**STATEMENT**

**REQUIREMENTS FOR THE TENDERER**

**no. RFP 024313 /****BIOANALITYCAL METHOD DEVELOPMENT, DETERMINATION OF AD-O51.4 AND ANTI-DRUG ANTIBODY LEVEL IN SERUM OF PATIENTS ENROLLED IN THE CLINICAL TRIAL (GLP STANDARD)**

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| **REQUIREMENTS** | **CONFIRMATION [YES/NO]** |
| The facility must have at least 2 years of experience in performing bioanalytical and pharmacokinetic service according to GLP standards |  |
| The facility have a qualified key employees involved in clinical projects of innovative drugs. In particular a project team whose employees have experience in: |
| work related to the analysis of molecules using high-performance liquid chromatography (HPLC) or liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) or ELISA in a certified laboratory (min. 3 years) |  |
| development and validation of analytical methods (LS-MS/MS, ELISA), their transfer, optimization, and validation in accordance with EMA/FDA guidelines (min. 3 years) |  |
| analysis of patient samples for determination of biological molecules level in patient serum during a clinical trial (pharmacokinetic analysis) (min. 2 years) |  |
| analysis of patient samples detecting ADA (min. 2 years) |  |
| The facility must have all resources necessary to provide bioanalytical testing services in the GLP standard (GLP certificate) |  |
| The facility must use a quality management and control system to ensure compliance with all regulatory requirements. |  |
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 *(date and signature of Tenderer's authorized representative)*