

Preclinical study report

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: in 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 dosed and/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	
Applicant (registration certificate holder)	(signature) (full name)

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