**Supplementary Table 1- Investigation of FDA validation bioanalytical parameters**

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| **Bioanalytical parameters** | **Area of methods assessing this parameter** |
| Reference standards | Paragraph 1 |
| Critical reagents | Paragraphs 1, 3 and 4 |
| Calibration curve | Paragraphs 1 and 12 |
| Quality control material | Paragraphs 1, 7 and 8 |
| Selectivity and specificity | Paragraphs 5 and 16 |
| Sensitivity | Paragraphs 14 |
| Accuracy | Paragraph 7 and 9 |
| Precision | Paragraph 8 |
| Recovery | Paragraphs 9 and 10 |
| Stability | Paragraph 17 |

The bioanalytical parameters which the FDA guideline recommends assessing in method validations (5), referenced by the section of the Materials which explains their investigation.