Appendix 1:

Characteristics of investigational drug product for clinical trial	
Current status (approved product)	Proposed status (drug product for new clinical trial)
1. Investigational product	
Active substance:	**Active substance:**
• Name	• Name
• Structural formula	• Structural formula
• Manufacturer	• Manufacturer
• Specification	• Specification
Finished product:	**Finished product:**
• Name, dosage form, strength	• Name, dosage form, strength
• Complete composition	• Complete composition
• Specification of excipients (e. g. reference to Pharmacopoeia)	• Specification of excipients (e. g. reference to Pharmacopoeia)
• Manufacturer	• Manufacturer
• Specification	• Specification
• Container	• Container
• Shelf-life	• Shelf-life
2. Comparator product	
Data requested for comparator product are to be found in SÚKL guideline KLH-19. In case the comparator product was assessed in the past as well and the sponsor refers to already assessed clinical trial, the same data as for the investigational product are requested.	

Appendix 2:

Statement:

Sponsor of clinical trial ……*(company, address)*

We declare that from last clinical trial

……*(protocol number of previous clinical trial)*
……*(date of submission of Application for approval/notification of clinical trial for previous clinical trial to SÚKL)*

……*(reference number of SÚKL)*
……*(number and date of approval – for biological/biotechnological product only)*

with the drug product
……*(name, stregth, dosage form)*

[*] no changes and variations to drug product quality and its manufacturing process were implemented.

*these changes and variations to drug product quality and its manufacturing process were implemented: (*describe*)

[**] no changes occured:

1) regarding TSE safety – for all material of animal origin
2) regarding virogogical safety of all material of human and animal origin

**these changes and variations were implemented:

1) regarding TSE safety – for all material of animal origin: (*describe*)
2) regarding virogogical safety of the material of human and animal origin: (*describe*)

Date, stamp and signature of responsible person of the sponsor:

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[*] delete if not applicable
[**] delete if not applicable