



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 07/09/2021 To 07/09/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210907-009		07/09/2021	04:02	FN	Butanona Normal Saline	3MM Whatman Sílica gel	189 3		11 326	0	pH (Low/Actual/High)	93,588 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210907-010		07/09/2021	04:03	FN	Butanona Normal Saline	3MM Whatman Sílica gel	184,5 10,2		1,5 174,8	0	pH (Low/Actual/High)	93,68 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210907-016		07/09/2021	07:30	FN	Butanona Normal Saline	3MM Whatman Sílica gel	159,3 10,2		0,4 139,7	0	pH (Low/Actual/High)	92,945 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210907-017		07/09/2021	07:31	FN	Butanona Normal Saline	3MM Whatman Sílica gel	137,3 12		1,3 200	0	pH (Low/Actual/High)	93,402 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210907-014		07/09/2021	07:04	BB	Citrato de Sódio 0,1M	Sílica gel	6,2		0,1	0	pH (Low/Actual/High)	98,413 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210907-020		07/09/2021	07:51	BB	Citrato de Sódio 0,1M	Sílica gel	8,9		0,2	0	pH (Low/Actual/High)	97,802 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210907-026		07/09/2021	13:08	BB	Citrato de Sódio 0,1M	Sílica gel	8,9		0,1	0	pH (Low/Actual/High)	98,889 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210907-006	RPH	07/09/2021	03:18	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	541 15		2 593	0	pH (Low/Actual/High)	97,165 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210907-015	RPH	07/09/2021	07:06	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	814 25		24 822	0	pH (Low/Actual/High)	94,184 %	Pass 3,80 <= 5,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210907-005		07/09/2021	03:11	FN	Butanona	3MM Whatman	242		10	0	pH (Low/Actual/High)	96,032 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210907-013		07/09/2021	06:37	FN	Butanona	3MM Whatman	588		6	0	pH (Low/Actual/High)	98,99 %	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
MAA-99mTc Lot # K-20210907-007		07/09/2021 03:47 FN	Butanona		3MM	Whatman		185		3	0	98,404 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210907-008		07/09/2021 03:51 FN	Butanona		3MM	Whatman		190		4	0	97,938 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210907-018		07/09/2021 07:37 FN	Butanona		3MM	Whatman		290		2	0	99,315 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210907-021		07/09/2021 09:27 PP	Butanona		3MM	Whatman		282		5	0	98,258 %	Pass	
							Turvo/Incolor				pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MDP-99mTc Lot # K-20210907-003		07/09/2021 03:05 FN	Acetona		3MM	Whatman		1072		3	0	99,52 %	Pass	
			Normal Saline		3MM	Whatman		3		1491	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210907-004		07/09/2021 03:08 FN	Acetona		3MM	Whatman		1387		5	0	99,217 %	Pass	
			Normal Saline		3MM	Whatman		6		1410	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210907-012		07/09/2021 06:27 FN	Acetona		3MM	Whatman		1480		5	0	98,384 %	Pass	
			Normal Saline		3MM	Whatman		17		1312	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MDP-99mTc Lot # K-20210907-019		07/09/2021 07:45 FN	Acetona		3MM	Whatman		449		1	0	99,19 %	Pass	
			Normal Saline		3MM	Whatman		3		507	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210907-001		07/09/2021 03:01 FN	Normal Saline		Sílica gel			287		5	0	97,414 %	Pass	
			Metanol		3MM	Whatman		2		227	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210907-002		07/09/2021 03:03 FN	Normal Saline		Sílica gel			1512		18	0	98,53 %	Pass	
			Metanol		3MM	Whatman		5		1699	pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210907-011		07/09/2021 06:25 FN	Normal Saline		Sílica gel			204		2	0	98,612 %	Pass	
			Metanol		3MM	Whatman		1		239	pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
							Límpido/Incolor							
PSMA-68Ga Lot # K-20210907-022		07/09/2021 09:59 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,2		7,5	0	97,403 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
PSMA-68Ga Lot # K-20210907-025		07/09/2021 10:42 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,2		6,9	0	97,183 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	

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-20210907-001		07/09/2021 02:57 FN	Butanona		3MM Whatman			10		1453	0		99,316 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-002		07/09/2021 02:58 FN	Butanona		3MM Whatman			4		273	0		98,556 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-003		07/09/2021 03:15 FN	Butanona		3MM Whatman			1		448	0		99,777 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-004		07/09/2021 06:23 FN	Butanona		3MM Whatman			3		360	0		99,174 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-005		07/09/2021 07:03 FN	Butanona		3MM Whatman			4		1883	0		99,788 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-008		07/09/2021 09:24 PP	Butanona		3MM Whatman			54		1515	0		96,558 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-009		07/09/2021 09:29 PP	Butanona		3MM Whatman			3		640	0		99,533 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-010		07/09/2021 09:30 PP	Butanona		3MM Whatman			5		694	0		99,285 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-011		07/09/2021 09:30 PP	Butanona		3MM Whatman			4		865	0		99,54 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210907-012		07/09/2021 09:55 PP	Butanona		3MM Whatman			41		4641	0		99,124 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00	
												Límpido e Incolor		
TRODAT-99mTc Lot # K-20210907-023		07/09/2021 10:01 PP	Normal Saline		Sílica gel			247		4	0		92,692 %	Pass
			Butanona		3MM Whatman			10		165			pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50
												Límpido/Incolor		
TRODAT-99mTc Lot # K-20210907-024		07/09/2021 10:04 PP	Normal Saline		Sílica gel			275		7	0		95,693 %	Pass
			Butanona		3MM Whatman			5		269			pH (Low/Actual/High)	6,50 <= 7,00 <= 8,50
												Límpido/Incolor		