GMProject®

Certificate of cGMP Compliance No: RFM002-AU–1

This is to certify that:

ZAO "Rafarma"
Terbuny
399540 Lipeckaya oblast
Str. Dorozhnaya 6a
Russian Federation

Is designed, validate and operate pharmaceutical facility in town **Terbuny** for manufacture of medicinal products according:

- **EudraLex - Volume 4,** Good Manufacturing Practices Medicinal Products for Human and Veterinary Use
- **Good Manufacturing Practice, Annex 1 "Manufacture of Sterile Medicinal Products"**
- **ISPE - Baseline® Pharmaceutical Engineering Guide , Volume 2,** 2nd Edition: Oral Solid Dosage Forms
- **ISPE - Baseline® Pharmaceutical Engineering Guide , Volume 3**, 1st Edition, March 1999: Sterile Manufacturing Facilites
- **ISPE - Baseline ® Pharmaceutical Engineering Guide, Volume 5,** Commissioning and Qualification, 1st Edition, March 2001

Application of these Engineering Standards complies with Directive **2001/83/EC** of the European Parliament and of the Council of November 2001 of the community code relating to medicinal products for human Use - *The Rules Governing Medicinal Products in the European Community, Volume IV, "Guide to Good Manufacturing Practice (GMP) for Medicinal Products*", and

Commission Directive **2003/94/EC** of 8 October 2003, *laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*

For and on behalf of G.M.PROJECT:

Jiri Moninec
Managing Director of G.M.PROJECT

G. M. PROJECT, s.r.o. GMProject OPAVA CZECH REPUBLIC

Igor Topnikov
Executive Director of G.M.PROJECT

Czech Republic, *Opava, December 19, 2014*