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(71) Applicant *(for GB only)*: **PFIZER LIMITED** [GB/GB]; Ramsgate Road, Sandwich, Kent CT13 9NJ (GB).

(71) Applicant *(for all designated States except GB, US)*: **PFIZER INC.** [US/US]; 235 East 42nd Street, New York, NY 10017 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DAVIS, John, Douglas** [GB/GB]; Pfizer Global Research and Development, Ramsgate Road, Sandwich, Kent CT13 9NJ (GB). **HUMPHREY, Michael, John** [GB/GB]; Pfizer Global Research and Development, Ramsgate Road, Sandwich, Kent CT13 9NJ (GB). **MACRAE, Ross, James** [GB/GB]; Pfizer Global Research and Development, Ramsgate Road, Sandwich, Kent CT13 9NJ (GB). **SMITH, Janet, Sarah** [GB/GB]; Pfizer Global Research and Development, Ramsgate Road, Sandwich, Kent CT13 9NJ (GB).

(74) Agents: **HAYLES, James, R.** et al.; Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ (GB).

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(54) Title: PHARMACEUTICAL FORMULATIONS FOR THE CONTROLLED RELEASE OF 4-AMINO-6,7-DIMETHOXY-2-(5-METHANESULFONAMIDO-1,2,3,4-TETRAHYDROISOQUINOL-2-YL)-5-(2-PYRIDYL) QUINAZOLINE

(57) Abstract: The invention provides a controlled-release pharmaceutical formulation for oral administration comprising 4-amino-6,7-dimethoxy-2-(5-methanesulfonamido-1,2,3,4-tetrahydroisoquinol-2-yl)-5-(2-pyridyl)quinazoline, or a pharmaceutically acceptable salt thereof; and a pharmaceutically acceptable adjuvant, diluent or carrier; characterized in that the formulation is adapted to release at least 50% by weight of the 4-amino-6,7-dimethoxy-2-(5-methanesulfonamido-1,2,3,4-tetrahydroisoquinol-2-yl)-5-(2-pyridyl)-quinazoline, or the pharmaceutically acceptable salt thereof, after 6 hours in Apparatus 1 described in the United States Pharmacopoeia 24 (2000), pp 1941-1943, having 1 litre vessels, baskets of 40 mesh (0.4 mm apertures), a rotation speed of 100 rpm, and a dissolution medium consisting of 900 ml of 0.01 M hydrochloric acid containing 0.7% w/v sodium chloride at 37 °C. Formulations according to the invention are suitable for the treatment of BPH.