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(71)Name of Applicant :

1)Dr Vijay Sharma

Address of Applicant :Faculty of Pharmacy, IFTM University, Moradabad, Uttar Pradesh, Pin Code: 244102 -----

2)Maneesh Kumar Singh

3)Saurabh Singh

4)Siddharth Dhaka

5)Ankur Gupta

6)Ms. Shikha Meena

7)Sarika Saini

8)Lucky Maurya

9)Dr. Mhaveer Singh

Name of Applicant : NA

Address of Applicant : NA

(72)Name of Inventor :

1)Dr Vijay Sharma

Address of Applicant :Faculty of Pharmacy, IFTM University, Moradabad, Uttar Pradesh, Pin Code: 244102 -----

2)Maneesh Kumar Singh

Address of Applicant :Dr K N Modi Institute of Pharmaceutical Education and Research, Modinagar, Ghaziabad, Uttar Pradesh, Pin Code: 201204 -----

3)Saurabh Singh

Address of Applicant :Dayanand Dinanath College, Institute of Pharmacy University, Kanpur Nagar, Uttar Pradesh, Pin Code: 209214 -----

4)Siddharth Dhaka

Address of Applicant :Dr K N Modi Institute of Pharmaceutical Education and Research Modinagar Ghaziabad, Uttar Pradesh, Pin Code: 201204 -----

5)Ankur Gupta

Address of Applicant :Gyan Vihar School of Pharmacy University: Suresh Gyan Vihar University, Jaipur, Rajasthan, Pin code: 302017 -----

6)Ms. Shikha Meena

Address of Applicant :Dayanand Dinanath College Institute of Pharmacy Kanpur, Uttar Pradesh, Pin Code: 209214 -----

7)Sarika Saini

Address of Applicant :Dayanand Dinanath College Of Pharmacy, Bicchipur, Kanpur, Uttar Pradesh , Pin Code: 209206 -----

8)Lucky Maurya

Address of Applicant :Sanskar College of Pharmacy and Research, Sanskar Educational Group NH-09, Ahead Masuri Canal, Opp. Jindal Pipes Ltd, Jindal Nagar, Ghaziabad, Uttar Pradesh, Pin Code: 201302 -----

9)Dr. Mhaveer Singh

Address of Applicant :Faculty of Pharmacy, IFTM University, Moradabad, Uttar Pradesh, Pin Code: 244102 -----

(57) Abstract :

The present invention relates to a sustained-release oral formulation of L-arginine using chitosan-coated calcium-alginate beads to enhance therapeutic efficacy and patient compliance. The beads were prepared by ionic gelation and optimized using a Quality by Design (QbD) approach, employing central composite design (CCD) to identify critical material attributes and process parameters. The optimized formulation exhibited desirable characteristics including bead size between 1.613–1.654 mm, swelling index up to 323%, and drug entrapment efficiency exceeding 95%. In-vitro studies showed minimal release in acidic media and sustained release of over 96% in phosphate buffer (pH 6.8) within 10 hours. Drug release followed Higuchi kinetics, indicating Fickian diffusion. The formulation remained stable for six months under ICH-recommended accelerated conditions. This delivery system offers an effective and biocompatible platform for the sustained release of L-arginine and potentially other therapeutics.

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