INTRODUCTION

The review team has two questions for you regarding the potency assay for determination of in vitro expression (IVE) by flow cytometry. The review team has requested a response by Friday, August 6, 2021.

The following comments pertain to the Report for Co-validation of Test Method TM100010380 – Determination of the In-vitro Expression of PF-07302048 (BNT162b2 Construct, Drug Product) by Flow Cytometry (VAL100147509).

QUERY 1

You reported an overall percent relative standard deviation (%RSD) of (b) (4) in Table 12-5 on Page 14 of the report. However, our calculation results in an overall %RSD (b) (4) using the Mean S1+% data from this table. Please explain how you calculated the overall %RSD for (b) (4)

RESPONSE 1

The overall percent relative standard deviation (%RSD) was calculated using individual standard deviation values rather than using the mean $S1^+$ (%) expression results, in error. The correct %RSD value is equal to (b) (4) using rounded mean $S1^+$ (%) expression values instead (b) (4) This calculation error has no impact on the validation since no acceptance criteria was required as this is a limit test. The validation report has been updated to correct this error along with 3.2.P.5.3 Validation of Analytical Procedures – Cell-based Flow Cytometry.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

3.2.P.5.3 Validation of Analytical Procedures – Cell-based Flow Cytometry – replaced

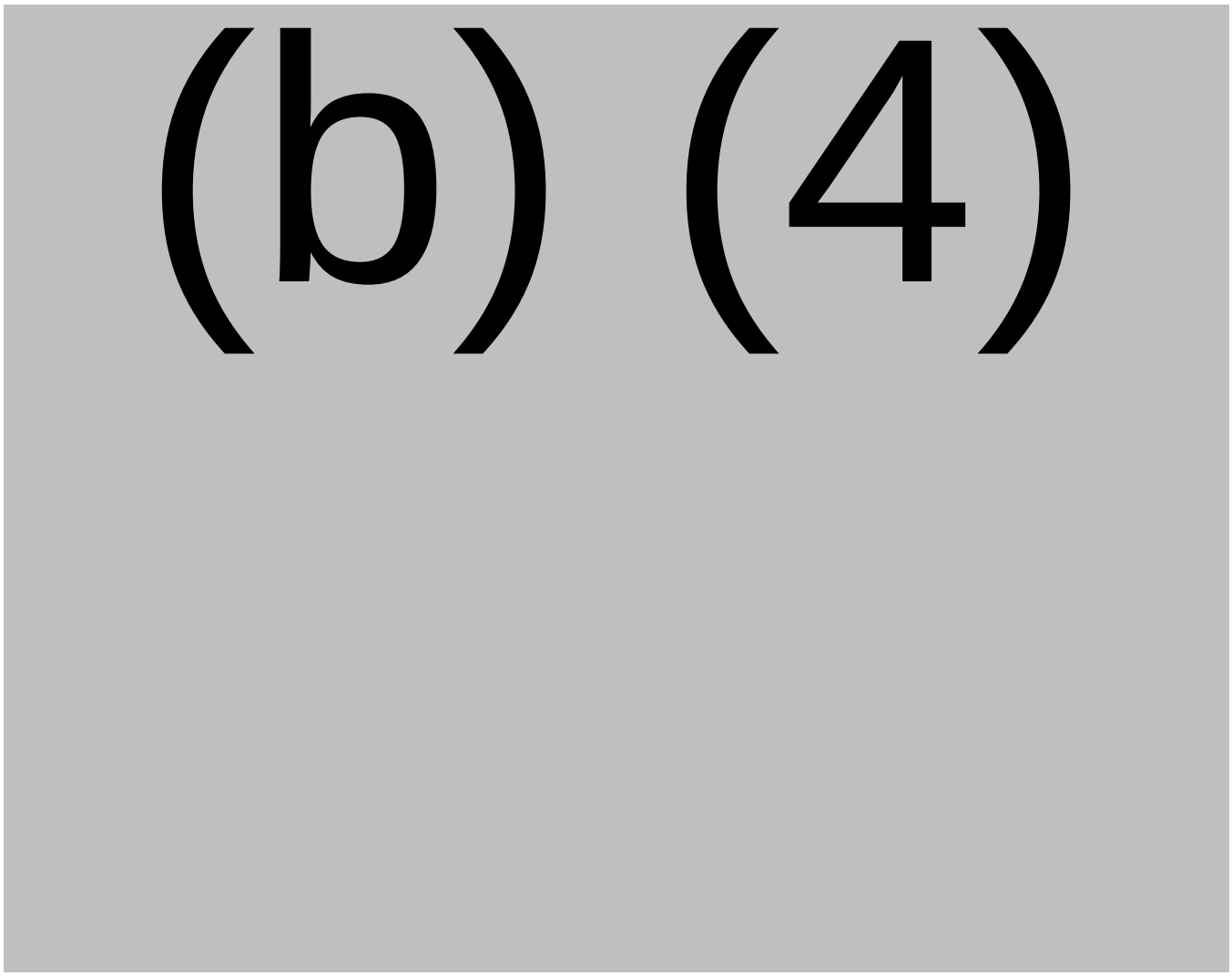
Previously submitted supporting documentation

None

QUERY 2

We note that, in Tables 14-1 and 14-2 on Page 21 of the report, the mean S1+ (%) results from (b) (4) (b) (4) compared to the results from (b) (4) . This trend becomes more (b) (4) (b) (4) , which may indicate some systematic difference between (b) (4) . Please comment and explain why you consider reproducibility to be acceptable given this observation.

RESPONSE 2



(b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None