



# 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 11/08/2021 To 11/08/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210811-021		11/08/2021	07:35	JS	Butanona Normal Saline	3MM Whatman Sílica gel	85,3 5		0,7 132	0	pH (Low/Actual/High)	95,536 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210811-022		11/08/2021	07:37	JS	Butanona Normal Saline	3MM Whatman Sílica gel	293 7		3 148	0	pH (Low/Actual/High)	94,47 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210811-034		11/08/2021	10:32	WG	Butanona Normal Saline	3MM Whatman Sílica gel	80,9 3		2,4 108,3	0	pH (Low/Actual/High)	94,423 %	Pass <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210811-015		11/08/2021	06:52	JS	Citrato de Sódio 0,1M	Sílica gel	27,8		0,1	0	pH (Low/Actual/High)	99,642 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210811-031		11/08/2021	10:04	FN	Citrato de Sódio 0,1M	Sílica gel	13,02		0,26	0	pH (Low/Actual/High)	98,042 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210811-044		11/08/2021	15:48	JS	Citrato de Sódio 0,1M	Sílica gel	17,8		0,6	0	pH (Low/Actual/High)	96,739 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210811-045		11/08/2021	16:45	JS	Citrato de Sódio 0,1M	Sílica gel	15,2		0,1	0	pH (Low/Actual/High)	99,346 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20210811-007	RPH	11/08/2021	03:29	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	408 13		20 512	0	pH (Low/Actual/High)	92,851 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20210811-020	RPH	11/08/2021	07:32	JS	Acetona Normal Saline	3MM Whatman 3MM Whatman	698 10		3 580	0	pH (Low/Actual/High)	97,877 %	Pass 3,80 <= 5,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20210811-033	RPH	11/08/2021	10:26	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	424 15		1 525	0	pH (Low/Actual/High)	96,987 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
FITATO-99mTc Lot # K-20210811-005		11/08/2021	02:51	FN	Butanona	3MM Whatman	712		2	0	pH (Low/Actual/High)	99,72 %	Pass 5,00 <= 6,00 <= 7,00
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
FITATO-99mTc Lot # K-20210811-023		11/08/2021 07:42 JS	Butanona		3MM	Whatman		357		1	0	99,721 %	Pass	
							Límpido/Incolor				pH (Low/Actual/High)	5,00 <= 7,00	<= 7,00	
MAA-99mTc Lot # K-20210811-024		11/08/2021 07:46 JS	Butanona		3MM	Whatman		150		2	0	98,684 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210811-025		11/08/2021 07:47 JS	Butanona		3MM	Whatman		291		1	0	99,658 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210811-026		11/08/2021 07:49 JS	Butanona		3MM	Whatman		221		1	0	99,55 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210811-035		11/08/2021 10:35 WG	Butanona		3MM	Whatman		111,8		1	0	99,113 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-036		11/08/2021 10:37 WG	Butanona		3MM	Whatman		111,3		1,4	0	98,758 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-037		11/08/2021 10:40 WG	Butanona		3MM	Whatman		79,2		1,1	0	98,63 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-038		11/08/2021 10:43 WG	Butanona		3MM	Whatman		216		3	0	98,63 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-039		11/08/2021 10:46 WG	Butanona		3MM	Whatman		120,3		0,4	0	99,669 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-040		11/08/2021 10:57 WG	Butanona		3MM	Whatman		85,9		2,5	0	97,172 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-041		11/08/2021 11:00 WG	Butanona		3MM	Whatman		110,6		0,9	0	99,193 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210811-042		11/08/2021 11:38 WG	Butanona		3MM	Whatman		138,9		4	0	97,201 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210811-006		11/08/2021 03:25 FN	Acetona		3MM	Whatman		730		1	0	98,876 %	Pass	
			Normal Saline		3MM	Whatman		10		1003	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-20210811-018		11/08/2021 07:17 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			988 3		4 1025	0 pH (Low/Actual/High)	99,305 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210811-019		11/08/2021 07:23 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			1153 2		3 708	0 pH (Low/Actual/High)	99,459 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210811-028		11/08/2021 08:14 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			1055 7		30 1305	0 pH (Low/Actual/High)	96,701 %	Pass	4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210811-032		11/08/2021 10:19 WG	Acetona Normal Saline		3MM Whatman 3MM Whatman			498 10		7 697	0 pH (Low/Actual/High)	97,199 %	Pass	4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-001		11/08/2021 01:59 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1442 1		20 1487	0 pH (Low/Actual/High)	98,565 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-002		11/08/2021 02:02 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			766 5		13 1050	0 pH (Low/Actual/High)	97,857 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-003		11/08/2021 02:43 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			547 6		12 597	0 pH (Low/Actual/High)	96,858 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-004		