


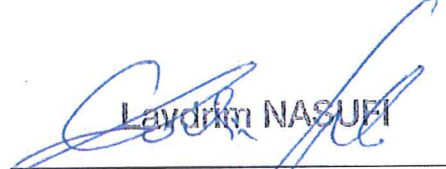
| | | |
|---|---|------------|
|  | ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS | DQ480D.02 |
| | | Alt.04 |
| | | 4876B0D.01 |

F VIII Mangelplasma immunads, 50x1mL

| | |
|---|------------|
| REF | 5154004 |
| LOT | 4876B0D.01 |
|  | 2019-09-30 |

| Analytische Verfahren Analytical Procedures | Anforderung Requirement | Ergebnis Result | |
|---|---|---|--|
| visuelle Kontrolle visual inspection | Cap color | blue | confirmed OK |
| | Vial type | clear glass vial | confirmed OK |
| | Vial label | according to packaging SOP | confirmed OK |
| | Vial barcode | according to packaging SOP | confirmed OK |
| | Box label | according to packaging SOP | confirmed OK |
| | Box barcode | according to packaging SOP | confirmed OK |
| | Package insert | present | confirmed OK |
| | Appearance before reconstitution | buff colored plug of lyophilized material | confirmed OK |
| Appearance after reconstitution | buff colored liquid without visible particles | confirmed OK | |
| Virologie / Virology | HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab | Negative Negative Negative | Negative Negative Negative OK |
| The testing methods applied were FDA-approved or CE marked. | | | |
| Kontrollwiederfindung FVIII am Ceveron® Alpha | Control N LOT 1P71B00 | 74.3 - 123.8 % | 119.5 % OK |
| Recovery of controls FVIII on Ceveron® Alpha | Control A LOT 3P71B00 | 20.1 - 33.5 % | 27.7 % OK |

Durchgeführt von
Prepared by


Laydri NASUFI

29. JAN. 2018

Datum / Date:

Freigabe von
Approved by


Stefan STEINER

29. JAN. 2018

Datum / Date: