On approval of the rules for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union within the framework of pharmaceutical inspection

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-181/2020 of November 4, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 5, 2020 under No. 21596

Unofficial translation

In obedience to Article 236(2) of the Code of the Republic of Kazakhstan of July 7, 2020 "On Public Health and the Health Care System", **I HEREBY ORDER**:

1. That the attached rules for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union within the framework of pharmaceutical inspection shall be approved.

2. That to the extent permitted by the applicable law of the Republic of Kazakhstan, the Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan shall:

1) ensure the state registration hereof with the Ministry of Justice of the Republic of Kazakhstan;

2) place this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after state registration hereof with the Ministry of Justice of the Republic of Kazakhstan, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan information on implementation of measures stipulated by sub-paragraphs 1) and 2) of this paragraph.

3. That the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan shall be charged with the control of execution of this order.

4. This order shall be put into effect ten calendar days after the date of its first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *A. Tsoy*

Approved by order
of the Minister of Healthcare
of the Republic of Kazakhstan
No. KR DSM-181/2020
dated November 4, 2020

Rules for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union within the framework of pharmaceutical inspection

Chapter 1. General provisions

1. These Rules for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union within the framework of pharmaceutical inspection (hereinafter - the Rules) have been developed pursuant to paragraph 2 of Article 236 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" dated July 7, 2020 (hereinafter - the Code) and determine the procedure for implementation within the framework of pharmaceutical inspection of materials assessment and and determine the procedure for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union within the framework of pharmaceutical inspection (hereinafter – an assessment).

2. Terms and concepts used in these Rules:

1) an authorized body in the field of healthcare (hereinafter referred to as authorized body) - central executive body carrying out management and inter-sectoral coordination in the field of healthcare of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of population, circulation of medicines and medical devices, quality of medical services (assistance);

2) preclinical (non-clinical) study - chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental study or series of studies to study the substance (medicinal product) under study by applying scientific methods of evaluation in order to study specific effect and (or) obtain evidence of safety for human health;

3) pharmaceutical inspectorate for good pharmaceutical practice (hereinafter - pharmaceutical inspectorate) - structural subdivisions of the state body in the field of circulation of medicinal products and medical devices, its territorial subdivisions and (or) organization determined by the authorized body, which perform inspection of compliance with good pharmaceutical practice for medicinal products and requirements for implementation, maintenance and evaluation of quality management system for medical devices subject to potential risks of the disease

4) pharmaceutical inspection on good pharmaceutical practices (hereinafter - pharmaceutical inspection) - evaluation of facility in the field of circulation of medicines in

order to determine its compliance with the requirements of good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

3. Pharmaceutical inspection of assessment of materials and compliance of conditions of preclinical (non-clinical) research with good laboratory practice (GLP) requirements of the Republic of Kazakhstan and (or) the Eurasian Economic Union shall be carried out by the pharmaceutical inspectorate in compliance with the procedure determined by the authorized body pursuant to paragraph 6 of Article 244 of the Code.

4 An assessment shall be carried out in testing laboratories carrying out preclinical (non-clinical) studies of medicinal products and medical devices (hereinafter referred to as testing laboratories).

5. An assessment shall be carried out by pharmaceutical inspectors (hereinafter referred to as inspectors) who have the necessary knowledge in the field of preclinical (non-clinical) studies of medicinal products and medical devices and legislation in the field of circulation of medicinal products and medical devices to carry out the assessment.

Persons involved in the assessment shall respect the confidentiality of information obtained in the process of preparation and conduct of the evaluation, as well as keep the results of the evaluation confidential.

Chapter 2: Procedures for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union

6. For the assessment, the testing laboratory shall provide the inspector with the necessary documentation and provide access to the premises, equipment, substances, materials and test systems used in pre-clinical (non-clinical) studies of medicinal products and medical devices as well as the presence of key personnel in the workplace.

