



## (51) International Patent Classification:

*A61K 9/22* (2006.01)      *A61K 9/20* (2006.01)  
*A61K 9/26* (2006.01)      *A61K 31/522* (2006.01)  
*A61K 47/30* (2006.01)      *A61K 47/38* (2006.01)  
*A61P 31/00* (2006.01)      *A61P 31/12* (2006.01)

## (21) International Application Number:

PCT/IN2009/000562

## (22) International Filing Date:

8 October 2009 (08.10.2009)

## (25) Filing Language:

English

## (26) Publication Language:

English

## (30) Priority Data:

2158/MUM/2008 8 October 2008 (08.10.2008) IN

(71) Applicant (for all designated States except US): **V.B. MEDICARE PVT. LTD.** [IN/IN]; 141 Walchand Hirachand Marg, Mumbai 400 001, Maharashtra (IN).

## (72) Inventors; and

(75) **Inventors/Applicants (for US only): JAIN, Subheet** [IN/IN]; Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, Punjab (IN). **DHALIWAL, Sumeet** [IN/IN]; Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, Punjab (IN). **RANA, Madhu** [IN/IN]; Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, Punjab (IN). **HARDEVINDER, Pal, Singh** [IN/IN]; Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, Punjab (IN). **TIWARY, A., K.** [IN/IN]; Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, Punjab (IN).

(74) Agent: **SAVANGIKAR, Vasant, Anantrao;** Krishna & Saurastri Associates, 74/F, Venus, Worli Sea Face, Mumbai 400 018, Maharashtra (IN).

(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

— of inventorship (Rule 4.17(iv))

**Published:**

— with international search report (Art. 21(3))

— with amended claims (Art. 19(1))

(88) **Date of publication of the international search report:**

1 July 2010

**Date of publication of the amended claims:**

10 September 2010

(54) **Title:** SUSTAINED RELEASE DRUG DELIVERY SYSTEM

(57) **Abstract:** The invention discloses a controlled release dosage form comprising a therapeutically effective amount of a pharmaceutically active agent, illustrated by Acyclovir, that would release in about 12 hours not more than about 90% of the said active agent in a simulated gastric juice in a first order rate of release in a USP type 1 dissolution test, and not containing a solubilizer or a swelling enhancer or both, comprising (a) a tablet made from polymer matrix of at least two biocompatible polymers, illustrated by Carbopol 974P and polyethylene oxide, the said pharmaceutically active agent and pharmaceutically permitted excipients; the said tablet capable of rapid swelling without disintegration in the said simulated gastric juice to a size that shall result in its gastric retention in the stomach and start controlled release of the said active agent by starting controlled erosion as well as diffusion immediately after coming into contact with the said gastric juice, or (b) microspheres of ungrafted chitosan or a chitosan derivative illustrated by thiolated chitosan and trimethyl chitosan, or Carbopol incorporating the said active agent, wherein the said pharmaceutically active agent is not a polymeric molecule and after administration in stomach, the said microspheres adhere to the gastric mucosa for a long time releasing the active agent in a controlled way.

