

When naming Monoclonal Antibodies the following items are required to be submitted with your application materials:

USAN Requirements for Monoclonal Antibodies

- ✓ Complete mature amino acid sequence in a [Microsoft Word document](#)
- ✓ Please ensure that the CAS Registry information includes the sequence, disulfide bridges and glycosylations
- ✓ A MS-Word document with single-letter codes for each amino acid, displayed in groups of 10 characters with 5 groups per line and a number indicating the position of the last amino acid at the end of each line
- ✓ Glycosylation patterns, including site and type of sugar, etc.
- ✓ Precursor nucleotide sequence with spaces between codons and translation, with numbered lines
- ✓ [CDR-IMGT and sequence analysis of the variable regions showing percentage of human content \(if -ximab, -zumab, or -umab is requested; >90% -umab, -zumab is typically >85%, <85% -ximab\)](#)
- ✓ CDR-Kabat (sequence and residue range)
- ✓ IG class and subclass, IG format
- ✓ Species or taxonomy related structure (chimeric, humanized, etc.)
- ✓ Name and/or structure of targeted antigen
- ✓ List of all disulfide bridges and their locations
- ✓ Expression system
- ✓ Clone name(s) and laboratory code name(s)
- ✓ If appropriate, the closest human V, J, and C genes and alleles (results obtained with IMGT/DomainGapAlign tool)
 - For the V-domains, if the domains are nominally human (e.g. produced from human antibodies, EBV immortalization of human B-cells, human phage display libraries, transgenic mice with human V-domain genes, or similar), the closest human gene/allele should be given
 - If the V-domains have been humanized by CDR-grafting onto a human framework, the closest human gene/allele to the parent human framework should be given
 - Otherwise the closest germline (human or other species) should be given
- ✓ If the terminal lysine is absent in the heavy chain amino acid sequence, a statement confirming that indeed there is no lysine codon in the nucleotide sequence (if not the lysine should be added in the amino acid sequence mentioning the posttranslational modification clipping)
- ✓ If relevant, amino acid differences with the native sequence (for a monoclonal antibody: constant region amino acid changes by comparison with the closer genomic C gene and allele)