7. Inspector when assessing preclinical (non-clinical) study materials, as well as assessing compliance of preclinical (non-clinical) study conditions with good laboratory practice requirements shall:

examine the test laboratory's organizational management structure and division of responsibility, staff job descriptions, qualifications and training of test laboratory personnel, and policies regarding the control of the health status of personnel and the organization's schedule of activities;

examine the quality manual of the testing laboratory, the activities of the quality assurance department, the programme of standard operating procedures, the organisation of internal training and the system of internal inspections and audits;

inspect the rooms for the maintenance of test systems, personnel rooms, rooms for auxiliary materials, and examine the information on flows and control of environmental conditions;

inspect the test laboratory equipment and measuring instruments, examine the information on their verification and calibration, operation and maintenance and verify their proper functioning;

verify the validation of measuring equipment and instruments, including computerised systems;

examine data on test systems, providing information on the types of test systems used in research, as well as procedures for controlling the conditions of maintenance and handling of test systems during their life cycle (from arrival at the testing laboratory to autopsy), including procedures for recording animal body weight, food (water) intake, dosing and administration, clinical observations and pathomorphology);

examine procedures designed to ensure the quality assurance of test and control substances, and examine the systems used to record their consumption and disposal;

examine Standard Operating Procedures (SOPs), including SOP system details, approval and revision procedures, training, and controlled access;

examine the list of ongoing and completed examinations and documents integral to the study (study plan, logbooks, laboratory logbooks, documents, worksheets, printouts of computer stored data, verification calculations, final report), and verify the data recording, verification and analysis system;

examine and verify procedures for the proper storage of documents and research materials , test samples, standard substances, solvents and reagents.

8. Based on the results of the assessment a report on assessment of materials and compliance of conditions of preclinical (non-clinical) studies with the requirements of Good Laboratory Practice (GLP) shall be provided in the form according to the Annex to these Rules (hereinafter - the Report).

9. The report shall be approved by the head of the state body in the field of circulation of pharmaceuticals and medical devices and shall be sent to the testing laboratory within five calendar days from the date of approval.

10. Non-conformities indicated in the Report shall be eliminated by the testing laboratory within a period not exceeding 3 months from the date of completion of the assessment.

11. The Report shall be valid for 3 years from the date of its issue.

Annex to the Rules
for the assessment of materials
and compliance of preclinical (non-clinical)
studies with Good Laboratory Practice
requirements of the Republic of
Kazakhstan and/or the
Eurasian Economic Union
Document form

Report on the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union

1. General information

Full name and address of the testing laboratory (centre)
Purpose of assessment
Composition of the inspection team to carry out the assessment
Date, time and location of evaluation
Brief description of the testing laboratory (centre), indicating the scope of accreditation, as well as information about the location of the testing laboratory (centre) and senior management
Full name and position of persons present at the evaluation

2. Observations and assessment results

Organisation of the testing laboratory (centre)
Personnel
Quality Assurance Programme
Premises
Equipment, materials, reagents and samples
Information systems
Physical and chemical test systems
Biological test systems, including maintenance, placement and containment
Test subjects and standard substances
Standard Operating Procedures
Conducting the study and reporting the results
Conditions and period of storage of records

3. Description of the discrepancies identified *

Critical	
Major	
Minor	

4. Information on non-conformities resolved in the course of the assessment

Description of the discrepancy	Qualification of non-compliance	Corrective action information (summary of corrective and preventive actions, supporting document)	Assessing the removal of non-compliance

5. Conclusion

Evaluation results	
Recommendations	

* Note

"Critical non-compliances" are non-compliances of a testing laboratory (centre) with the principles of good laboratory practice which may affect the integrity and quality of the obtained data of a non-clinical (pre-clinical) laboratory examination;

"Major non-compliances" - non-compliances of a testing laboratory (centre) to the principles of good laboratory practice that may affect the integrity and quality of the obtained data of a non-clinical (preclinical) laboratory study;

"Minor non-compliances" are non-compliances of a testing laboratory (centre) to the principles of good laboratory practice that are not systematic and do not affect the integrity and quality of the non-clinical (pre-clinical) laboratory test data obtained.

Head of the inspection team: _____ _____ _____

Signature

Surname, first name, patronymic (if any)

Members of the inspection team: _____ _____ _____

Signature

Surname, first name, patronymic (if any)

_____ _____ _____

Signature

Surname, first name, patronymic (if any)

"_____" _____20_____