

10. Outlier

| Sr.No. | Date    | Product /Prospective /Non-confirmation | SD value of IQC result | Root cause                 |  | Corrective/ Preventive Action    |                            |      | Responsible Person          | CA/PA closed on date | Follow up for effectiveness of CA/PA taken | QM Sign |
|--------|---------|--|------------------------|----------------------------|--|----------------------------------|----------------------------|------|-----------------------------|----------------------|--|---------|
|        |         |  |                        | Instrument function checks | Technical Error in IQC Specimen handling | Repeat Run (Within range or not) | Calibration and repeat IQC | ILCP |                             |                      |  |         |
| (1)    | 30/4/22 | wire                                   | ~                      | OK                         | No                                       | -NA-                             | -NA-                       | -NA- | Typing error                | kanishk 30/4/22      | Good                                       | Mehra   |
|        |         | result                                 |                        |                            |  |                                  |                            |      | error                       |                      |  |         |
|        |         | entry                                  |                        |                            |  |                                  |                            |      | error                       |                      |  |         |
|        |         | showed                                 |                        |                            |  |                                  |                            |      | found                       |                      |  |         |
|        |         | typing error                           |                        |                            |  |                                  |                            |      | Resolved                    |                      |  |         |
|        |         | ↓                                      |                        |                            |  |                                  |                            |      | ↓                           |                      |  |         |
|        |         | Z score not generated                  |                        |                            |  |                                  |                            |      | showed satisfactory result. |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |
|        |         |  |                        |                            |  |                                  |                            |      |                             |                      |  |         |