11/08/2021 02:43 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1070 2		16 276	0 pH (Low/Actual/High)	97,807 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-008		11/08/2021 03:42 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1886 2		22 229	0 pH (Low/Actual/High)	97,981 %	Pass	5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-009		11/08/2021 04:19 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			952 6		15 1013	0 pH (Low/Actual/High)	97,86 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-010		11/08/2021 04:25 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1177 1		22 211	0 pH (Low/Actual/High)	97,693 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-016		11/08/2021 07:05 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			245 4		5 214	0 pH (Low/Actual/High)	96,165 %	Pass	5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210811-017		11/08/2021 07:06 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			805 50		6 1393	0 pH (Low/Actual/High)	95,795 %	Pass	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-20210811-027	11/08/2021	07:51 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1150 3		1 1616	0	pH (Low/Actual/High)	99,728 % 5,00 <= 5,00 <= 6,00	Pass
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210811-029	11/08/2021	09:01 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			991 2		13 715	0	pH (Low/Actual/High)	98,426 % 5,00 <= 6,00 <= 6,00	Pass
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210811-030	11/08/2021	10:03 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			616 11		2 984	0	pH (Low/Actual/High)	98,571 % 5,00 <= 6,00 <= 6,00	Pass
							Límpido/Incolor							
PSMA-177Lu Lot # K-20210811-011	11/08/2021	05:42 BB	Citrato de Sódio 0,1M		Sílica gel			801		2	0	pH (Low/Actual/High)	99,751 % 4,00 <= 4,50 <= 5,00	Pass
							Límpido							
QC Notes: HPLC: 96,40														
PSMA-177Lu Lot # K-20210811-012	11/08/2021	05:56 BB	Citrato de Sódio 0,1M		Sílica gel			269		1	0	pH (Low/Actual/High)	99,63 % 4,00 <= 4,50 <= 5,00	Pass
							Límpido							
QC Notes: HPLC: 95,50														
PSMA-177Lu Lot # K-20210811-013	11/08/2021	06:15 BB	Citrato de Sódio 0,1M		Sílica gel			982		1	0	pH (Low/Actual/High)	99,898 % 4,00 <= 4,50 <= 5,00	Pass
							Límpido							
QC Notes: HPLC: 98,99%														
PSMA-177Lu Lot # K-20210811-014	11/08/2021	06:31 BB	Citrato de Sódio 0,1M		Sílica gel			666		1	0	pH (Low/Actual/High)	99,85 % 4,00 <= 4,50 <= 5,00	Pass
							Límpido							
QC Notes: HPLC: 97,41%														
PSMA-68Ga Lot # K-20210811-043	11/08/2021	12:48 JS	Acetato de amônio 1M:Metanol		Sílica gel			0,2		26,9	0	pH (Low/Actual/High)	99,262 % 4,00 <= 5,00 <= 8,00	Pass
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210811-001	11/08/2021	01:54 FN	Butanona		3MM Whatman			1		1159	0	pH (Low/Actual/High)	99,914 % 5,00 <= 5,00 <= 6,00	Pass
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210811-002	11/08/2021	01:54 FN	Butanona		3MM Whatman			2		203	0	pH (Low/Actual/High)	99,024 % 5,00 <= 6,00 <= 6,00	Pass
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210811-003	11/08/2021	02:39 FN	Butanona		3MM Whatman			0,2		189,1	0	pH (Low/Actual/High)	99,894 % 5,00 <= 6,00 <= 6,00	Pass
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210811-004	11/08/2021	02:39 FN	Butanona		3MM Whatman			2		986	0	pH (Low/Actual/High)	99,798 % 5,00 <= 6,00 <= 6,00	Pass
							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-20210811-005		11/08/2021 03:40	FN	Butanona		3MM Whatman		2		242	0		99,18 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-006		11/08/2021 04:16	FN	Butanona		3MM Whatman		3		412	0		99,277 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-008		11/08/2021 06:59	JS	Butanona		3MM Whatman		1		418	0		99,761 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-009		11/08/2021 07:00	JS	Butanona		3MM Whatman		3		274	0		98,917 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-010		11/08/2021 07:14	JS	Butanona		3MM Whatman		4		253	0		98,444 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-011		11/08/2021 07:19	JS	Butanona		3MM Whatman		5		962	0		99,483 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-012		11/08/2021 07:43	JS	Butanona		3MM Whatman		3		225	0		98,684 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-013		11/08/2021 08:12	JS	Butanona		3MM Whatman		2		887	0		99,775 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-014		11/08/2021 08:54	FN	Butanona		3MM Whatman		8		670	0		98,82 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-015		11/08/2021 09:56	FN	Butanona		3MM Whatman		6		2119	0		99,718 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-017		11/08/2021 10:16	FN	Butanona		3MM Whatman		6		306	0		98,077 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-018		11/08/2021 10:20	FN	Butanona		3MM Whatman		1		688	0		99,855 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210811-019		11/08/2021 12:16	JS	Butanona		3MM Whatman		2		678	0		99,706 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor