ABSTRACT

POTENCY ASSAYS FOR ANTIBODY DRUG SUBSTANCE BINDING TO AN FC RECEPTOR

The invention relates to a method of characterizing an antibody, which method is suitable as a potency assay for batch release of a pharmaceutical composition comprising an antibody, specifically for use when applying for marketing authorization for said pharmaceutical composition. The assay provided is a method for determining the potency of a drug product comprising an FcR binding peptide, wherein at least one mechanism of action of the FcR binding peptide of the drug product is mediated through the binding of the FcR binding peptide of the drug product to a Fc receptor, wherein said method comprises determining the binding of the FcR binding peptide of the drug product to an Fc receptor.

Figure 1