CERTIFICATE OF ANALYSIS AK-Calibrant



Attachment 07

DQ0U00.05

Temp.:

0U41C00.02

REF

5010004-RUO

LOT

0U41C00.02

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2026-07-31

| Content | volume | Reagent | LOT | <u> </u> | | |
|---------|--------|----------------------|---------|------------|--|--|
| 1x | 1 mL | AK-Calibrant Level A | 1N32C01 | 2026-07-31 | | |
| 1x | 1 mL | AK-Calibrant Level B | 3L35C01 | 2026-07-31 | | |
| 1x | 1 mL | AK-Calibrant Level C | 3M32C01 | 2026-07-31 | | |
| 1x | 1 mL | AK-Calibrant Level D | 3N32C01 | 2026-07-31 | | |

| Analytical Procedures | | | Requirement | | | | Result | | |
|------------------------------|----------------|---------|----------------------------|------|-----|-----------|-----------|----|--|
| | Content | accordi | according to packaging SOP | | | | confirmed | | |
| | Vial label | accordi | according to packaging SOP | | | confirmed | | ОК | |
| | Vial barcode | accordi | according to packaging SOP | | | | confirmed | | |
| visual inspection | Box label | accordi | according to packaging SOP | | | | confirmed | | |
| | Box barcode | accordi | according to packaging SOP | | | | confirmed | | |
| | Package insert | | present | | | confirmed | | ОК | |
| | Batch table | | present | | | | confirmed | | |
| | Control N | 0.83 | 2. | 1,11 | INR | 0.94 | INR | ок | |
| Recovery of controls | LOT 1P31C01 | 0.83 | | | | | | | |
| TECHNOPLASTIN HIS | Control A | 2.02 | ÷. | 2 72 | INR | 2.37 | INR | ок | |
| | LOT 3P42C00 | 2.02 | | 2.72 | | | | | |

Prepared by

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15. OKT. 2024

Date

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