



# 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 01/12/2021 To 01/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211201-016		01/12/2021	04:02	PM	Butanona Normal Saline	3MM Whatman Sílica gel	178,6 3		1,9 106,6	0	pH (Low/Actual/High)	96,21 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211201-017		01/12/2021	04:05	PM	Butanona Normal Saline	3MM Whatman Sílica gel	143,6 6,3		1,6 90,1	0	pH (Low/Actual/High)	92,363 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211201-028		01/12/2021	07:54	PM	Butanona Normal Saline	3MM Whatman Sílica gel	162,1 9,5		1,6 146,2	0	pH (Low/Actual/High)	92,921 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211201-029		01/12/2021	07:55	PM	Butanona Normal Saline	3MM Whatman Sílica gel	128,5 4,2		0,4 112,3	0	pH (Low/Actual/High)	96,085 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211201-040		01/12/2021	10:49	VS	Butanona Normal Saline	3MM Whatman Sílica gel	222 9		1 194	0	pH (Low/Actual/High)	95,118 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211201-036		01/12/2021	09:39	VS	Citrato de Sódio 0,1M	Sílica gel	522		7	0	pH (Low/Actual/High)	98,677 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211201-044		01/12/2021	15:54	MB	Citrato de Sódio 0,1M	Sílica gel	77,9		2,4	0	pH (Low/Actual/High)	97,011 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20211201-013	RPH	01/12/2021	03:55	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	361 8		3 349	0	pH (Low/Actual/High)	96,935 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211201-035	RPH	01/12/2021	09:39	VS	Acetona Normal Saline	3MM Whatman 3MM Whatman	964 9		5 527	0	pH (Low/Actual/High)	97,805 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211201-012		01/12/2021	03:53	PM	Butanona	3MM Whatman	307		2	0	pH (Low/Actual/High)	99,353 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211201-026		01/12/2021	07:11	PM	Butanona	3MM Whatman	374		2	0	pH (Low/Actual/High)	99,468 %	Pass
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
MAA-99mTc Lot # K-20211201-014		01/12/2021 03:58 PM	Butanona		3MM	Whatman		135,3		0,3	0		99,779 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20211201-015		01/12/2021 04:00 PM	Butanona		3MM	Whatman		125,4		1	0		99,209 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20211201-027		01/12/2021 07:35 PM	Butanona		3MM	Whatman		113,1		0,3	0		99,735 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20211201-038		01/12/2021 10:13 VS	Butanona		3MM	Whatman		432		4	0		99,083 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MDP-99mTc Lot # K-20211201-009		01/12/2021 03:47 PM	Acetona		3MM	Whatman		1035		4	0		98,493 %	Pass
			Normal Saline		3MM	Whatman		10		881		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-010		01/12/2021 03:49 PM	Acetona		3MM	Whatman		1105		2	0		99,164 %	Pass
			Normal Saline		3MM	Whatman		8		1213		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-011		01/12/2021 03:50 PM	Acetona		3MM	Whatman		1018		2	0		97,995 %	Pass
			Normal Saline		3MM	Whatman		24		1303		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-022		01/12/2021 06:49 PM	Acetona		3MM	Whatman		397		1	0		99,011 %	Pass
			Normal Saline		3MM	Whatman		5		673		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-030		01/12/2021 07:59 PM	Acetona		3MM	Whatman		662		15	0		96,835 %	Pass
			Normal Saline		3MM	Whatman		8		835		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-031		01/12/2021 08:00 PM	Acetona		3MM	Whatman		1039		28	0		97,003 %	Pass
			Normal Saline		3MM	Whatman		5		1337		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-033		01/12/2021 09:31 VS	Acetona		3MM	Whatman		1754		4	0		99,582 %	Pass
			Normal Saline		3MM	Whatman		2		1047		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-039		01/12/2021 10:16 VS	Acetona		3MM	Whatman		220		1	0		99,082 %	Pass
			Normal Saline		3MM	Whatman		1		214		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20211201-042		01/12/2021 11:08 VS	Acetona		3MM	Whatman		990		2	0		98,83 %	Pass
			Normal Saline		3MM	Whatman		16		1637		pH (Low/Actual/High)	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-20211201-003		01/12/2021 01:54 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			626,6 17		11,8 1387	0 pH (Low/Actual/High)	96,941 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-004		01/12/2021 01:55 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1412 1		12 1583	0 pH (Low/Actual/High)	99,094 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-005		01/12/2021 02:07 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			603 3		6 1386	0 pH (Low/Actual/High)	98,799 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-006		01/12/2021 02:08 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			689 14		9 1402	0 pH (Low/Actual/High)	97,722 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-007		01/12/2021 03:28 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1056 19		12 1949	0 pH (Low/Actual/High)	97,911 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-008		01/12/2021 03:29 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1322 