



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 07/07/2021 To 07/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210707-013		07/07/2021	04:03	PP	Butanona	3MM Whatman	209		2	0	pH (Low/Actual/High)	96,727 %	Pass
					Normal Saline	Silica gel	4		168	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210707-022		07/07/2021	07:32	FN	Butanona	3MM Whatman	171		2	0	pH (Low/Actual/High)	92,336 %	Pass
					Normal Saline	Silica gel	6,3		90,5	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210707-023		07/07/2021	07:33	FN	Butanona	3MM Whatman	168		3	0	pH (Low/Actual/High)	92,519 %	Pass
					Normal Saline	Silica gel	13		214	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210707-036		07/07/2021	10:36	WG	Butanona	3MM Whatman	144,6		0,4	0	pH (Low/Actual/High)	95,361 %	Pass
					Normal Saline	Silica gel	5,1		111,8	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DMSA-99mTc Lot # K-20210707-037		07/07/2021	10:38	WG	Butanona	3MM Whatman	185,5		0,9	0	pH (Low/Actual/High)	94,715 %	Pass
					Normal Saline	Silica gel	7,3		144,7	2,00 <= 3,00 <= 3,00			
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210707-030		07/07/2021	09:38	MP	Citrato de Sódio 0,1M	Silica gel	46,3		0,1	0	pH (Low/Actual/High)	97,634 %	Pass
					Metanol/Acetato de Amonio 1	Silica gel	1		45,5	4,00 <= 4,50 <= 8,00			
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210707-019		07/07/2021	07:13	FN	Citrato de Sódio 0,1M	Silica gel	40,7		1	0	pH (Low/Actual/High)	97,602 %	Pass
										4,00 <= 6,00 <= 8,00			
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210707-031		07/07/2021	09:51	JS	Citrato de Sódio 0,1M	Silica gel	25,9		0,2	0	pH (Low/Actual/High)	99,234 %	Pass
										4,00 <= 5,00 <= 8,00			
Límpido e Incolor													
DTPA-99mTc Lot # K-20210707-009	RPH	07/07/2021	03:45	PP	Acetona	3MM Whatman	292		1	0	pH (Low/Actual/High)	96,165 %	Pass
					Normal Saline	3MM Whatman	8		221	3,80 <= 6,00 <= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20210707-024	RPH	07/07/2021	07:35	FN	Acetona	3MM Whatman	329		2	0	pH (Low/Actual/High)	96,42 %	Pass
					Normal Saline	3MM Whatman	10		326	3,80 <= 6,00 <= 7,50			
Límpido/Incolor													
DTPA-99mTc Lot # K-20210707-034	RPH	07/07/2021	10:27	WG	Acetona	3MM Whatman	698		5	0	pH (Low/Actual/High)	98,453 %	Pass
					Normal Saline	3MM Whatman	5		593	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
FITATO-99mTc Lot # K-20210707-005		07/07/2021 02:59 PP	Butanona		3MM	Whatman		322		1	0	99,69 %	Pass	
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00	
FITATO-99mTc Lot # K-20210707-021		07/07/2021 07:31 FN	Butanona		3MM	Whatman		481		1	0	99,793 %	Pass	
							Límpido/Incolor					pH (Low/Actual/High)	5,00 <= 6,00 <= 7,00	
MAA-99mTc Lot # K-20210707-011		07/07/2021 03:57 PP	Butanona		3MM	Whatman		389		3	0	99,235 %	Pass	
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
MAA-99mTc Lot # K-20210707-025		07/07/2021 07:37 FN	Butanona		3MM	Whatman		200		1	0	99,502 %	Pass	
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
MAA-99mTc Lot # K-20210707-026		07/07/2021 07:39 FN	Butanona		3MM	Whatman		140		1	0	99,291 %	Pass	
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
MAA-99mTc Lot # K-20210707-027		07/07/2021 07:43 FN	Butanona		3MM	Whatman		131		2	0	98,496 %	Pass	
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
MDP-99mTc Lot # K-20210707-007		07/07/2021 03:16 PP	Acetona		3MM	Whatman		1194		1	0	99,736 %	Pass	
			Normal Saline		3MM	Whatman		2		1105		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210707-008		07/07/2021 03:24 PP	Acetona		3MM	Whatman		1534		1	0	96,812 %	Pass	
			Normal Saline		3MM	Whatman		38		1179		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210707-020		07/07/2021 07:22 FN	Acetona		3MM	Whatman		1194		10	0	98,907 %	Pass	
			Normal Saline		3MM	Whatman		3		1142		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210707-028		07/07/2021 07:45 FN	Acetona		3MM	Whatman		1009		12	0	98,321 %	Pass	
			Normal Saline		3MM	Whatman		6		1186		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210707-035		07/07/2021 10:33 WG	Acetona		3MM	Whatman		960		5	0	99,175 %	Pass	
			Normal Saline		3MM	Whatman		2		649		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210707-002		07/07/2021 02:11 PP	Normal Saline		Sílica gel			1042		20	0	97,24 %	Pass	
			Metanol		3MM	Whatman		29		3278		pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210707-003		07/07/2021 02:12 PP	Normal Saline		Sílica gel			2193		13	0	98,822 %	Pass	
