



Kit Quality Control Report

RPH CENTRAL PHARMA

CNPJ: 19.315.658/0001-10
 R: Maestro Cardim, 769 - São Paulo/SP
 Farm. RT: Priscila Larcher CRF/SP-74.417

Date: From 13/11/2021 To 13/11/2021

| Product: | Manuf: | Calibration | D/T | QC By | Solution | Media | Origin | Middle | Top | Background | Particle Size/ OK? | % Tag | Pass Fail |
|--------------------------------------|--------|-------------|-------|-------|---------------|-------------|--------|--------|--------------|------------|----------------------|----------|-----------|
| DMSA-99mTc Lot # K-20211113-012 | | 13/11/2021 | 04:13 | MB | Butanona | 3MM Whatman | 139,8 | | 1,7 | 0 | pH (Low/Actual/High) | 96,967 % | Pass |
| | | | | | Normal Saline | Silica gel | 2,2 | 117,9 | 2,00 <= 3,00 | <= 3,00 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| DTPA-99mTc Lot # K-20211113-005 | RPH | 13/11/2021 | 02:37 | MB | Acetona | 3MM Whatman | 292 | | 1 | 0 | pH (Low/Actual/High) | 99,633 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 14 | 55251 | 3,80 <= 5,00 | <= 7,50 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| DTPA-99mTc Lot # K-20211113-009 | RPH | 13/11/2021 | 03:47 | MB | Acetona | 3MM Whatman | 251 | | 3 | 0 | pH (Low/Actual/High) | 97,354 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 4 | 269 | 3,80 <= 5,00 | <= 7,50 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| FITATO-99mTc Lot # K-20211113-007 | | 13/11/2021 | 03:06 | MB | Butanona | 3MM Whatman | 1656 | | 2 | 0 | pH (Low/Actual/High) | 99,879 % | Pass |
| | | | | | | | | | 5,00 <= 5,00 | <= 7,00 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| FITATO-99mTc Lot # K-20211113-020 | | 13/11/2021 | 05:49 | MB | Butanona | 3MM Whatman | 615 | | 3 | 0 | pH (Low/Actual/High) | 99,515 % | Pass |
| | | | | | | | | | 5,00 <= 5,00 | <= 7,00 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MAA-99mTc Lot # K-20211113-015 | | 13/11/2021 | 04:50 | MB | Butanona | 3MM Whatman | 162,7 | | 1,6 | 0 | pH (Low/Actual/High) | 99,026 % | Pass |
| | | | | | | | | | 3,00 <= 5,00 | <= 6,00 | | | |
| Turvo/Incolor | | | | | | | | | | | | | |
| MAA-99mTc Lot # K-20211113-021 | | 13/11/2021 | 06:01 | MB | Butanona | 3MM Whatman | 868 | | 3 | 0 | pH (Low/Actual/High) | 99,656 % | Pass |
| | | | | | | | | | 3,00 <= 5,00 | <= 6,00 | | | |
| Turvo/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20211113-004 | | 13/11/2021 | 02:37 | MB | Acetona | 3MM Whatman | 695 | | 2 | 0 | pH (Low/Actual/High) | 99,088 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 5 | 795 | 4,00 <= 5,00 | <= 7,80 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20211113-006 | | 13/11/2021 | 02:58 | MB | Acetona | 3MM Whatman | 1362 | | 3 | 0 | pH (Low/Actual/High) | 98,862 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 10 | 1079 | 4,00 <= 6,00 | <= 7,80 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20211113-008 | | 13/11/2021 | 03:44 | MB | Acetona | 3MM Whatman | 876 | | 26 | 0 | pH (Low/Actual/High) | 96,114 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 12 | 1184 | 4,00 <= 6,00 | <= 7,80 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20211113-016 | | 13/11/2021 | 04:51 | MB | Acetona | 3MM Whatman | 562 | | 7 | 0 | pH (Low/Actual/High) | 98,569 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 1 | 497 | 4,00 <= 6,00 | <= 7,80 | | | |
| Límpido/Incolor | | | | | | | | | | | | | |

