



# 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 08/09/2021 To 08/09/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210908-026		08/09/2021	07:35	JS	Butanona Normal Saline	3MM Whatman Sílica gel	143,7 4,8		1,4 141,7	0	pH (Low/Actual/High)	95,759 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210908-027		08/09/2021	07:39	JS	Butanona Normal Saline	3MM Whatman Sílica gel	149 5		1,5 192	0	pH (Low/Actual/High)	96,465 %	Pass
Límpido/Incolor													
DMSA-99mTc Lot # K-20210908-049		08/09/2021	11:22	JS	Butanona Normal Saline	3MM Whatman Sílica gel	195 3		2,7 158	0	pH (Low/Actual/High)	96,771 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210908-033		08/09/2021	09:40	BB	Citrato de Sódio 0,1M	Sílica gel	23,5		0,33	0	pH (Low/Actual/High)	98,615 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210908-052		08/09/2021	15:40	MP	Citrato de Sódio 0,1M	Sílica gel	23,4		0,2	0	pH (Low/Actual/High)	99,153 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210908-053		08/09/2021	16:32	MP	Citrato de Sódio 0,1M	Sílica gel	18,2		0,3	0	pH (Low/Actual/High)	98,378 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20210908-009	RPH	08/09/2021	03:51	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	805 36		7 552	0	pH (Low/Actual/High)	93,015 %	Pass
Límpido/Incolor													
DTPA-99mTc Lot # K-20210908-034	RPH	08/09/2021	09:56	MP	Acetona Normal Saline	3MM Whatman 3MM Whatman	234 3		2 262	0	pH (Low/Actual/High)	98,02 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210908-015		08/09/2021	04:06	PP	Butanona	3MM Whatman	557		6	0	pH (Low/Actual/High)	98,934 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20210908-023		08/09/2021	07:05	JS	Butanona	3MM Whatman	189,8		2,1	0	pH (Low/Actual/High)	98,906 %	Pass
Límpido/Incolor													
MAA-99mTc Lot # K-20210908-010		08/09/2021	03:56	PP	Butanona	3MM Whatman	339		8	0	pH (Low/Actual/High)	97,695 %	Pass
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-20210908-011		08/09/2021 03:57 PP	Butanona		3MM	Whatman		177		1	0	99,438 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210908-012		08/09/2021 03:59 PP	Butanona		3MM	Whatman		137		6	0	95,804 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210908-013		08/09/2021 04:02 PP	Butanona		3MM	Whatman		197		8	0	96,098 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210908-014		08/09/2021 04:03 PP	Butanona		3MM	Whatman		140		6	0	95,89 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210908-024		08/09/2021 07:09 FN	Butanona		3MM	Whatman		152,6		3,1	0	98,009 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210908-025		08/09/2021 07:09 FN	Butanona		3MM	Whatman		183,3		1,4	0	99,242 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210908-035		08/09/2021 10:03 MP	Butanona		3MM	Whatman		36,7		1,2	0	96,834 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210908-036		08/09/2021 10:05 MP	Butanona		3MM	Whatman		70,8		0,2	0	99,718 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210908-037		08/09/2021 10:07 MP	Butanona		3MM	Whatman		125,6		0,3	0	99,762 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210908-038		08/09/2021 10:29 JS	Butanona		3MM	Whatman		71		1,2	0	98,338 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210908-039		08/09/2021 10:31 JS	Butanona		3MM	Whatman		94		2,1	0	97,815 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210908-040		08/09/2021 10:35 JS	Butanona		3MM	Whatman		237		3	0	98,75 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00	
MAA-99mTc Lot # K-20210908-042		08/09/2021 10:38 JS	Butanona		3MM	Whatman		48		0,8	0	98,361 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00	<= 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
MAA-99mTc Lot # K-20210908-043		08/09/2021 10:49 JS	Butanona		3MM	Whatman		87,4		0,4	0		99,544 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210908-044		08/09/2021 10:58 JS	Butanona		3MM	Whatman		53,5		0,8	0		98,527 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MAA-99mTc Lot # K-20210908-045		08/09/2021 11:00 JS	Butanona		3MM	Whatman		120		2	0		98,361 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00	
MAA-99mTc Lot # K-20210908-046		08/09/2021 11:01 JS	Butanona		3MM	Whatman		101		0,7	0		99,312 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00	
MDP-99mTc Lot # K-20210908-016		08/09/2021 04:11 PP	Acetona		3MM	Whatman		1530		30	0		95,242 %	Pass
			Normal Saline		3MM	Whatman		54		1851		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210908-018		08/09/2021 04:16 PP	Acetona		3MM	Whatman		1051		2	0		94,326 %	Pass
			Normal Saline		3MM	Whatman		17		293		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210908-022		08/09/2021 07:01 FN	Acetona		3MM	Whatman		683		1	0		99,496 %	Pass
			Normal Saline		3MM	Whatman		6		1671		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210908-029		08/09/2021 07:49 JS	Acetona		3MM	Whatman		475		13	0		92,791 %	Pass
			Normal Saline		3MM	Whatman		5		105		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210908-032		08/09/2021 09:24 MP	Acetona		3MM	Whatman		373		1	0		99,008 %	Pass
			Normal Saline		3MM	Whatman		2		274		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210908-047		08/09/2021 11:04 JS	Acetona		3MM	Whatman		346		5	0		97,443 %	Pass
			Normal Saline		3MM	Whatman		6		524		pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210908-050		08/09/2021 11:42 JS	Acetona		3MM	Whatman		470		2	0		98,949 %	Pass
			Normal Saline		3MM	Whatman		6		950		pH (Low/Actual/High)	4,00 <= 5,00 <= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210908-003		08/09/2021 01:48 PP	Normal Saline		Sílica gel			1473		24	0		97,092 %	Pass
			Metanol		3MM	Whatman		29		2193		pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210908-004		08/09/2021 01:51 PP	Normal Saline		Sílica gel			2221		36	0		97,954 %	Pass
