



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 31/07/2021 To 31/07/2021

| Product: | Manuf: | Calibration | D/T | QC By | Solution | Media | Origin | Middle | Top | Background | Particle Size/ OK? | % Tag | Pass Fail |
|--------------------------------------|--------|-------------|-------|-------|---------------|-------------|--------|--------|------|----------------------|----------------------|----------|-----------|
| DTPA-99mTc Lot # K-20210731-010 | RPH | 31/07/2021 | 03:31 | PP | Acetona | 3MM Whatman | 481 | | 7 | 0 | | 93,297 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 48 | | 863 | pH (Low/Actual/High) | 3,80 <= 6,00 <= 7,50 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| FITATO-99mTc Lot # K-20210731-012 | | 31/07/2021 | 03:36 | PP | Butanona | 3MM Whatman | 12004 | | 4 | 0 | | 99,967 % | Pass |
| | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 6,00 <= 7,00 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MAA-99mTc Lot # K-20210731-013 | | 31/07/2021 | 03:46 | PP | Butanona | 3MM Whatman | 163 | | 8 | 0 | | 95,322 % | Pass |
| | | | | | | | | | | pH (Low/Actual/High) | 3,00 <= 6,00 <= 6,00 | | |
| Turvo/Incolor | | | | | | | | | | | | | |
| MAA-99mTc Lot # K-20210731-014 | | 31/07/2021 | 11:41 | BB | Butanona | 3MM Whatman | 55,6 | | 0,4 | 0 | | 99,286 % | Pass |
| | | | | | | | | | | pH (Low/Actual/High) | 3,00 <= 5,00 <= 6,00 | | |
| Turvo/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20210731-008 | | 31/07/2021 | 03:26 | PP | Acetona | 3MM Whatman | 1848 | | 9 | 0 | | 97,003 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 20 | | 776 | pH (Low/Actual/High) | 4,00 <= 6,00 <= 7,80 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20210731-009 | | 31/07/2021 | 03:28 | PP | Acetona | 3MM Whatman | 1333 | | 6 | 0 | | 96,95 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 16 | | 599 | pH (Low/Actual/High) | 4,00 <= 6,00 <= 7,80 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MDP-99mTc Lot # K-20210731-011 | | 31/07/2021 | 03:34 | PP | Acetona | 3MM Whatman | 2123 | | 22 | 0 | | 96,39 % | Pass |
| | | | | | Normal Saline | 3MM Whatman | 23 | | 867 | pH (Low/Actual/High) | 4,00 <= 6,00 <= 7,80 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20210731-002 | | 31/07/2021 | 02:22 | PP | Normal Saline | Sílica gel | 2113 | | 49 | 0 | | 97,289 % | Pass |
| | | | | | Metanol | 3MM Whatman | 13 | | 2911 | pH (Low/Actual/High) | 5,00 <= 6,00 <= 6,00 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20210731-001 | | 31/07/2021 | 02:22 | PP | Normal Saline | Sílica gel | 2151 | | 86 | 0 | | 95,64 % | Pass |
| | | | | | Metanol | 3MM Whatman | 19 | | 3665 | pH (Low/Actual/High) | 5,00 <= 6,00 <= 6,00 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20210731-003 | | 31/07/2021 | 02:35 | PP | Normal Saline | Sílica gel | 1778 | | 50 | 0 | | 95,977 % | Pass |
| | | | | | Metanol | 3MM Whatman | 35 | | 2683 | pH (Low/Actual/High) | 5,00 <= 6,00 <= 6,00 | | |
| Límpido/Incolor | | | | | | | | | | | | | |
| MIBI-99mTc Lot # K-20210731-004 | | 31/07/2021 | 02:35 | PP | Normal Saline | Sílica gel | 1277 | | 12 | 0 | | 98,49 % | Pass |
| | | | | | Metanol | 3MM Whatman | 12 | | 2061 | pH (Low/Actual/High) | 5,00 <= 6,00 <= 6,00 | | |
| 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-20210731-005 | | 31/07/2021 02:45 PP | Normal Saline Metanol | | Sílica gel 3MM Whatman | | | 2500 12 | | 65 2033 | 0 | pH (Low/Actual/High) | 96,879 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido/Incolor | | | | | | | |
| MIBI-99mTc Lot # K-20210731-006 | | 31/07/2021 02:46 PP | Normal Saline Metanol | | Sílica gel 3MM Whatman | | | 521 16 | | 6 407 | 0 | pH (Low/Actual/High) | 95,079 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido/Incolor | | | | | | | |
| MIBI-99mTc Lot # K-20210731-007 | | 31/07/2021 03:21 PP | Normal Saline Metanol | | Sílica gel 3MM Whatman | | | 1608 27 | | 46 2393 | 0 | pH (Low/Actual/High) | 96,103 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido/Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-001 | | 31/07/2021 02:18 PP | Butanona | | 3MM Whatman | | | 2 | | 439 | 0 | pH (Low/Actual/High) | 99,546 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-002 | | 31/07/2021 02:32 PP | Butanona | | 3MM Whatman | | | 6 | | 414 | 0 | pH (Low/Actual/High) | 98,571 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-003 | | 31/07/2021 02:42 PP | Butanona | | 3MM Whatman | | | 3 | | 660 | 0 | pH (Low/Actual/High) | 99,548 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-004 | | 31/07/2021 03:19 PP | Butanona | | 3MM Whatman | | | 2 | | 733 | 0 | pH (Low/Actual/High) | 99,728 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-005 | | 31/07/2021 03:32 PP | Butanona | | 3MM Whatman | | | 8 | | 1282 | 0 | pH (Low/Actual/High) | 99,38 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-006 | | 31/07/2021 03:43 PP | Butanona | | 3MM Whatman | | | 30 | | 2107 | 0 | pH (Low/Actual/High) | 98,596 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-007 | | 31/07/2021 04:42 PP | Butanona | | 3MM Whatman | | | 29 | | 3080 | 0 | pH (Low/Actual/High) | 99,067 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-009 | | 31/07/2021 04:42 PP | Butanona | | 3MM Whatman | | | 15 | | 1420 | 0 | pH (Low/Actual/High) | 98,955 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-010 | | 31/07/2021 04:45 PP | Butanona | | 3MM Whatman | | | 10 | | 1539 | 0 | pH (Low/Actual/High) | 99,354 % | Pass 5,00 <= 6,00 <= 6,00 |
| | | | | | | | Límpido e Incolor | | | | | | | |
| Tecnécio-99m Lot # E-20210731-008 | | 31/07/2021 04:45 PP | Butanona | | 3MM Whatman | | | 6 | | 3705 | 0 | pH (Low/Actual/High) | 99,838 % | Pass 5,00 <= 6,00 <= 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-20210731-012 | | 31/07/2021 04:45 | PP | Butanona | | 3MM Whatman | | 16 | | 2413 | 0 | | | 99,341 % Pass |
| | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 6,00 | <= 6,00 | |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20210731-011 | | 31/07/2021 04:49 | PP | Butanona | | 3MM Whatman | | 71 | | 1577 | 0 | | | 95,692 % Pass |
| | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 6,00 | <= 6,00 | |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20210731-013 | | 31/07/2021 04:50 | PP | Butanona | | 3MM Whatman | | 23 | | 1714 | 0 | | | 98,676 % Pass |
| | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 6,00 | <= 6,00 | |
| | | | | | | | | | | | | | | Límpido e Incolor |
| Tecnécio-99m Lot # E-20210731-014 | | 31/07/2021 11:38 | BB | Butanona | | 3MM Whatman | | 1 | | 452 | 0 | | | 99,779 % Pass |
| | | | | | | | | | | | pH (Low/Actual/High) | 5,00 <= 5,00 | <= 6,00 | |
| | | | | | | | | | | | | | | Límpido e Incolor |