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| Annex 29to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during the Validity Period of Registration Certificate (item 4 section IV) |

**Preclinical study report**

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| 1. Name of medicinal product (registration certificate №, if any): |  |
| 1) type of medicinal product according to which registration has been conducted or is planned to be conducted  |  |
| 2) studies conducted  | yes         no    if no, please justify |
| 2. Pharmacology: |  |
| 1) Primary pharmacodynamics |  |
| 2) Secondary pharmacodynamics |  |
| 3) Safety pharmacology |  |
| 4) Pharmacodynamic interactions |  |
| 3. Pharmacokinetics: |
| 1) Analytical Methods and validation reports |  |
| 2) Absorption |  |
| 3) Distribution |  |
| 4) Metabolism |  |
| 5) Excretion |  |
| 6) Pharmacokinetic Interactions (preclinical)  |  |
| 7) Other Pharmacokinetic Studies |  |
| 4. Toxicology: |
| 1) Single-Dose Toxicity |  |
| 2) Repeat-Dose Toxicity |  |
| 3) Genotoxicity: іn vitro |  |
| in vivo (including supportive toxicokinetics evaluation) |  |
| 4) Carcinogenicity: |  |
| Long-term studies |  |
| Short- or medium-term studies  |  |
| Additional studies |  |
| 5) Reproductive and Developmental Toxicity: |  |
| Fertility and early embryonic development |  |
| Embryotoxicity |  |
| Prenatal and postnatal toxicity |  |
| Studies in which the offspring (juvenile animals) are dosedand/or further evaluated  |  |
| 6) Local Tolerance |  |
| 7) Additional Toxicity Studies: |  |
| Antigenicity (production of antibodies) |  |
| Immunotoxicity |  |
| Mechanistic studies |  |
| Dependence |  |
| Metabolites toxicity |  |
| Impurities toxicity |  |
| Other  |  |
| 5. Preclinical study conclusions  |  |

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| Applicant (registration certificate holder) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (full name) |

{Procedure amended by new annex 29 according to MoH Ukraine Order № 1528 of 27.06.2019 }