



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 28/07/2021 To 28/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc		28/07/2021	07:36	FN	Butanona	3MM Whatman	164,5		2,2	0		98,564 %	Pass
Lot # K-20210728-023					Normal Saline	Silica gel	2		1711	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		28/07/2021	07:37	FN	Butanona	3MM Whatman	247		2	0		94,672 %	Pass
Lot # K-20210728-024					Normal Saline	Silica gel	10		211	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		28/07/2021	07:38	FN	Butanona	3MM Whatman	193,8		2,3	0		92,194 %	Pass
Lot # K-20210728-025					Normal Saline	Silica gel	12		168,9	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		28/07/2021	10:45	JS	Butanona	3MM Whatman	138,5		2	0		97,311 %	Pass
Lot # K-20210728-039					Normal Saline	Silica gel	1		78	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DMSA-99mTc		28/07/2021	10:46	JS	Butanona	3MM Whatman	182		2	0		95,404 %	Pass
Lot # K-20210728-040					Normal Saline	Silica gel	6		165	pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
						Límpido/Incolor							
DOTATOC-68Ga		28/07/2021	07:02	BB	Citrato de Sódio 0,1M	Silica gel	64,4		0,4	0		99,383 %	Pass
Lot # K-20210728-020										pH (Low/Actual/High)		4,00 <= 6,00	<= 8,00
						Límpido e Incolor							
DOTATOC-68Ga		28/07/2021	09:56	BB	Citrato de Sódio 0,1M	Silica gel	30,6		0,2	0		99,351 %	Pass
Lot # K-20210728-033										pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
						Límpido e Incolor							
DOTATOC-68Ga		28/07/2021	15:55	PL	Citrato de Sódio 0,1M	Silica gel	11,22		0	0		100,00 %	Pass
Lot # K-20210728-053										pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
						Límpido e Incolor							
DTPA-99mTc	RPH	28/07/2021	04:01	FN	Acetona	3MM Whatman	227		1	0		94,156 %	Pass
Lot # K-20210728-015					Normal Saline	3MM Whatman	12		210	pH (Low/Actual/High)		3,80 <= 5,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	28/07/2021	07:53	FN	Acetona	3MM Whatman	331		6	0		94,897 %	Pass
Lot # K-20210728-029					Normal Saline	3MM Whatman	10		291	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						Límpido/Incolor							
DTPA-99mTc	RPH	28/07/2021	10:30	JS	Acetona	3MM Whatman	812		4	0		99,243 %	Pass
Lot # K-20210728-038					Normal Saline	3MM Whatman	1		374	pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
						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
DTPA-99mTc Lot # K-20210728-051	RPH	28/07/2021 11:20	JS	Acetona Normal Saline	3MM	Whatman		642 15		4 560	0		96,772 %	Pass
											pH (Low/Actual/High)	3,80 <= 7,00	<= 7,50	
											Límpido/Incolor			
FITATO-99mTc Lot # K-20210728-017		28/07/2021 04:06	FN	Butanona	3MM	Whatman		297		2	0		99,331 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
											Límpido/Incolor			
FITATO-99mTc Lot # K-20210728-027		28/07/2021 07:44	FN	Butanona	3MM	Whatman		183,9		1,3	0		99,298 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
											Límpido/Incolor			
MAA-99mTc Lot # K-20210728-013		28/07/2021 03:58	FN	Butanona	3MM	Whatman		102,1		1,2	0		98,838 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-014		28/07/2021 04:00	FN	Butanona	3MM	Whatman		224		2	0		99,115 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-016		28/07/2021 04:04	FN	Butanona	3MM	Whatman		395		5	0		98,75 %	Pass
											pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-031		28/07/2021 08:20	FN	Butanona	3MM	Whatman		190,7		1,1	0		99,426 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-032		28/07/2021 08:22	FN	Butanona	3MM	Whatman		163,1		2,5	0		98,49 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-041		28/07/2021 10:51	JS	Butanona	3MM	Whatman		109		2	0		98,198 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-042		28/07/2021 10:52	JS	Butanona	3MM	Whatman		157		1	0		99,367 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-043		28/07/2021 10:54	JS	Butanona	3MM	Whatman		97,5		3	0		97,015 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-044		28/07/2021 10:56	JS	Butanona	3MM	Whatman		143		1,8	0		98,757 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210728-045		28/07/2021 10:59	JS	Butanona	3MM	Whatman		105		1,5	0		98,592 %	Pass
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/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-20210728-047		28/07/2021 11:10 JS	Butanona		3MM	Whatman		134		1,3	0	99,039 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210728-048		28/07/2021 11:13 JS	Butanona		3MM	Whatman		215		3	0	98,624 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210728-049		28/07/2021 11:14 JS	Butanona		3MM	Whatman		190		5	0	97,436 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210728-050		28/07/2021 11:16 JS	Butanona		3MM	Whatman		228		1	0	99,563 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210728-009		28/07/2021 03:16 FN	Acetona		3MM	Whatman		1163		12	0	97,342 %	Pass	
			Normal Saline		3MM	Whatman		12		721	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210728-026		28/07/2021 07:40 FN	Acetona		3MM	Whatman		1468		2	0	99,411 %	Pass	
			Normal Saline		3MM	Whatman		6		1318	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210728-028		28/07/2021 07:49 FN	Acetona		3MM	Whatman		1234		1	0	98,749 %	Pass	
			Normal Saline		3MM	Whatman		10		845	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210728-030		28/07/2021 08:08 FN	Acetona		3MM	Whatman		1145		2	0	98,937 %	Pass	
			Normal Saline		3MM	Whatman		12		1339	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210728-036		28/07/2021 10:26 JS	Acetona		3MM	Whatman		347		1	0	97,04 %	Pass	
			Normal Saline		3MM	Whatman		17		619	pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-002		28/07/2021 01:32 FN	Normal Saline		Sílica gel			618		20	0	96,391 %	Pass	
			Metanol		3MM	Whatman		4		840	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-004		28/07/2021 01:45 FN	Normal Saline		Sílica gel			1936		12	0	98,432 %	Pass	
			Metanol		3MM	Whatman		2		208	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-007		28/07/2021 03:04 FN	Normal Saline		Sílica gel			226		2	0	98,71 %	Pass	
			Metanol		3MM	Whatman		1		241	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-008		28/07/2021 03:10 FN	Normal Saline		Sílica gel			212		5	0	96,841 %	Pass	
			Metanol		3MM	Whatman		2		232	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-20210728-010	28/07/2021	03:22 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			319 1		5 204	0	pH (Low/Actual/High)	97,969 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-011	28/07/2021	03:26 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			227 1		5 311	0	pH (Low/Actual/High)	97,524 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-018	28/07/2021	04:20 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			253 2		5 420	0	pH (Low/Actual/High)	97,588 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-019	28/07/2021	04:27 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			435 3		4 521	0	pH (Low/Actual/High)	98,516 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-021	28/07/2021	07:09 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1863 2		20 268	0	pH (Low/Actual/High)	98,197 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-022	28/07/2021	07:20 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			398 4		12 262	0	pH (Low/Actual/High)	95,569 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-034	28/07/2021	10:00 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1232 38		12 1556	0	pH (Low/Actual/High)	96,651 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-035	28/07/2021	10:10 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1016 12		14 732	0	pH (Low/Actual/High)	97,028 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210728-046	28/07/2021	11:03 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1941 4		9 965	0	pH (Low/Actual/High)	99,126 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido/Incolor							
PIRO-99mTc Lot # K-20210728-012	28/07/2021	03:29 FN	Butanona Normal Saline		3MM Whatman 3MM Whatman			560 6		2 964	0	pH (Low/Actual/High)	99,026 %	Pass 5,00 <= 6,00 <= 7,00
							Límpido/Incolor							
PIRO-99mTc Lot # K-20210728-037	28/07/2021	10:28 JS	Butanona Normal Saline		3MM Whatman 3MM Whatman			432 2		1 241	0	pH (Low/Actual/High)	98,946 %	Pass 5,00 <= 5,00 <= 7,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20210728-001	28/07/2021	01:29 BB	Citrato de Sódio 0,1M		Sílica gel			156,1		0,7	0	pH (Low/Actual/High)	99,554 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 97,51%														
PSMA-177Lu Lot # K-20210728-003	28/07/2021	01:35 BB	Citrato de Sódio 0,1M		Sílica gel			204		1	0	pH (Low/Actual/High)	99,512 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							

Product:	Manuf:	Calibration	D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
QC Notes: HPLC: 97,94%															
PSMA-177Lu	28/07/2021	01:48	BB	Citrato de Sódio 0,1M	Sílica gel				181,8		1	0	99,453 %	Pass	
Lot # K-20210728-005								Limpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: HPLC: 98,10%															
PSMA-177Lu	28/07/2021	01:48	PL	Citrato de Sódio 0,1M	Sílica gel				232		2	0	99,145 %	Pass	
Lot # K-20210728-006								Limpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: HPLC: 96,95%															
PSMA-68Ga	28/07/2021	12:40	JS	Acetato de amônio 1M:Metanol	Sílica gel				0,4		28,6	0	98,621 %	Pass	
Lot # K-20210728-052								Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Tecnécio-99m	28/07/2021	01:30	FN	Butanona	3MM Whatman				2		288	0	99,31 %	Pass	
Lot # E-20210728-001								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	01:35	FN	Butanona	3MM Whatman				1		292	0	99,659 %	Pass	
Lot # E-20210728-002								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	03:02	FN	Butanona	3MM Whatman				1		169	0	99,412 %	Pass	
Lot # E-20210728-003								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	03:07	FN	Butanona	3MM Whatman				1		1150	0	99,913 %	Pass	
Lot # E-20210728-004								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m	28/07/2021	03:20	FN	Butanona	3MM Whatman				2		638	0	99,688 %	Pass	
Lot # E-20210728-005								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	03:24	FN	Butanona	3MM Whatman				2		454	0	99,561 %	Pass	
Lot # E-20210728-006								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	03:55	FN	Butanona	3MM Whatman				2		453	0	99,56 %	Pass	
Lot # E-20210728-007								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	04:18	FN	Butanona	3MM Whatman				3		1093	0	99,726 %	Pass	
Lot # E-20210728-008								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m	28/07/2021	07:05	FN	Butanona	3MM Whatman				1		394	0	99,747 %	Pass	
Lot # E-20210728-010								Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		

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-20210728-011	28/07/2021	07:17 FN	Butanona		3MM	Whatman		2		403	0		99,506 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-012	28/07/2021	07:31 FN	Butanona		3MM	Whatman		2		185	0		98,93 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-013	28/07/2021	07:47 FN	Butanona		3MM	Whatman		1		245	0		99,593 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-014	28/07/2021	08:06 FN	Butanona		3MM	Whatman		2		535	0		99,628 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-015	28/07/2021	08:18 FN	Butanona		3MM	Whatman		2		483	0		99,588 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-017	28/07/2021	09:55 JS	Butanona		3MM	Whatman		1		514	0		99,806 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-018	28/07/2021	10:05 JS	Butanona		3MM	Whatman		2		413	0		99,518 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-019	28/07/2021	10:23 JS	Butanona		3MM	Whatman		2		260	0		99,237 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-020	28/07/2021	10:40 JS	Butanona		3MM	Whatman		1		669	0		99,851 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210728-021	28/07/2021	11:00 JS	Butanona		3MM	Whatman		9		1877	0		99,523 %	Pass
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	