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Таблица 1. *Содержание раздела «Специфическая активность» проекта нормативной документации на моноклональные антитела для медицинского применения*

Table 1. *Content of the Potency section of a draft product specification file for a monoclonal antibody for human use*

Subsection	Subsection content
Requirements	*Specify the upper and lower limits with units of measurement (as indicated in the Specification)*
Method	*Name the test method (as indicated in the Specification); the title of the potency evaluation procedure may be specified in round brackets (e.g. in vitro bioassay (determination of complement-dependent cytotoxicity))*
Principle	*Briefly describe the mechanism of action of the medicinal product determining the selection of the test procedure*
Equipment	*List and number all equipment, specifying manufacturers and models, and indicate the possibility of substitution*
Materials	*List and number all materials, specifying manufacturers and valid catalogue numbers, and indicate the possibility of substitution, if allowed, or its impossibility, if the materials are critical*
Reagents	*List and number all reagents, specifying manufacturers and valid catalogue numbers, and indicate the possibility of substitution, if allowed, or its impossibility, if the reagents are critical*
Standard / control samples (if applicable)	*Provide the full name, potency/concentration (with units of measurement for the certified characteristic), manufacturer (order codes / catalogue numbers for international standards / compendial reference standards), storage conditions and shelf-life periods before and after use, data on being calibrated relative to international standards / compendial reference standards (for in-house standards), and data on being an independently established in-house standard / independent serial dilution of the international standard / compendial reference standard (for control samples)*
Cell lines	*Specify full names of cell lines, collections of cell cultures, catalogue numbers (or indicate that the cells are sourced from the manufacturer's working cell bank), and storage conditions. Provide data on cell lines that do not require routine cultivation and are ready for the preparation of a working suspension immediately after thawing (ready-to-use/ ready-to-plate cells)*
Software	*List all software (with version numbers) for statistical analysis of test results*
Preparation of culture media and working solutions	*Provide a detailed sequential description of preparation procedures for culture media and reagent solutions. Specify sample weights, solvent volumes, and final concentrations/percentages of all solution components. Describe the conditions for medium/solution preparation (heating, mixing, filtering, aseptic conditions, etc.), use (heating, cooling, protection from light, etc.), and storage (temperature, permissibility and duration of storage before and after use for testing, etc.). The name of the solution/medium should reflect its purpose.*
Cell culture process	*Describe the stages of the cell culture process in detail:* *1. Cell culture initiation: thawing time and conditions and post-thawing manipulations, including neutralisation of the freezing medium, centrifugation, cell counting, transfer to culture flasks, subsequent incubation conditions, viability limits for recovered cells;* *2. Routine culture (not required for ready-to-use cells): passaging procedure, cell suspension concentration as a function of passaging frequency and flask area, cell viability and confluency limits, cell counting procedure, formulae for calculating cell density and viability (with explanations below), incubation conditions, number of passages from cell culture initiation to testing, and passage limit after which the culture should not be used;* *3. Cell suspension preparation for testing: procedure for diluting the suspension to a suitable working concentration, sufficient volume per plate*
Preparation of standard/ control/test sample dilutions	*Provide a detailed and consistent description of the sample preparation procedure, describing preliminary sample manipulations (thawing, recovery, holding at room temperature), conditions and duration of storage after thawing/ recovery, and preparation of initial sample dilutions (indicating the solvent and the concentration of the sample). Include a step-by-step serial dilution table (indicating the multiplicity of dilution, initial and final concentrations at each stage, sample and solvent volumes for each concentration), a dilution plate layout with explanations (if applicable), and the number of replicates for each dilution of each sample supposed to be transferred to the assay plate*
Test procedure	*Provide a detailed and consistent description of assay plate filling stages in the order of the test procedure. Specify the volume and concentration of cell suspension, volumes and concentrations of samples transferred into wells, volumes and concentrations of other reagents involved in the test, and time and conditions of plate incubation at each stage of filling. Include an assay plate layout with explanations. Explain what constitutes an independent replicate (for example, a result obtained using one assay plate with independently prepared cell suspension, serial dilutions of each sample, and reagents). Specify the number of independent replicates (e.g. 3) sufficient to obtain a reported value*
Results registration	*Describe the procedure and conditions for recording the results (shaking the plates before reading, wavelengths, number of flashes per well, reading point (bottom/surface), reading direction (rows/columns), and other non-default device settings)*
Data analysis	*Provide a statistical model to analyse plate readings, statistical software settings required to obtain the reported value, calculation formulae with explanations and units of measurement below, and an example of a typical dose–response curve. Indicate if assay plates should be analysed independently*
System suitability criteria	*List the acceptance criteria for the results obtained for the reference standard (dose–response curve symmetry, response amplitude, correlation and variation coefficients of primary data for replicates of each concentration, etc.)*
Acceptance criteria for test results	*List the criteria proving the similarity of the test (control) sample and the reference standard (slope ratios, upper and lower asymptotes of the curves of the test (control) sample and the standard; coefficients of variation of primary data for replicates of each concentration of the test (control) sample)*
Reported potency value	*Specify the formula for calculating the relative potency value for one independent potency determination and the formula for calculating the reported potency value of the test sample based on the values obtained in a set number of independent tests that meet all system suitability criteria and acceptance criteria (with explanations below the formulae). Provide acceptable coefficients of variation for independent potency determinations*
Unsatisfactory results	*Describe the procedure for the cases of obtaining unsatisfactory results (poor system suitability, out-of-specification results, miscalculated reported values)*

Таблица составлена авторами / The table is prepared by the authors