Accepted Manuscript

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PII: S0928-0987(17)30235-X

DOI: doi: 10.1016/j.ejps.2017.05.007

Reference: PHASCI 4021

To appear in: European Journal of Pharmaceutical Sciences

Received date: 10 January 2017 Revised date: 17 April 2017 Accepted date: 4 May 2017

Please cite this article as: A.G. Ogienko, E.G. Bogdanova, N.A. Trofimov, S.A. Myz, A.A. Ogienko, B.A. Kolesov, A.S. Yunoshev, N.V. Zubikov, E.V. Boldyreva, A.Yu Manakov, V.V. Boldyrev , Large porous particles for respiratory drug delivery. Glycine-based formulations, *European Journal of Pharmaceutical Sciences* (2017), doi: 10.1016/j.ejps.2017.05.007

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ACCEPTED MANUSCRIPT

Large porous particles for respiratory drug delivery. Glycine-based formulations.

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Abstract

Large porous particles are becoming increasingly popular as carriers for pulmonary drug delivery with both local and systemic applications. These particles have high geometric diameters (5-30 μ m) but low bulk density (~0.1 g/cm³ or less) such that the aerodynamic diameter remains low (1-5 μ m). In this study salbutamol and budesonide serve as model inhalable drugs with poor water solubility. A novel method is proposed for the production of dry powder inhaler formulations with enhanced aerosol performance (e.g. for salbutamol-glycine formulation the fine particle fraction (FPF \leq 4.7 μ m) value is 67.0 \pm 1.3%) from substances that are poorly soluble in water. To overcome the problems related to extremely poor aqueous solubility of the APIs, not individual solvents are used for spray freeze-drying of API solutions, but organic-water mixtures, which can form clathrate hydrates at low temperatures and release APIs or their complexes as fine powders,

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