| Product: | Manuf: | Calibration D/T | Solution | Media | Origin | Middle | Top | Solution 2 | Media 2 | Origin 2 | Top 2 | % Tag | QC By | Pass Fail |
|--------------------------------------|--------|------------------|----------|---------------------------|----------------------------|--------|-----|------------|---------|------------|-------|----------------------|----------|------------------------------|
| MIBI-99mTc Lot # K-20211113-001 | | 13/11/2021 02:22 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 1584 8 | | 43 920 | 0 | pH (Low/Actual/High) | 96,495 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-002 | | 13/11/2021 02:24 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 1098 10 | | 16 1413 | 0 | pH (Low/Actual/High) | 97,861 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-003 | | 13/11/2021 02:26 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 761 6 | | 15 1196 | 0 | pH (Low/Actual/High) | 97,568 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-010 | | 13/11/2021 03:54 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 723 2 | | 15 800 | 0 | pH (Low/Actual/High) | 97,718 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-011 | | 13/11/2021 03:55 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 1034 38 | | 9 1045 | 0 | pH (Low/Actual/High) | 95,628 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-013 | | 13/11/2021 04:15 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 1543 27 | | 17 1733 | 0 | pH (Low/Actual/High) | 97,376 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-017 | | 13/11/2021 05:26 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 670 8 | | 14 1286 | 0 | pH (Low/Actual/High) | 97,335 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-018 | | 13/11/2021 05:26 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 1645 4 | | 11 329 | 0 | pH (Low/Actual/High) | 98,135 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20211113-019 | | 13/11/2021 05:36 | MB | Normal Saline Metanol | Sílica gel 3MM Whatman | | | 768 6 | | 10 1630 | 0 | pH (Low/Actual/High) | 98,348 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| PIRO-99mTc Lot # K-20211113-014 | | 13/11/2021 04:31 | MB | Butanona Normal Saline | 3MM Whatman 3MM Whatman | | | 422 9 | | 1 374 | 0 | pH (Low/Actual/High) | 97,414 % | Pass 5,00 <= 5,00 <= 7,00 |
| Límpido/Incolor | | | | | | | | | | | | | | |
| Tecnécio-99m Lot # E-20211113-001 | | 13/11/2021 02:15 | MB | Butanona | 3MM Whatman | | | 7 | | 870 | 0 | pH (Low/Actual/High) | 99,202 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido e Incolor | | | | | | | | | | | | | | |
| Tecnécio-99m Lot # E-20211113-002 | | 13/11/2021 02:33 | MB | Butanona | 3MM Whatman | | | 15 | | 1272 | 0 | pH (Low/Actual/High) | 98,834 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido e Incolor | | | | | | | | | | | | | | |
| Tecnécio-99m Lot # E-20211113-003 | | 13/11/2021 02:54 | MB | Butanona | 3MM Whatman | | | 17 | | 1867 | 0 | pH (Low/Actual/High) | 99,098 % | Pass 5,00 <= 5,00 <= 6,00 |
| Límpido e Incolor | | | | | | | | | | | | | | |

| Product: | Manuf: | Calibration D/T | Solution | Media | Origin | Middle | Top | Solution 2 | Media 2 | Origin 2 | Top 2 | % Tag | QC By | Pass Fail |
|--------------------------------------|--------|------------------|----------|----------|--------|-------------|-----|------------|---------|----------|-------|----------------------|--------------|-------------------|
| Tecnécio-99m Lot # E-20211113-004 | | 13/11/2021 03:00 | MB | Butanona | | 3MM Whatman | | 3,1 | 141,4 | | 0 | 97,855 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-005 | | 13/11/2021 03:39 | MB | Butanona | | 3MM Whatman | | 18 | 1956 | | 0 | 99,088 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-007 | | 13/11/2021 03:52 | MB | Butanona | | 3MM Whatman | | 7 | 849 | | 0 | 99,182 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-006 | | 13/11/2021 03:52 | MB | Butanona | | 3MM Whatman | | 48 | 1630 | | 0 | 97,139 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-008 | | 13/11/2021 04:11 | MB | Butanona | | 3MM Whatman | | 3 | 1443 | | 0 | 99,793 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-009 | | 13/11/2021 04:48 | MB | Butanona | | 3MM Whatman | | 2 | 230 | | 0 | 99,138 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-010 | | 13/11/2021 05:21 | MB | Butanona | | 3MM Whatman | | 10 | 898 | | 0 | 98,899 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-011 | | 13/11/2021 05:22 | MB | Butanona | | 3MM Whatman | | 7 | 509 | | 0 | 98,643 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-012 | | 13/11/2021 05:31 | MB | Butanona | | 3MM Whatman | | 14 | 428 | | 0 | 96,833 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20211113-013 | | 13/11/2021 05:37 | MB | Butanona | | 3MM Whatman | | 2 | 502 | | 0 | 99,603 % | Pass | |
| | | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 |
| | | | | | | | | | | | | | | Límpido e Incolor |