



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 08/11/2021 To 08/11/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211108-024		08/11/2021	07:46	FL	Butanona Normal Saline	3MM Whatman Sílica gel	127 3,1		1,6 94,1	0	pH (Low/Actual/High)	95,567 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211108-025		08/11/2021	07:50	FL	Butanona Normal Saline	3MM Whatman Sílica gel	193,7 1		2,2 479	0	pH (Low/Actual/High)	98,669 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211108-028		08/11/2021	08:04	FL	Butanona Normal Saline	3MM Whatman Sílica gel	198,3 8,1		1,6 176,1	0	pH (Low/Actual/High)	94,802 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211108-045		08/11/2021	10:36	MB	Butanona Normal Saline	3MM Whatman Sílica gel	98,8 2		1 77,1	0	pH (Low/Actual/High)	96,47 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20211108-051		08/11/2021	14:27	WG	Butanona Normal Saline	3MM Whatman Sílica gel	283 2		5 206	0	pH (Low/Actual/High)	97,302 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211108-041		08/11/2021	09:47	JS	Citrato de Sódio 0,1M	Sílica gel	39,8		0,5	0	pH (Low/Actual/High)	98,759 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20211108-014	RPH	08/11/2021	04:19	FL	Acetona Normal Saline	3MM Whatman 3MM Whatman	584,62 26,3		0,38 555,7	0	pH (Low/Actual/High)	95,416 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211108-015	RPH	08/11/2021	04:20	FL	Acetona Normal Saline	3MM Whatman 3MM Whatman	370,4 10,56		1,6 323,44	0	pH (Low/Actual/High)	96,408 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211108-026	RPH	08/11/2021	07:53	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman	578 5		2 568	0	pH (Low/Actual/High)	98,783 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211108-042	RPH	08/11/2021	10:06	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	667 5		10 388	0	pH (Low/Actual/High)	97,251 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20211108-047	RPH	08/11/2021	11:02	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	398 2		7 297	0	pH (Low/Actual/High)	97,603 %	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
FITATO-99mTc Lot # K-20211108-011		08/11/2021 03:48	FL	Butanona		3MM Whatman		343,63		2,37	0		99,315 %	Pass
												pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00
												Límpido/Incolor		
FITATO-99mTc Lot # K-20211108-027		08/11/2021 07:55	FL	Butanona		3MM Whatman		277		2	0		99,283 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
FITATO-99mTc Lot # K-20211108-043		08/11/2021 10:22	MB	Butanona		3MM Whatman		834		1	0		99,88 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20211108-013		08/11/2021 04:17	FL	Butanona		3MM Whatman		144,1		1,9	0		98,699 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211108-030		08/11/2021 08:12	FL	Butanona		3MM Whatman		58,6		1,4	0		97,667 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211108-031		08/11/2021 08:14	FL	Butanona		3MM Whatman		50,1		0,9	0		98,235 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211108-032		08/11/2021 08:16	FL	Butanona		3MM Whatman		20,9		1	0		95,434 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211108-048		08/11/2021 11:32	WG	Butanona		3MM Whatman		334		4	0		98,817 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20211108-049		08/11/2021 11:35	WG	Butanona		3MM Whatman		608		2	0		99,672 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20211108-009		08/11/2021 03:42	FL	Acetona		3MM Whatman		730,3		2,7	0		99,021 %	Pass
				Normal Saline		3MM Whatman		2,35		382,65		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-010		08/11/2021 03:45	FL	Acetona		3MM Whatman		844,8		1,2	0		98,692 %	Pass
				Normal Saline		3MM Whatman		6,25		529,75		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-012		08/11/2021 04:04	FL	Acetona		3MM Whatman		641,68		1,32	0		99,144 %	Pass
				Normal Saline		3MM Whatman		4,25		648,75		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-021		08/11/2021 07:03	FL	Acetona		3MM Whatman		958,92		1,08	0		99,111 %	Pass
				Normal Saline		3MM Whatman		8,61		1100,39		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
MDP-99mTc Lot # K-20211108-022		08/11/2021 07:17	FL	Acetona Normal Saline	3MM Whatman 3MM Whatman			1024,5 4,02	38,5 709,98	0		95,815 %	Pass	
												pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-029		08/11/2021 08:06	FL	Acetona Normal Saline	3MM Whatman 3MM Whatman			432 2	2 440	0		99,087 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-033		08/11/2021 08:37	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1397 26	7 1466	0		97,759 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-034		08/11/2021 08:44	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			537 2	6 593	0		98,559 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-039		08/11/2021 09:36	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			863 2	3 751	0		99,388 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20211108-040		08/11/2021 09:39	BB	Acetona Normal Saline	3MM Whatman 3MM Whatman			1322 6	25 832	0		97,428 %	Pass	
												pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-001		08/11/2021 01:56	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			559 28,7	9,3 1812	0		96,804 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-002		08/11/2021 02:05	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			903 13,27	17,84 706	0		96,218 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-003		08/11/2021 02:06	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			837 14,88	14,87 1225	0		97,054 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-004		08/11/2021 02:07	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			1169 16,34	17,9 1087	0		97,011 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-005		08/11/2021 02:13	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			563 38,7	11,4 2320	0		96,375 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-006		08/11/2021 02:14	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			924 25,5	14,2 1758	0		97,057 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido/Incolor		
MIBI-99mTc Lot # K-20211108-007		08/11/2021 03:12	FL	Normal Saline Metanol	Sílica gel 3MM Whatman			1058 16,64	20,4 1129,36	0		96,656 %	Pass	
												pH (Low/Actual/High)	5,00 <= 5,00	<= 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-20211108-008		08/11/2021 03:13 FL	Normal Saline Metanol		Sílica gel 3MM Whatman			1184,42 18,48	18,58 1662,52	0		pH (Low/Actual/High)	97,356 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-016		08/11/2021 06:26 FL	Normal Saline Metanol		Sílica gel 3MM Whatman			938,82 14,3	18,18 1320,7	0		pH (Low/Actual/High)	97,029 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-017		08/11/2021 06:35 FL	Normal Saline Metanol		Sílica gel 3MM Whatman			1213,1 21,9	28,9 960,1	0		pH (Low/Actual/High)	95,443 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-018		08/11/2021 06:36 FL	Normal Saline Metanol		Sílica gel 3MM Whatman			1163,9 26,5	24,1 1595,5	0		pH (Low/Actual/High)	96,338 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-020		08/11/2021 06:55 FL	Normal Saline Metanol		Sílica gel 3MM Whatman			1395 25	31 1217	0		pH (Low/Actual/High)	95,813 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-035		08/11/2021 08:48 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			630 4	7 717	0		pH (Low/Actual/High)	98,346 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-036		08/11/2021 09:21 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			1453 5	15 1646	0		pH (Low/Actual/High)	98,675 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-037		08/11/2021 09:24 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			1795 16	24 1954	0		pH (Low/Actual/High)	97,868 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-038		08/11/2021 09:26 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			970 22	13 1447	0		pH (Low/Actual/High)	97,18 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-044		08/11/2021 10:27 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			1478 4	24 1634	0		pH (Low/Actual/High)	98,158 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211108-046		08/11/2021 10:44 MB	Normal Saline Metanol		Sílica gel 3MM Whatman			573 1	5 664	0		pH (Low/Actual/High)	98,985 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20211108-023		08/11/2021 07:17 FL	Butanona Normal Saline		3MM Whatman 3MM Whatman			253,33 1,22	2,67 227,78	0		pH (Low/Actual/High)	98,424 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211108-019		08/11/2021 06:40 FL	Acetato de amônio 1M:Metanol		Sílica gel			0,79	35,51	0		pH (Low/Actual/High)	97,824 %	Pass 4,00 <= 5,00 <= 8,00
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
PSMA-68Ga Lot # K-20211108-050		08/11/2021 13:00	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,2		23,4	0		99,153 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-001		08/11/2021 01:52	FL	Butanona		3MM Whatman		12,7		1238	0		98,985 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-002		08/11/2021 01:58	FL	Butanona		3MM Whatman		12,45		1286	0		99,041 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-003		08/11/2021 02:09	FL	Butanona		3MM Whatman		1,62		911	0		99,822 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-004		08/11/2021 03:05	FL	Butanona		3MM Whatman		2,61		790	0		99,671 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-005		08/11/2021 04:02	FL	Butanona		3MM Whatman		117		2240	0		95,036 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-006		08/11/2021 06:24	FL	Butanona		3MM Whatman		1		511	0		99,805 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-007		08/11/2021 06:29	FL	Butanona		3MM Whatman		8,46		1647,54	0		99,489 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-009		08/11/2021 06:56	FL	Butanona		3MM Whatman		2		1749	0		99,886 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-010		08/11/2021 07:46	FL	Butanona		3MM Whatman		4		581	0		99,316 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-011		08/11/2021 09:18	BB	Butanona		3MM Whatman		8		3775	0		99,789 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-012		08/11/2021 09:28	BB	Butanona		3MM Whatman		23		3153	0		99,276 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20211108-014		08/11/2021 10:24	MB	Butanona		3MM Whatman		1		415	0		99,76 %	Pass
												pH (Low/Actual/High)	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-20211108-015		08/11/2021 11:08	MB	Butanona		3MM Whatman		1		416	0			99,76 % Pass
												pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211108-016		08/11/2021 11:15	MP	Butanona		3MM Whatman		1		222	0			99,552 % Pass
												pH (Low/Actual/High)		5,00 <= 5,00 <= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20211108-018		08/11/2021 14:21	WG	Butanona		3MM Whatman		14		2611	0			99,467 % Pass
												pH (Low/Actual/High)		5,00 <= 6,00 <= 6,00
												Límpido e Incolor		