

Checklist for Conduction of a Bioequivalence Study

Please revert this form by fax or email to your personal contact at hameln rds a.s.:

Dr. Miroslava Beňová

hameln rds a.s.
Key Account Manager
Sales and Marketing

T: +421 33 69 04 491
F: +421 33 6904 401
m.benova@hameln-rds.com

Horná 36
900 01 Modra
Slovakia

**Basic Information from Sponsor (BIS) is required in order to generate a price quotation
Study Specification Form**

Please change, correct or complete where appropriate:

1. Name of the active substance:	
2. Strengths developed	
3. Strength to be investigated in this study (if not appointed we shall specify):	
4. Kind of formulation (capsule, solution, tablet, immediate release, modified release, extended release ...)	
5. Which market (Reg. Authority, e.g. EMEA, FDA, EU, USA ...):	
6. Reference medicinal product information (e.g. product name, strength, pharmaceutical form, kind of formulation, Marketing Authorisation Holder, Marketing Authorisation number, country):	
7. Will the study protocol be provided by sponsor?	
8. Specification of the aim of the study (e.g. to prove bioequivalence, to control safety ...)	
9. Sponsor's Address	