			Metanol		3MM	Whatman		7		1544		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-20210908-005		08/09/2021 02:36 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2643 78		51 2708	0	pH (Low/Actual/High)	95,307 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-006		08/09/2021 03:02 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1789 36		53 2590	0	pH (Low/Actual/High)	95,752 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-007		08/09/2021 03:03 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2689 34		75 2544	0	pH (Low/Actual/High)	95,968 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-008		08/09/2021 03:08 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1545 89		22 3514	0	pH (Low/Actual/High)	96,126 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-017		08/09/2021 04:14 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2319 10		40 889	0	pH (Low/Actual/High)	97,192 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-019		08/09/2021 06:43 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1885 1		21 220	0	pH (Low/Actual/High)	98,446 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-020		08/09/2021 06:45 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1619 7		30 1892	0	pH (Low/Actual/High)	97,812 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-021		08/09/2021 06:49 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1099 1		10 1077	0	pH (Low/Actual/High)	99,006 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-030		08/09/2021 07:53 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			335 1		4 228	0	pH (Low/Actual/High)	98,383 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-031		08/09/2021 08:33 MP	Normal Saline Metanol		Sílica gel 3MM Whatman			333 5		5 241	0	pH (Low/Actual/High)	96,488 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-041		08/09/2021 10:36 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			541 13		8 617	0	pH (Low/Actual/High)	96,479 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-048		08/09/2021 11:10 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1243 3		10 254	0	pH (Low/Actual/High)	98,035 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210908-051		08/09/2021 11:48 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			510 27		9 583	0	pH (Low/Actual/High)	93,84 %	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
PIRO-99mTc Lot # K-20210908-028		08/09/2021 07:42 JS	Butanona Normal Saline		3MM Whatman			272 1,5		1 120,3	0	pH (Low/Actual/High)	98,402 %	Pass 5,00 <= 5,00 <= 7,00
							Límpido/Incolor							
PSMA-177Lu Lot # K-20210908-001		08/09/2021 01:03 BB	Citrato de Sódio 0,1M		Sílica gel			476		2	0	pH (Low/Actual/High)	99,582 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 96%														
PSMA-177Lu Lot # K-20210908-002		08/09/2021 01:21 BB	Citrato de Sódio 0,1M		Sílica gel			206		1	0	pH (Low/Actual/High)	99,517 %	Pass 4,00 <= 4,50 <= 5,00
							Límpido							
QC Notes: HPLC: 97,37%														
Tecnécio-99m Lot # E-20210908-001		08/09/2021 01:39 PP	Butanona		3MM Whatman			40		2183	0	pH (Low/Actual/High)	98,201 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-002		08/09/2021 01:40 PP	Butanona		3MM Whatman			11		5959	0	pH (Low/Actual/High)	99,816 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-003		08/09/2021 02:34 PP	Butanona		3MM Whatman			11		403	0	pH (Low/Actual/High)	97,343 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-004		08/09/2021 02:58 PP	Butanona		3MM Whatman			10		305	0	pH (Low/Actual/High)	96,825 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-005		08/09/2021 02:59 PP	Butanona		3MM Whatman			7		743	0	pH (Low/Actual/High)	99,067 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-006		08/09/2021 03:53 PP	Butanona		3MM Whatman			3		780	0	pH (Low/Actual/High)	99,617 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-007		08/09/2021 04:09 PP	Butanona		3MM Whatman			1		239	0	pH (Low/Actual/High)	99,583 %	Pass 5,00 <= 6,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-008		08/09/2021 06:39 FN	Butanona		3MM Whatman			1		370	0	pH (Low/Actual/High)	99,73 %	Pass 5,00 <= 5,00 <= 6,00
							Límpido e Incolor							
Tecnécio-99m Lot # E-20210908-009		08/09/2021 06:42 FN	Butanona		3MM Whatman			4		576	0	pH (Low/Actual/High)	99,31 %	Pass 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-20210908-010		08/09/2021 06:46	FN	Butanona		3MM Whatman		1		283	0	99,648 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-011		08/09/2021 07:04	MP	Butanona		3MM Whatman		1		139	0	99,286 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-012		08/09/2021 07:51	JS	Butanona		3MM Whatman		1		326	0	99,694 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-013		08/09/2021 08:31	MP	Butanona		3MM Whatman		1		214	0	99,535 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-014		08/09/2021 08:57	MP	Butanona		3MM Whatman		1		442	0	99,774 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-016		08/09/2021 09:53	MP	Butanona		3MM Whatman		1		405	0	99,754 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-017		08/09/2021 10:33	JS	Butanona		3MM Whatman		2		243	0	99,184 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-018		08/09/2021 10:33	JS	Butanona		3MM Whatman		1		390	0	99,744 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-019		08/09/2021 11:05	JS	Butanona		3MM Whatman		4		710	0	99,44 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-020		08/09/2021 11:21	JS	Butanona		3MM Whatman		4		553	0	99,282 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
Tecnécio-99m Lot # E-20210908-021		08/09/2021 11:46	JS	Butanona		3MM Whatman		18		1033	0	98,287 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	