Andhra Pradesh, India-518360 ---

5)Dr. Kalirajan Rajagopal

Address of Applicant :Associate Professor &amp; Head, Department of Pharmaceutical Chemistry, JSS College Of Pharmacy, JSS Academy of Higher Education &amp; Research, Ooty-643001, The Nilgiris, Tamil Nadu -----

6)Shabana Parveen

Address of Applicant :Assistant Professor, Department of Pharmaceutics, Nimra College of Pharmacy Nimra Nagar Jupudi, Ibrahimpatnam Vijayawada NTR Dt- 521456 Andhra Pradesh, India -----

7)Dr. Karthickeyan Krishnan

Address of Applicant :Professor and Head, Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels Institute of Science, Technology and Advanced Studies (VISTAS), Pallavaram, Chennai 600117 -----

8)Katroju Neelima Santhoshi

Address of Applicant :Assistant professor, Department of pharmacy SVS group of institutions bheemaram, Hanamkonda, Telangana, India 506015 -----

9)Dr. Prakash Srichand Sukhramani

Address of Applicant :Professor, Veerayatan Institute of Pharmacy, Jakhania, Bhuj- Mandvi Road, Mandvi- Kutch, Gujarat, Pin Code: 370460 -----

10)Mekala Sumathi

Address of Applicant :Assistant professor Department of pharmacy SVS group of institutions bheemaram, Hanamkonda, Telangana, India 506015 -----

## (57) Abstract :

The present invention provides a fast dissolving oral thin film of Cetirizine for immediate release of drug in oral cavity. The formulation of oral thin film of Cetirizine, comprises of polymer; film forming agent; plasticizer; artificial sweetener; drug; and diluent, wherein the polymer is Hydroxypropyl methylcellulose, film forming agent is Polyvinyl alcohol, plasticizer is Glycerin, artificial sweetener is Aspartame, drug is Cetirizine hydrochloride and diluent is water; wherein the combination of Hydroxypropyl methylcellulose, Polyvinyl alcohol resulting into fast dissolving oral thin film for fast action. The process for the preparation of fast dissolving oral thin film of Cetirizine, comprising of dissolving Hydroxypropyl methylcellulose polymer in 13ml of water; adding Polyvinyl alcohol and heating to obtain a clear solution; dissolving aspartame and adding to the solution by continuous stirring; dispersing drug in to the polymer solution and adding Glycerin to the solution; degassing the solution in to bubble free solution; pouring the solution onto glass plate and drying the plates by keeping on flat surface for 24 to 48 hours at room temperature; removing the film; preserving in a butter paper and storing in desiccator. The drug content of the film ranges from 93% to 99%; weight of the film ranges from 859mg to 1050 mg and thickness of the film ranges from 0.18mm and 0.39mm; the rate of dissolution of the film 63.86% in 30 min. The rate of in-vitro drug release of the film 98.54% in 2min and the film is prepared by solvent casting method. The film is useful for fast drug dissolution, absorption and offering rapid onset of action.

No. of Pages : 18 No. of Claims : 6