



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 22/06/2021 To 22/06/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210622-016		22/06/2021	04:01	PP	Butanona Normal Saline	3MM Whatman Sílica gel	233 10		1 216	0	pH (Low/Actual/High)	95,148 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210622-024		22/06/2021	07:35	WG	Butanona Normal Saline	3MM Whatman Sílica gel	222 9		3 136,6	0	pH (Low/Actual/High)	92,485 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DMSA-99mTc Lot # K-20210622-025		22/06/2021	07:37	WG	Butanona Normal Saline	3MM Whatman Sílica gel	263 7,7		1 122,7	0	pH (Low/Actual/High)	93,716 %	Pass 2,00 <= 3,00 <= 3,00
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20210622-018		22/06/2021	06:50	BB	Citrato de Sódio 0,1M	Sílica gel	11,3		0,1	0	pH (Low/Actual/High)	99,123 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210622-026		22/06/2021	07:38	BB	Citrato de Sódio 0,1M	Sílica gel	23,6		0,3	0	pH (Low/Actual/High)	98,745 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210622-033		22/06/2021	08:33	WG	Citrato de Sódio 0,1M	Sílica gel	18,5		0,1	0	pH (Low/Actual/High)	99,462 %	Pass 4,00 <= 7,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210622-035		22/06/2021	09:20	BB	Citrato de Sódio 0,1M	Sílica gel	13,6		0,6	0	pH (Low/Actual/High)	95,775 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210622-053		22/06/2021	13:00	SB	Citrato de Sódio 0,1M	Sílica gel	18,4		0,9	0	pH (Low/Actual/High)	95,337 %	Pass 4,00 <= 4,00 <= 8,00
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210622-054		22/06/2021	13:41	SB	Citrato de Sódio 0,1M	Sílica gel	37,6		0,4	0	pH (Low/Actual/High)	98,947 %	Pass 4,00 <= 4,00 <= 8,00
Límpido e Incolor													
DTPA-99mTc Lot # K-20210622-011	RPH	22/06/2021	03:49	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1001 31		4 880	0	pH (Low/Actual/High)	96,199 %	Pass 3,80 <= 6,00 <= 7,50
Límpido/Incolor													
DTPA-99mTc Lot # K-20210622-012	RPH	22/06/2021	03:50	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	878 45		6 521	0	pH (Low/Actual/High)	91,371 %	Pass 3,80 <= 7,00 <= 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-20210622-029	RPH	22/06/2021 07:53	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			745 5		1 674	0	pH (Low/Actual/High)	99,13 %	Pass 3,80 <= 6,00 <= 7,50
														Límpido/Incolor
DTPA-99mTc Lot # K-20210622-030	RPH	22/06/2021 08:06	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			489 10		1 343	0	pH (Low/Actual/High)	96,963 %	Pass 3,80 <= 6,00 <= 7,50
														Límpido/Incolor
DTPA-99mTc Lot # K-20210622-044	RPH	22/06/2021 10:21	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman			522 7		4 365	0	pH (Low/Actual/High)	97,358 %	Pass 3,80 <= 6,00 <= 7,50
														Límpido/Incolor
FITATO-99mTc Lot # K-20210622-007		22/06/2021 03:16	PP	Butanona	3MM Whatman			764		2	0	pH (Low/Actual/High)	99,739 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
FITATO-99mTc Lot # K-20210622-028		22/06/2021 07:50	WG	Butanona	3MM Whatman			1040		1	0	pH (Low/Actual/High)	99,904 %	Pass 5,00 <= 6,00 <= 7,00
														Límpido/Incolor
MAA-99mTc Lot # K-20210622-013		22/06/2021 03:53	PP	Butanona	3MM Whatman			262		6	0	pH (Low/Actual/High)	97,761 %	Pass 3,00 <= 6,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-014		22/06/2021 03:56	PP	Butanona	3MM Whatman			244		3	0	pH (Low/Actual/High)	98,785 %	Pass 3,00 <= 6,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-015		22/06/2021 03:59	PP	Butanona	3MM Whatman			354		6	0	pH (Low/Actual/High)	98,333 %	Pass 3,00 <= 6,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-031		22/06/2021 08:08	WG	Butanona	3MM Whatman			147,9		0,7	0	pH (Low/Actual/High)	99,529 %	Pass 3,00 <= 6,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-032		22/06/2021 08:10	WG	Butanona	3MM Whatman			115,8		0,1	0	pH (Low/Actual/High)	99,914 %	Pass 3,00 <= 6,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-037		22/06/2021 10:01	JS	Butanona	3MM Whatman			297		3	0	pH (Low/Actual/High)	99,00 %	Pass 3,00 <= 6,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-039		22/06/2021 10:07	JS	Butanona	3MM Whatman			137,5		2	0	pH (Low/Actual/High)	98,566 %	Pass 3,00 <= 5,00 <= 6,00
														Turvo/Incolor
MAA-99mTc Lot # K-20210622-040		22/06/2021 10:09	JS	Butanona	3MM Whatman			233		3	0	pH (Low/Actual/High)	98,729 %	Pass 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-20210622-041		22/06/2021 10:12 JS	Butanona		3MM	Whatman		56		1,6	0	97,222 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210622-042		22/06/2021 10:14 JS	Butanona		3MM	Whatman		125		2	0	98,425 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 5,00 <= 6,00		
MAA-99mTc Lot # K-20210622-043		22/06/2021 10:17 JS	Butanona		3MM	Whatman		378		9	0	97,674 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210622-051		22/06/2021 10:47 WG	Butanona		3MM	Whatman		276		2	0	99,281 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MAA-99mTc Lot # K-20210622-052		22/06/2021 10:54 WG	Butanona		3MM	Whatman		103,7		2,1	0	98,015 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00 <= 6,00		
MDP-99mTc Lot # K-20210622-009		22/06/2021 03:30 PP	Acetona		3MM	Whatman		757		1	0	99,469 %	Pass	
			Normal Saline		3MM	Whatman		4		998	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210622-010		22/06/2021 03:46 PP	Acetona		3MM	Whatman		1657		2	0	99,608 %	Pass	
			Normal Saline		3MM	Whatman		6		2208	pH (Low/Actual/High)	4,00 <= 7,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210622-022		22/06/2021 07:25 WG	Acetona		3MM	Whatman		1148		1	0	98,145 %	Pass	
			Normal Saline		3MM	Whatman		9,4		522,2	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210622-027		22/06/2021 07:45 WG	Acetona		3MM	Whatman		1785		4	0	96,417 %	Pass	
			Normal Saline		3MM	Whatman		38		1093	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MDP-99mTc Lot # K-20210622-034		22/06/2021 08:54 WG	Acetona		3MM	Whatman		840		8	0	97,501 %	Pass	
			Normal Saline		3MM	Whatman		11		696	pH (Low/Actual/High)	4,00 <= 6,00 <= 7,80		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210622-001		22/06/2021 01:56 PP	Normal Saline		Sílica gel			1608		22	0	95,355 %	Pass	
			Metanol		3MM	Whatman		76		2230	pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210622-002		22/06/2021 02:31 PP	Normal Saline		Sílica gel			1586		28	0	97,135 %	Pass	
			Metanol		3MM	Whatman		31		2712	pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210622-003		22/06/2021 02:31 PP	Normal Saline		Sílica gel			1143		24	0	96,384 %	Pass	
			Metanol		3MM	Whatman		35		2209	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-20210622-004	22/06/2021	02:44	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			2656 1		34 3652	0	pH (Low/Actual/High)	98,709 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-005	22/06/2021	03:00	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1188 14		20 2628	0	pH (Low/Actual/High)	97,814 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-006	22/06/2021	03:01	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1747 48		45 1891	0	pH (Low/Actual/High)	95,013 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-008	22/06/2021	03:28	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1717 68		20 4110	0	pH (Low/Actual/High)	97,221 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-017	22/06/2021	04:03	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1369 15		18 1376	0	pH (Low/Actual/High)	97,624 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-019	22/06/2021	07:02	JS	Normal Saline Metanol	Sílica gel 3MM Whatman			1123 2		17 1010	0	pH (Low/Actual/High)	98,311 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-020	22/06/2021	07:18	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1320 33		22 1017	0	pH (Low/Actual/High)	95,218 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-021	22/06/2021	07:19	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1345 22		61 1680	0	pH (Low/Actual/High)	94,369 %	Pass
Límpido/Incolor														
MIBI-99mTc Lot # K-20210622-038	22/06/2021	10:04	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			878 2		20 1208	0	pH (Low/Actual/High)	97,608 %	Pass
Límpido/Incolor														
PIRO-99mTc Lot # K-20210622-023	22/06/2021	07:27	WG	Butanona Normal Saline	3MM Whatman 3MM Whatman			626 3		1,5 492	0	pH (Low/Actual/High)	99,155 %	Pass
Límpido/Incolor														
PSMA-68Ga Lot # K-20210622-036	22/06/2021	09:49	JS	Acetato de amônio	Sílica gel			0,5		33,1	0	pH (Low/Actual/High)	98,512 %	Pass
Límpido e Incolor														
Tecnécio-99m Lot # E-20210622-001	22/06/2021	01:47	PP	Butanona	3MM Whatman			52		5123	0	pH (Low/Actual/High)	98,995 %	Pass
Límpido e Incolor														
Tecnécio-99m Lot # E-20210622-003	22/06/2021	02:26	PP	Butanona	3MM Whatman			21		4663	0	pH (Low/Actual/High)	99,552 %	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
Tecnício-99m Lot # E-20210622-002		22/06/2021 02:26	PP	Butanona		3MM Whatman		10		4891	0	99,796 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-004		22/06/2021 02:55	PP	Butanona		3MM Whatman		14		1693	0	99,18 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-005		22/06/2021 03:26	PP	Butanona		3MM Whatman		8		820	0	99,034 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-006		22/06/2021 03:45	PP	Butanona		3MM Whatman		65		1284	0	95,182 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-008		22/06/2021 06:54	JS	Butanona		3MM Whatman		1		3740	0	99,973 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-009		22/06/2021 07:11	JS	Butanona		3MM Whatman		40		2882	0	98,631 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-010		22/06/2021 07:22	JS	Butanona		3MM Whatman		4		1510	0	99,736 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-011		22/06/2021 07:38	WG	Butanona		3MM Whatman		72		2622	0	97,327 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-013		22/06/2021 08:04	WG	Butanona		3MM Whatman		12		322	0	96,407 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-017		22/06/2021 09:58	JS	Butanona		3MM Whatman		2		1087	0	99,816 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-018		22/06/2021 10:02	JS	Butanona		3MM Whatman		1		2740	0	99,964 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnício-99m Lot # E-20210622-019		22/06/2021 10:19	JS	Butanona		3MM Whatman		18		1644	0	98,917 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
TRODAT-99mTc Lot # K-20210622-045		22/06/2021 10:38	JS	Normal Saline		Sílica gel		23,6		0,3	0	98,162 %	Pass	
				Butanona		3MM Whatman		0,5		85,3	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
							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
TRODAT-99mTc Lot # K-20210622-046		22/06/2021 10:40	JS	Normal Saline Butanona	Sílica gel 3MM Whatman			29,3 1,5		1 25,6	0	pH (Low/Actual/High)	91,165 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210622-047		22/06/2021 10:41	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			79,6 0,8		3 55,7	0	pH (Low/Actual/High)	94,952 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210622-048		22/06/2021 10:42	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			112,8 1		9 77	0	pH (Low/Actual/High)	91,329 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210622-049		22/06/2021 10:43	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			92,7 4		1,8 67,9	0	pH (Low/Actual/High)	92,532 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210622-050		22/06/2021 10:44	WG	Normal Saline Butanona	Sílica gel 3MM Whatman			89,8 4		1,7 137,9	0	pH (Low/Actual/High)	95,323 %	Pass
														6,50 <= 7,00 <= 8,50
														Límpido/Incolor