13		36 1066	0 pH (Low/Actual/High)	96,144 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-018		01/12/2021 04:23 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1644 5		9 1732	0 pH (Low/Actual/High)	99,168 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-019		01/12/2021 04:35 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			946 38		17 1855	0 pH (Low/Actual/High)	96,227 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-020		01/12/2021 06:41 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1584 21		18 1771	0 pH (Low/Actual/High)	97,705 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-021		01/12/2021 06:42 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1243 3		20 214	0 pH (Low/Actual/High)	97,034 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-024		01/12/2021 07:05 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1879 5		28 1767	0 pH (Low/Actual/High)	98,25 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-025		01/12/2021 07:06 PM	Normal Saline Metanol		Sílica gel 3MM Whatman			1845 5		35 1436	0 pH (Low/Actual/High)	97,791 % 5,00 <= 5,00 <= 6,00	Pass	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-032		01/12/2021 08:39 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			429 9		4 410	0 pH (Low/Actual/High)	96,928 % 5,00 <= 6,00 <= 6,00	Pass	
							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-20211201-034	01/12/2021	09:36 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			262 5		6 352	0	pH (Low/Actual/High)	96,361 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-037	01/12/2021	10:09 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			312 8		5 554	0	pH (Low/Actual/High)	96,999 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20211201-041	01/12/2021	11:04 VS	Normal Saline Metanol		Sílica gel 3MM Whatman			720 8		10 1683	0	pH (Low/Actual/High)	98,157 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20211201-001	01/12/2021	00:51 BB	Citrato de Sódio 0,1M		Sílica gel			371		1	0	pH (Low/Actual/High)	99,731 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC 99,9														
PSMA-177Lu Lot # K-20211201-002	01/12/2021	01:12 BB	Citrato de Sódio 0,1M		Sílica gel			117,9		3	0	pH (Low/Actual/High)	97,519 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC 99,9														
PSMA-68Ga Lot # K-20211201-023	01/12/2021	06:54 PM	Acetato de amônio 1M:Metanol		Sílica gel			0,2		30,6	0	pH (Low/Actual/High)	99,351 %	Pass 4,00 <= 5,00 <= 8,00
							Límpido e Incolor							
PSMA-68Ga Lot # K-20211201-043	01/12/2021	12:46 VS	Acetato de amônio 1M:Metanol		Sílica gel			6		717	0	pH (Low/Actual/High)	99,17 %	Pass 4,00 <= 6,00 <= 8,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211201-001	01/12/2021	01:48 MB	Butanona		3MM Whatman			2,6		462,6	0	pH (Low/Actual/High)	99,441 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211201-002	01/12/2021	02:03 MB	Butanona		3MM Whatman			15		1440	0	pH (Low/Actual/High)	98,969 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211201-003	01/12/2021	03:23 PM	Butanona		3MM Whatman			2		1416	0	pH (Low/Actual/High)	99,859 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211201-004	01/12/2021	03:42 PM	Butanona		3MM Whatman			2		708	0	pH (Low/Actual/High)	99,718 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20211201-005	01/12/2021	04:21 PM	Butanona		3MM Whatman			1		706	0	pH (Low/Actual/High)	99,859 %	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-20211201-006		01/12/2021 04:30 PM	Butanona		3MM Whatman			2		207	0		99,043 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-007		01/12/2021 06:36 PM	Butanona		3MM Whatman			1		552	0		99,819 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-009		01/12/2021 07:02 PM	Butanona		3MM Whatman			6		1032	0		99,422 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-010		01/12/2021 07:31 PM	Butanona		3MM Whatman			16		1115	0		98,585 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-011		01/12/2021 07:50 PM	Butanona		3MM Whatman			3		379	0		99,215 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-012		01/12/2021 08:24 PM	Butanona		3MM Whatman			10		1012	0		99,022 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-013		01/12/2021 08:37 PM	Butanona		3MM Whatman			5		244	0		97,992 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-014		01/12/2021 09:26 VS	Butanona		3MM Whatman			4		263	0		98,502 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-015		01/12/2021 09:33 VS	Butanona		3MM Whatman			6		206	0		97,17 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-017		01/12/2021 10:04 VS	Butanona		3MM Whatman			7		825	0		99,159 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-018		01/12/2021 10:05 VS	Butanona		3MM Whatman			8		1126	0		99,295 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-019		01/12/2021 10:44 VS	Butanona		3MM Whatman			7		235	0		97,107 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211201-020		01/12/2021 11:01 VS	Butanona		3MM Whatman			7		324	0		97,885 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor