SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MON.TEK $^{99}Mo/^{99m}Tc$ GENERATOR, 5-50 GBq radionuclide generator

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
Mother nuclide:
Sodium Molibdate ($Na^{99}MoO_4$) 5-50 GBq / Generator
(Mo-99 radioactivity at calibration date)

Daughter nuclide:
^{99m} Technetium sodium pertechnetate ($Na\ ^{99m}Tc\ O_4$)
(Obtained from $^{99}Mo/^{99m}$ Tc generator system.)

Excipients:
Sodium chloride: 9 mg/mL
Sodium hydroxide: q.s. to adjust pH.

See section 6.1 for a full list of excipients

3. PHARMACEUTICAL FORM

Radionuclide generator.
Clear, colorless solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium pertechnetate (^{99m}Tc) solution is used only for diagnostic purposes.
The eluate from the generator (Sodium Pertechnetate ^{99m}Tc) may be used as a reagent for labelling of various carrier compounds supplied as kits or administered directly *in-vivo.*

When administered intravenously, the sterile sodium pertechnetate (^{99m}Tc) solution is used as a diagnostic purpose in the following:
- Thyroid scintigraphy
- Salivary gland scintigraphy
- Ectopic gastric mucosa localisation

- Cerebral scintigraphy
- Cardiac and vascular scintigraphy
- Lachrymal duct scintigraphy
- Gastrointestinal bleeding scintigraphy
- Artroscintigraphy
- Organ perfusion scintigraphy

4.2 Posology and method of administration
RADIOPHARMACEUTICALS SHOULD BE ADMINISTERED ONLY BY NUCLEAR MEDICINE PHYSICIANS IN NUCLEAR MEDICINE CENTERS.

Posology and administration method
Sodium pertechnetate (^{99m}Tc) is administered to the patient by dropping into eye and injection into articulation or intravenously at different radioactivity levels required by the clinic pre-diagnosis and the specifications of device used. Pre-treatment of patients with thyroid blocking agents or reducing agents may be necessary for certain indications.

Dosage: The average dosages recommended for the main applications on adults and old patients are given below:

- Thyroid scintigraphy: 18.5-80 MBq (0.5 -2.16 mCi)
- Salivary gland scintigraphy: 37-185 MBq (1-5 mCi)
- Ectopic gastric mucosa localization: 400 MBq (10.8 mCi)
- Cerebral scintigraphy: 370-740 MBq (10-20 mCi)
- Cardiac and vascular scintigraphy: 740 - 925 MBq (20- 25 mCi)
- Lachrymal duct scintigraphy: 2-4 MBq (0.05-0.11mCi) for each eye
- Gastrointestinal bleeding scintigraphy: 740-925 MBq (20-25 mCi)
- Artroscintigraphy: 74-370 MBq(2-10) mCi
- Organ perfusion scintigraphy: 518-777 MBq (14-21 mCi)

Additional information on special populations

Renal/hepatic impairment
There is not safety and efficiency studies on patients with renal and liver failure.

Paediatric Population
The dosage to be administered to children is less than the dosage administered to adults and it is calculated by using the following formula:

$$\text{Pediatric dosage} = \frac{\text{Adult dose x Weight of child (kg)}}{70\ \text{kg}}$$

Furthermore, the dose for children is calculated by EANM as a fraction of adult dose and it is informed by EU. According to these references, ^{99m}Tc-Pertechnetate activity dosage to be applied to children can be calculated easily.

Table 1: Table showing the fractions of adult dosage to be used for the dosages that will be calculated for children

3 Kg	=	0.1	22 Kg	=	0.50	42 Kg	=	0.78
4 Kg	=	0.14	24 Kg	=	0.53	44 Kg	=	0.80
6 Kg	=	0.19	26 Kg	=	0.56	46 Kg	=	0.82
8 Kg	=	0.23	28 Kg	=	0.58	48 Kg	=	0.85
10 Kg	=	0.27	30 Kg	=	0.62	50 Kg	=	0.88
12 Kg	=	0.32	32 Kg	=	0.65	52-54 Kg	=	0.90
14 Kg	=	0.36	34 Kg	=	0.68	56-58 Kg	=	0.92
16 Kg	=	0.40	36 Kg	=	0.71	60-62 Kg	=	0.96
18 Kg	=	0.44	38 Kg	=	0.73	64-66 Kg	=	0.98
20 Kg	=	0.46	40 Kg	=	0.76	68 Kg	=	0.99

(Pediatric Task Group, EANM)

Minimum activity dosages used for children are 10 MBq for thyroid scintigraphy, 80 MBq for blood pool, and 20 MBq for direct cystography.

Geriatric population
The adult dosage is applied.

4.3 Contraindications
It is contraindicated in the patients who have hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use
RADIOPHARMACEUTICALS SHOULD BE ADMINISTERED ONLY BY NUCLEAR MEDICINE PHYSICIANS IN NUCLEAR MEDICINE CENTERS.

Sodium pertechnetate solution that is derived from MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is radioactive. Therefore, vial containing the solution must be kept in a suitable lead shield.

Adrenaline, antihistamines and corticosteroids must be kept available against potential allergic reactions in the course of application of product to the patient.

Patient dose preparation and application must be performed using aseptic techniques.

Adequate shield must be available to avoid unnecessary radiation exposure to patients, staff and other people.

Each mL of sodium pertechnetate solution that is derived from MON.TEK 99Mo / 99mTc GENERATOR contains sodium that is less than 1 mmol (23 mg); in other words, “it does not actually contain sodium”.

4.5 Interaction with other medicinal products and other forms of interaction
In abdominal imaging, atropine, isoprenaline and analgesic effective drugs may cause delay in gastric discharge and re-circulation of pertechnetate

Sodium pertechnetate does not indicate any interaction with any food and beverage.

4.6 Pregnancy and lactation

General recommendation
Pregnancy category: C

Women of childbearing potential / Contraception
Effect of ^{99m}Tc-sodium pertechnetate on fertility ability is unknown.

When it is necessary to apply the radioactive product on women that have the potential of being pregnant, it should definitely be inquired whether she is pregnant or not. Awoman who has missed a menstruation period should be assumed to be pregnant unless otherwise evidenced. Application of ionizing radiation on pregnant women brings radiation dosages to fetus as well. Therefore, the minimum dosage required for optimum imaging should be applied where necessary.

Application of 800 MBq (^{99m}Tc) sodium pertechnetate results in the absorbed radiation dosage of 6.5 mGy.

Therefore, it should be investigated through whether the patient is pregnant or not and risk assessment should be made before application.

The examinations on the women at fertility age should be performed within 10 days following menstruation.

Pregnancy
The studies conducted to animals are insufficient in terms of effects on pregnancy/ and-or/ embryonic/ fetal growth/ and-or/ natal/ and-or/ post-natal growth. (See section 5.3) Risk for humans is not known.

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR should not be applied in pregnancy (except for the cases where the benefits to be provided in the event of application may cover the potential damage to arise).

Lactation
^{99m}Tc pertechnetate is discharged through the mother milk.
Therefore, if MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is to be applied on women at lactation, the lactation should be stopped and the milk should be discharged. Breasting should be resumed only when the radiation dosage in the mother milk is below 1 mSv.

Fertility
Effect of sodium pertechnetate on fertility ability is unknown. Therefore, if it is necessary to apply ^{99m}Tc pertechnetate, it is very important that the radiation dose to be administered to get the clinical data is minimum (ALARA principle).

Following direct administration of 800 MBq sodium pertechnetate (^{99m}Tc) on patient, the dose absorbed at uterus is 6.5 mGy. If blocking drugs are administered to the patient prior to application, the dosage absorbed at uterus as a result of application of 800 MBq sodium pertechnetate is 5.3 mGy. As a result of labelling the red blood cells with 925 MBq ^{99m}Tc, the dose absorbed at uterus is 4.3 mGy. Over the dose of 0.5 mGy is assumed as potential risk for fetus. If it is necessary to apply ^{99m}Tc pertechnetate, information must be obtained about the pregnancy of patient before administration.

4.7 Effects on ability to drive and use machines
Sodium pertechnetate administration has no adverse effect on driving and using machines.

4.8 Undesirable effects
Undesired effects are listed according to the following level of frequency:
Very common (≥1/10); common (≥1/100 to <1/10) ; uncommon (≥1/1000 to ≤1/100) ; rare (≥1/10.000 to ≤1/1000) ; very rare (≤1/10.000); unknown.

The adverse effects reported following application of sodium pertechnetate (^{99m}Tc) intravenously are listed below though the level of frequency is not known:

Nervous system diseases
Unknown: Coma

Cardiac diseases
Unknown: Cardiac arrhythmia

Vascular diseases
Unknown: Vasodilatation

Dermal and subdermal diseases
Unknown: Urticaria, edema on face, irritation

As in all radiopharmaceuticals, it should be administered to the patient if the benefit of application of sodium pertechnetate (^{99m}Tc) is more than the risk of ionizing radiation. In this case, the minimum dose to protect against radiation and to get the optimum result should be applied.

Exposure to ionizing radiation may trigger cancer or may lead to hereditary disorders. These adverse effects may arise with the low dosage used for nuclear medicine researches and little application.

The dosage used in nuclear medicine researches for diagnosis purpose is less than 20 mSv. It may be applied at higher doses depending on the clinic conditions.

4.9 Overdose
No overdose event has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Diagnostic Radiopharmaceuticals
ATC Code: V09FX01

No pharmacodynamic effect is expected when applied at normal dosage limits.

5.2 Pharmacokinetic characteristics

General properties
Pertechnetate ion has similar biological dispersion characteristics with iodine and perchlorate ions. It is retained temporarily at salivary glands, choroid plexus, stomach (gastric mucosa), thyroid gland and is released from these points without any change.
The brain examinations reveal that, following injection, the pertechnetate ion shows the tendency of concentration on the areas where vascularization increases or where there is abnormal vascular permeability. ^{99m}Tc is discharged through brain spinal liquid selectively.

<u>Absorption</u>
Technetium pertechnetate is bound with transferrin protein in blood after intravenous application. This bound form accumulates in thyroid, salivary glands, stomach and kidneys. In thyroid gland, technetium pertechnetate is not bound with organic compounds such as thyroid hormones and their precursors. Its retention decreases in the cases of cyst, inflammation, bleeding, benign and malign tumors in thyroid (cold areas) in comparison with the normal thyroid activity. On the other hand, the rate of retention at thyroid gland in hyperthyroid

cases such as autonomous adenoma increases. Retention of technetium pertechnetate in the salivary gland occurs through active transport by bounding with transferrin. While accumulation increases in acute sialadenitis, it decreases in chronic sialadenitis.

Distribution

Dispersion of technetium ions is same with iodine and perchlorate ions.

Technetium is localized at relatively high quantity in salivary glands, thyroid glands, stomach, liver and bladder. It is retained for a longer time in the colon. Though specific activity of technetium is high in the nasal secretion, there is no accumulation in eye drops and sweat glands. Technetium is localized in bladder 10 minutes following injection. It is observed in all tissues and organs apart from brain independently from the way of administration 2 hours following injection or oral administration.

Biotransformation

Technetium is discharged directly from the body without noticeable metabolisation.

Elimination

It is removed with feces more lately than the rapid urinal way following oral or intravenous application. According to the results from the studies, the technetium is removed from the body with a 3-phase exponential curve. In this first phase, the rapid discharge of technetium in the first three days, and removal of longer half-life compounds in 2 and 10 days occurs in the following phases. 0.06% of dosage applied per day is removed through urine on 28^{th} day following administration of technetium.

Linearity/ Non-Linear Case

Effect of Technetium^{99m} does not have a linear relation with dosage.

5.3 Preclinical safety data

Half-life of ^{99m}Tc radionuclide is 6 hours. This relatively rapid destruction ensures safe use of drug. The patient and around the patient is exposed to short term radiation. ^{99m}Tc is non-carrier.

There is no information about acute, sub-acute and chronic toxicity at single dosage or repeated dosages. The quantity of ^{99m}Tc sodium pertechnetate to be applied for diagnostic purpose is very low and any adverse reaction apart from allergic reactions has not been reported.

Fertility Toxicity

Penetration of sodium pertechnetate to placenta following intravenous application has been studied on rats. If perchlorate is not applied before the application, more than 60% of the dosage of ^{99m}Tc applied in pregnancy is found in uterus. The studies have been completed during pregnancy of the pregnant rats and change in weight of offspring during pregnancy and lactation and only during lactation and falling hair and change in sterility have been observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients used in Generator:
Aluminum oxide
Molibdene trioxide
0.9 % Sodium chloride solution
Sodium hydroxide
Hydrochloric acid
Hydrogen peroxide

6.2 Incompatibilities

^{99m}Tc is incompatible with both degrading and upgrading agents. Presence of upgrading agents may decrease the labelling efficiency of in vivo kits. Presence of degrading agents may lead to retention of molibdenum in colon and accordingly decrease in ^{99m}Tc activity.
Contact of colons with strong acids or bases should be avoided as eluate causes molibdenum and aluminum impurities.

6.3 Shelf life

The shelf life for generator is 21 days following the date of production and 15 days following the date of calibration.

^{99m}Tc sodium pertechnetate solution is suitable for use for 12 hours as from the date and time of labeling.

The shelf life after labelling with the kit should be determined according to the shorter one by taking the shelf life of labelling product into account.

6.4 Special precautions for storage

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR must be stored at room temperature below 25 ºC in the original package and lead shield and must not be frozen.

Eluate derived elution must be stored at room temperature below 25 °C.

6.5 Nature and content of container

Packaging structure Generator is placed inside lead shiled covered by plastic outer container, and then supported with sytropor filling materials and placed within tin box, and closed and sealed. There must be the product labels as well as the labels indicating the Transportation Index and the labels for identification of international radioactive agents.

Content of a generator set:
One $^{99}Mo/^{99m}Tc$ radionuclide generator in a special packaging,
10 no's of l0 ml or 5 ml sterile %0.9 NaCl solution in cardboard box packages,
10 no's of sterile vacuumed vial inside the cardboard box,
10 no's of technetium pertechnetate solution (^{99m}Tc) vial label,
10 no's of lead shield label,
10 no's of 70% isopropyl alcohol tissues,
1 no of Package Leaflet and Product Information Manual.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product
Since generator and used vacuumed vials have radioactive characteristics, any unused product or waste material should be disposed of in accordance with local requirements for radioactive material.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

223/48

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

Date of first authorisation: 05. 02 2010
Date of last renewal:-

10. DATE OF REVISION OF THE TEXT

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11. DOSIMETRY

Table 2: Calculated radiation dose equivalents (mSv/MBq)

Organ	**New born**	**Child**				**Adult**
		1 year	**5 years**	**10 years**	**15 years**	
Large intestine wall	0.41	0.17	0.089	0.056	0.034	0.027
Small intestine	0.068	0.035	0.021	0.014	0.010	0.0082
Stomach wall	0.20	0.069	0.037	0.023	0.016	0.013
Upper large intestine wall	0.43	0.18	0.095	0.060	0.036	0.028
Ovary	0.068	0.034	0.021	0.014	0.011	0.0086
Bone surface	0.044	0.021	0.012	0.0081	0.0057	0.0048
Red marrow	0.029	0.014	0.0082	0.0057	0.0040	0.0033
Testicles	0.031	0.014	0.0086	0.0054	0.0043	0.0032
Thyroid	0.32	0.23	0.12	0.056	0.037	0.023
Bladder wall	0.12	0.051	0.048	0.032	0.046	0.036
Effective dose equivalent	0.11	0.051	0.029	0.018	0.014	0.011

Ref: *Radiation Internal Dose Information Center*

Table 3: Molibden - 99 Degradation Table
Half-life- 66 hours

t(hour)	0	1	2	3	4	5	6	7	8	9
0	1.0000	0.9896	0.9792	0.9690	0.9589	0.9488	0.9389	0.9291	0.9194	0.9098
10	0.9003	0.8909	0.8816	0.8724	0.8633	0.8542	0.8453	0.8365	0.8278	0.8191
20	0.8105	0.8021	0.7937	0.7854	0.7772	0.7691	0.7610	0.7531	0.7452	0.7374
30	0.7297	0.7221	0.7146	0.7071	0.6997	0.6924	0.6852	0.6780	0.6709	0.6639
40	0.6570	0.6501	0.6433	0.6366	0.6300	0.6234	0.6169	0.6104	0.6040	0.5977
50	0.5915	0.5853	0.5792	0.5731	0.5672	0.5612	0.5554	0.5496	0.5438	0.5381
60	0.5325	0.5270	0.5215	0.5160	0.5106	0.5053	0.5000	0.4948	0.4896	0.4845
70	0.4794	0.4744	0.4695	0.4646	0.4597	0.4549	0.4502	0.4454	0.4408	0.4362
80	0.4316	0.4271	0.4227	0.4182	0.4139	0.4096	0.4053	0.4010	0.3968	0.3927
90	0.3886	0.3845	0.3805	0.3765	0.3726	0.3687	0.3649	0.3611	0.3573	0.3536
100	0.3499	0.3462	0.3426	0.3390	0.3355	0.3320	0.3285	0.3251	0.3217	0.3183

Table 4: Technetium-99m Degradation Table

Half-life- 6.007 hours

Hour	Minute 0	6	12	18	24	30	36	42	48	54
0	1.0000	0.9885	0.9772	0.9660	0.9549	0.9439	0.9331	0.9224	0.9118	0.9014
1	0.8910	0.8808	0.8707	0.8607	0.8508	0.8411	0.8314	0.8219	0.8124	0.8031
2	0.7939	0.7848	0.7758	0.7669	0.7581	0.7494	0.7408	0.7323	0.7239	0.7156
3	0.7074	0.6993	0.6913	0.6833	0.6755	0.6677	0.6601	0.6525	0.6450	0.6376
4	0.6303	0.6231	0.6159	0.6089	0.6019	0.5950	0.5881	0.5814	0.5747	0.5681
5	0.5616	0.5552	0.5488	0.5425	0.5363	0.5301	0.5240	0.5180	0.5121	0.5062
6	0.5004	0.4947	0.4890	0.4834	0.4778	0.4723	0.4669	0.4616	0.4563	0.4510
7	0.4459	0.4408	0.4357	0.4307	0.4258	0.4209	0.4160	0.4113	0.4066	0.4019
8	0.3973	0.3927	0.3882	0.3838	0.3794	0.3750	0.3707	0.3664	0.3622	0.3581
9	0.3540	0.3499	0.3459	0.3419	0.3380	0.3341	0.3303	0.3265	0.3228	0.3191
10	0.3154	0.3118	0.3882	0.3047	0.3012	0.2977	0.2943	0.2909	0.2876	0.2843
11	0.2810	0.2778	0.2746	0.2715	0.2684	0.2653	0.2622	0.2592	0.2562	0.2533
12	0.2504	0.2475	0.2447	0.2419	0.2391	0.2364	0.2337	0.2310	0.2283	0.2557

Table 5: ^{99m} Tc Activity Table

TABLE OF ACTIVITIES DERIVED FROM MON-TEK ^{99}Mo/^{99m}Tc GENERATORS

DAYS		MON.TEK 5		MON.TEK 10		MON.TEK 15		MON.TEK 20		MON.TEK 25		MON.TEK 30		MON.TEK 35		MON.TEK 40		MON.TEK 50	
		mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq
-6	Friday	543	20.091	1.079	39.923	1.631	60.347	2.183	80.771	2.734	101.158	3.286	121.582	3.838	142.006	4.390	162.430	5.521	204.277
-5	Saturday	418	15.466	831	30.747	1.256	46.472	1.680	62.160	2.105	77.885	2.530	93.610	2.955	109.335	3.380	125.060	4251	157.287
-4	Sunday	322	11.914	640	23.680	967	35.779	1.294	47.878	1.621	59.977	1.948	72.076	2.275	84.175	2.602	96.274	3273	121.101
-3	Monday	248	9.176	492	18.204	744	27.528	996	36.852	1.248	46.176	1.500	55.500	1.752	64.824	2.004	74.148	2520	93.240
-2	Tuesday	191	7.067	379	14.023	573	21.201	767	28.379	961	35.557	1.155	42.735	1.349	49.913	1.543	57.091	1940	71.780
-1	Wednesday	147	5.439	292	10.804	441	16.317	590	21.830	740	27.380	889	32.893	1.038	38.406	1.188	43.956	1494	55.278
0	**Thursday**	**113**	**4.181**	**225**	**8.325**	**340**	**12.580**	**455**	**16.835**	**570**	**21.090**	**685**	**25.345**	**800**	**29.600**	**915**	**33.855**	**1150**	42.550
+1	Friday	87	3.219	173	6.401	261	9.657	350	12.950	438	16.206	527	19.499	616	22.792	704	26.048	886	32.782
+2	Saturday	67	2.479	133	4.921	201	7.437	269	9.953	337	12.469	406	15.022	474	17.538	542	20.054	682	25.234
+3	Sunday	52	1.924	102	3.774	155	5.735	207	7.659	260	9.620	312	11.544	365	13.505	417	15.429	525	19.425
+4	Monday	40	1.480	79	2.923	119	4.403	159	5.883	200	7.400	240	8.880	281	10.397	321	11.877	404	14.948
+5	Tuesday	31	1.147	60	2.220	92	3.404	123	4.551	154	5.698	185	6.845	216	7.992	247	9.139	311	11.507
+6	Wednesday	24	888	46	1.702		2.590	94	3.478	118	4.366	142	5.254	166	6.142	190	7.030	240	8.880
+7	Thursday	18	666	36	1.332	54	1.998	73	2.701	91	3.367	109	4.033	128	4.736	146	5.402	185	6.845
+8	Friday	14	518	27	999	42	1.554	56	2.072	70	2.590	84	3.108	98	3.626	113	4.181	142	5.254
+9	Saturday	11	407	21	777	32	1.184	43	1.591	54	1.998	65	2.405	76	2.812	87	3.219	109	4.033
+10	Sunday	8	296	16	592	24	888	33	1.221	41	1.517	50	1.850	58	2.146	67	2.479	84	3.108
+11	Monday	6	222	12	444	19	703	25	925	32	1.184	38	1.406	45	1.665	51	1.887	65	2.405
+12	Tuesday	5	185	9	333	14	518	19	703	24	888	29	1.073	34	1.258	39	1.443	50	1.850
+13	Wednesday	4	148	7	259	11	407	15	555	19	703	22	814	26	962	30	1.110	38	1.406
+14	Thursday	3	111	5	185	8	296	11	407	14	518	17	629	20	740	23	851	29	1.073
+15	Friday	2	74	4	148	6	222	9	333	11	407	13	481	15	555	18	666	22	814

* Given activities are the eluted activity at 08.00 a.m. eluting minimum 5 cc NaCl solution from the generator which has not been eluted last 24 hours.

** The activities to be obtained are between 90 – 110% of the quantity of activities provided.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

MON.TEK $^{99}Mo/^{99m}Tc$ GENERATOR can be eluted at any time, however the quantity of ^{99m}Tc obtained from eluate depends on the time between the last elution and the first elution.

^{99m}Tc sodium pertechnetate eluate obtained after elution must be stored in lead shield. At these conditions, the eluate is suitable for use for 12 hours at the temperatures below 25 ^{o}C as from the date and time of elution. Any unused product or waste material should be disposed of in accordance with local requirements for radioactive material.

MON.TEK $^{99}Mo/^{99m}Tc$ GENERATOR Use (Elution) Instruction:

Please perform the elution procedure as described below to obtain sterile and isotonic ^{99m}Tc pertechnetate solution from generator. The generator elution process is illustrated in Figure 1 as a guide for the elution processes.

- The vials containing MON.TEK $^{99}Mo/^{99m}Tc$ GENERATOR and %0.9NaCl and the vacuum vials are prepared under aseptic conditions and the pertechnetate solution that you will get is sterile, non-pyrogenic and isotonic.
- Observe the aseptic working rules during elution process for safety of product and your safety.
- Put on mask and sterile disposable gloves before starting the process.
- Place MON.TEK $^{99}Mo/^{99m}Tc$ GENERATOR behind the lead shiled inside LAF.
- Wipe the rubber plugs of the vacuum vials and 0.9% NaCl solution vials with 70% isopropyl alcohol.
- Place vacuumed vial in lead shield.
- Remove the cover of generator and remove the vials that protect the needles on white plastic.
- Place the 0.9% NaCl solution vials as shown on the vial (Figure 1, Position A).
- Place vacuumed vial with lead protective shield as shown in the figure (Figure 1, Position B).
- Elution from generator is realized after vacuumed vial is placed and pertechnetate solution is accumulated in vacuumed vial.
- Wait for 1-2 minutes before taking the vacuumed vial out after all 0.9% NaCl solution is finished.
- Place another vacuumed vial in Position B before moving the emptied 0.9% NaCl vial. Thus, the sterility of needle will be protected.
- Put the label containing the elution activity, solution volume and elution time on the lead shield.
- ^{99m}Tc sodium pertechnetate is taken from generator at appropriate quantity according to the process and administered to patients through venous injection and injection in articulation or dropping on eye and scintigraphy is performed.
- Patient dosage is calculated using the factors given Table 3 and Table 4 and radioactivity value is measured before application on patient.

- As in all preparations to be applied parentally, check the ^{99m}Tc sodium pertechnetate solution physically before application to patient. Do not apply discolored or particle containing solution to patient.

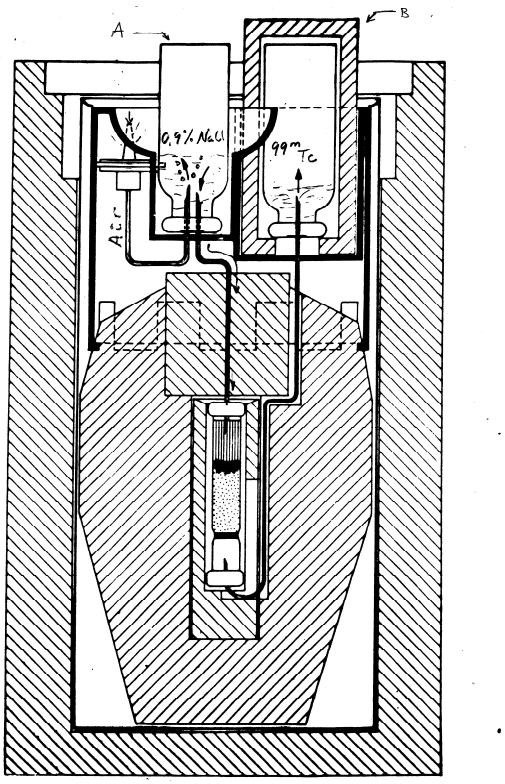

Figure 1: MON.TEK ^{99}Mo/^{99m}Tc GENERATOR elution diagram

General Characteristics
Production of ^{99m}Tc radionuclide is based on β degradation by radiating energy in the form of γ beam of molibden-99, which is the main radionuclide of it.
^{99}Mo/^{99m}Tc generator contains ^{99}Mo, fusion product that is adsorbed on aluminum oxide (Al_2O_3)
Half-life is 66 hours. The most important energy is the γ energy of 740 keV. With Beta (β) degradation, it transforms into ^{99m}Tc by 87.5%. ^{99m}Tc half-life used for Nuclear Medicine applications is 6 hours and energy is 140 keV.

Physical characteristics:
It degrades with (^{99m}Tc) isometric transition. It has the half-life of 6 hours. The main photon used in screening and imaging studies and its characteristics are given in Table 1.

Table 1.3.1-1 **6:** Basic radiation*

Radiation	**Degradation / % average**	**Average Energy (keV)**
Gama-2	89.07	140.5

*Kocher, David C., "Radioactive Decay Data Tables" DOE/TIC-11026, p. 108, (1981)

External Radiation:

Specific gama ray constant for ^{99m}Tc is 0.78 R/mCi/hour in 1 cm. The thickness of lead required to reduce the radiation value by half is 0.017 cm for the first half value. Various lead thicknesses for the attenuation degrees of rays are given in Table 2.

Table 1.3.1-2 **7:** Radiation reduced with lead shielding

Lead shield thickness (cm)	**Attenuation coefficient**
0.017	0.5
0.08	10-1
0.16	10-2
0.25	10-3
0.33	10-4

Molibden (^{99}Mo) has the half-life of 66 hours (2.75 days) and degrades to Technetium (^{99m}Tc). The physical decay characteristic of Molibden is in the form of transformation of only 87.5% of degraded ^{99}Mo atoms into Technetium (^{99m}Tc). Therefore, MON.TEK ^{99}Mo/^{99m}Tc GENERATOR can be eluted at any time, but the quantity of ^{99m}Tc obtained from eluate depends on the time between the last elution and the first elution.