			Metanol		3MM	Whatman		8		1350		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-20210707-004		07/07/2021 02:48 PP	Normal Saline Metanol		Silica gel 3MM Whatman			1521 4		16 2662	0	pH (Low/Actual/High)	98,809 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-006		07/07/2021 03:03 PP	Normal Saline Metanol		Silica gel 3MM Whatman			2069 8		34 1612	0	pH (Low/Actual/High)	97,889 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-010		07/07/2021 03:49 PP	Normal Saline Metanol		Silica gel 3MM Whatman			1556 24		23 1736	0	pH (Low/Actual/High)	97,18 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-012		07/07/2021 04:00 PP	Normal Saline Metanol		Silica gel 3MM Whatman			2833 19		33 1429	0	pH (Low/Actual/High)	97,536 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-016		07/07/2021 06:45 FN	Normal Saline Metanol		Silica gel 3MM Whatman			159 4		2 210	0	pH (Low/Actual/High)	96,889 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-017		07/07/2021 06:46 FN	Normal Saline Metanol		Silica gel 3MM Whatman			772 2		3 604	0	pH (Low/Actual/High)	99,283 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-018		07/07/2021 06:58 FN	Normal Saline Metanol		Silica gel 3MM Whatman			379 2		5 1028	0	pH (Low/Actual/High)	98,504 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-029		07/07/2021 08:08 FN	Normal Saline Metanol		Silica gel 3MM Whatman			1099 3		12 1200	0	pH (Low/Actual/High)	98,671 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-032		07/07/2021 10:15 JS	Normal Saline Metanol		Silica gel 3MM Whatman			573 12		4 3190	0	pH (Low/Actual/High)	98,932 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210707-033		07/07/2021 10:17 WG	Normal Saline Metanol		Silica gel 3MM Whatman			387 4		2 569	0	pH (Low/Actual/High)	98,788 %	Pass
Límpido/Incolor														
PSMA-177Lu Lot # K-20210707-001		07/07/2021 01:41 BB	Citrato de Sódio 0,1M		Silica gel			383		1	0	pH (Low/Actual/High)	99,74 %	Pass
Límpido														
QC Notes: HPLC: 99,81%														
PSMA-177Lu Lot # K-20210707-014		07/07/2021 05:54 BB	Citrato de Sódio 0,1M		Silica gel			572		3	0	pH (Low/Actual/High)	99,478 %	Pass
Límpido														
QC Notes: HPLC: 99,21%														

Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
PSMA-177Lu Lot # K-20210707-015	07/07/2021	06:22	BB	Citrato de Sódio 0,1M	Sílica gel			232		1	0	99,571 %	Pass	
							Límpido				pH (Low/Actual/High)	4,00 <= 4,50 <= 5,00		
QC Notes: 96HPLC: 96,96%														
PSMA-68Ga Lot # K-20210707-038	07/07/2021	12:53	JS	Acetato de amônio	Sílica gel			0,3	25,6		0	98,842 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Tecnécio-99m Lot # E-20210707-001	07/07/2021	01:57	PP	Butanona	3MM Whatman			2	2915		0	99,931 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-002	07/07/2021	02:06	PP	Butanona	3MM Whatman			19	4063		0	99,535 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-003	07/07/2021	02:46	PP	Butanona	3MM Whatman			10	466		0	97,899 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-004	07/07/2021	03:01	PP	Butanona	3MM Whatman			10	1162		0	99,147 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-005	07/07/2021	03:14	PP	Butanona	3MM Whatman			3	527		0	99,434 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-006	07/07/2021	03:41	PP	Butanona	3MM Whatman			6	3546		0	99,831 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-007	07/07/2021	03:57	PP	Butanona	3MM Whatman			13	544		0	97,666 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-008	07/07/2021	06:40	FN	Butanona	3MM Whatman			1	568		0	99,824 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-009	07/07/2021	06:40	FN	Butanona	3MM Whatman			2	155		0	98,726 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20210707-010	07/07/2021	06:56	FN	Butanona	3MM Whatman			1	265		0	99,624 %	Pass	
							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
Tecnício-99m Lot # E-20210707-012	07/07/2021	07:18	FN	Butanona	3MM	Whatman		1		207	0	99,519 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-013	07/07/2021	07:23	FN	Butanona	3MM	Whatman		1		176	0	99,435 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-014	07/07/2021	07:43	FN	Butanona	3MM	Whatman		1		207	0	99,519 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-015	07/07/2021	08:06	FN	Butanona	3MM	Whatman		3		1306	0	99,771 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-018	07/07/2021	10:05	JS	Butanona	3MM	Whatman		1		315	0	99,684 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-019	07/07/2021	10:14	JS	Butanona	3MM	Whatman		2		166,3	0	98,812 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-020	07/07/2021	10:19	JS	Butanona	3MM	Whatman		3		97	0	97,00 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210707-021	07/07/2021	10:31	JS	Butanona	3MM	Whatman		2		178	0	98,889 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		