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UPDATE ON OPERATIONAL EXPERIENCE OF ZIRCONIUM MOLYBDATE – ^{99}Mo GEL GENERATOR PRODUCTION IN INDIA

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ABSTRACT

A production facility for processing Zirconium Molybdate – ^{99}Mo (Zr^{99}Mo) generator was successfully commissioned in BRIT, India, in 2006 after successfully overcoming numerous technological challenges. The facility comprises of four shielded cells equipped with tongs and special process gadgets amenable for remote operations. To date, more than 100 batches of generators have been processed using upto 1040GBq ^{99}Mo per batch, with a maximum of 24 generators per batch, containing upto 44GBq ^{99}Mo. Marketed as the 'Geltech' generator, the generators have performed to provide ~75% ^{99m}Tc elution efficiency when eluted with 10ml saline. ^{99}Mo breakthrough was within the permissible limit. ^{99m}Tc based radiopharmaceuticals such as ^{99m}Tc-MDP, ^{99m}Tc -MIBI, ^{99m}Tc -EC, ^{99m}Tc -ECD, and ^{99m}Tc -DTPA have been prepared and used in patients yielding good quality images. Over 1000 generators have been supplied thus far and the eluted sodium pertechnetate has been used in over 25,000 patient investigations. The feasibility of collecting back and re-cycling of spent generators from the hospitals has been established which has helped BRIT to supply generators at a reasonable price and also avoid lead waste.

1.0 Introduction:

The development of column type ^{99m}Tc generator based on conversion of $(n,\gamma)^{99}$Mo as zirconium molybdate -^{99}Mo gel (Zr^{99}Mo, ZrO^{99}MoO$_4$.xH$_2$O) matrix and subsequent separation of ^{99m}Tc with normal saline elution is a unique and important development in the history of ^{99m}Tc generator system [**1-5**], as this combines the advantages of using $(n,\gamma)^{99}$Mo and a column based separation technique. In view of the important need for such column type and user-friendly generator system, particularly for developing nations having abundant production capability of $(n,\gamma)^{99}$Mo, considerable volume of work has been carried out in Board of Radiation and Isotope

Technology (BRIT) both independently and as a part of IAEA's CRP **[4,8-10]**for standardization of the process and applicability of such generators in hospital radiopharmacies have been well demonstrated.

After successful completion of feasibility studies and small scale production and supply of gel generator to local hospitals, a capital project, Tc-99m column generator production facility (TCGPF), was undertaken for large scale production and supply. Funds were sanctioned by Government of India for the project and a multidisciplinary core team comprising of scientist, technologist and engineers was constituted for execution and commissioning of the project. The project was a major R&D project since there was no precedence of such a facility for conversion of large quantities of highly radioactive solution into solid radioactive powder material and handling the radioactive powder for preparation of column generator for end user.

The preparation of zirconium molybdate gel generator involves various complex steps of precipitation, filtration, drying, disintegration, washing and finally obtaining $Zr^{99}Mo$ gel granules for column filling and all these steps have to be done remotely inside closed shielded plant facility

The setting up of a facility for safe, reliable operation and processing reproducible quality $Zr^{99}Mo$ gel powder material as a column source for ^{99m}Tc thus poses several challenges. The major technological and engineering challenges in the production facility were

a) Adaptation of lab scale radioactive chemical process involving multiple complex steps of mixing, precipitation, filtration, drying of residue, disintegration, further drying to obtain free flowing powder, transferring of product etc for automation.

b) Indigenous design, development and deployment of need based specific gadgets in operation

c) Erection of production facility with appropriate shielding and accommodating of different gadgets inside such a facility

d) Design of a compact, portable, easy to assemble and reusable generator assembly.

Concurrent to the development of $Zr^{99}Mo$ gel processing and addressing all the major challenges for large scale production technology development, a full-fledged lead-shielded production facility comprising 4 interconnected molybdenum processing cells (MPC-1 to MPC-4) has been erected and successfully commissioned in BRIT in the year 2006 **[11-16].** Formal review of the safety features was carried out by the national Atomic Energy Regulatory Board (AERB) and stage-wise clearance for handling upto 1110Gbq(30Ci) ^{99}Mo activity was obtained. Initial cold trials were followed by radioactive trials in which the ^{99}Mo activity were progressively increased from 14.8GBq (4Ci) to 37GBq (10Ci) and presently upto 1036GBq (28Ci) per batch, which was processed and supplied to the users. To date over 100 batches of geltech generators have been processed, with a maximum of 24 generators per batch, containing upto 44GBq (1.2Ci) ^{99}Mo (on production date, usually on Saturday) in 5-6 g $Zr^{99}Mo$ gel powder and supplied to user hospitals. Few numbers of higher capacity (jumbo) geltech generators containing 9-10g $Zr^{99}Mo$ gel powder (3-4gMo) were also prepared and supplied to the users. Whenever indigenously produced $(n,\gamma)^{99}Mo$ had low specific activity of ^{99}Mo [typically , 7.4- 14.8GBq (200-400mCi) /g of ^{99}Mo], it was spiked with fission produced ^{99}Mo (imported) so as to prepare generator of desired capacity to meet the demands of customers. One generator from each batch was kept for in-house quality control for complete evaluation of the generator performance and quality of pertechnetate. ^{99m}Tc activities obtained on the first day of use at the hospitals were in the range of ~11.1-25.9 GBq (300-700mCi) from the generator capacity of ~14.8 - 30GBq (400-800mCi) ^{99}Mo on calibration date (usually Monday), yielding ~75% ^{99m}Tc elution efficiency in 10ml saline. ^{99}Mo breakthrough was always less than the permissible limit. A wide variety of ^{99m}Tc based radiopharmaceuticals were prepared using ^{99m}Tc accessed from the geltech generator and good quality of images were reported by the users. Over 1000 'Geltech' generators have been supplied and the eluted pertechnetate has been used in approximately over 25,000 patient investigations. The unique, indigenous design of the generator assembly renders it practicable to recycle and reuse thus making it environment friendly and cost saving. Indigenous development of gel technology and unique generator development in India have paved the way for gaining international recognition. Technology transfer and sale of 'cold' geltech generator assembly sets and spare part sets to Kazakhstan was done through IAEA in 2008.

Another fruitful outcome of the approaches based on post-elution concentration was in establishing the feasibility of dual-purpose use of the secondary trap column of alumina for ^{99}Mo used in the $Zr^{99}Mo$ gel column generators [17-20]. The effective use of the alumina trap column for purification-cum-concentration of pertechnetate after eluting the gel column with de-ionized water widened the scope of utility of gel generator, even when faced with lower specific activities of ^{99}Mo.

The extensive work done with column type ^{99m}Tc generator based on zirconium molybdate - ^{99}Mo ($Zr^{99}Mo$) matrix and our experience on production and supplies from our Centre forms the basis of this paper.

2.0 Materials and Methods

All the chemicals used were from commercial sources and mostly of GR / AR grade. Aluminium oxide active acidic, 100-200 mesh, of Brockman grade 1, for chromatographic analysis, from Prabhat Chemicals, Mumbai was used. $(n,\gamma)^{99}Mo$ was available as sodium molybdate in 3.5M NaOH (150mg of Mo / ml , Concentration : 1.1-2.2GBq/ml, specific activity:7.4-14.8GBq/g of Mo) from Radiochemicals Section, Radiopharmaceuticals Division, BARC. Fission product ^{99}Mo (fission moly) suitable for preparing ^{99m}Tc for medical use was obtained from National Technology Products, A.E.C., South Africa, 111- 148GBq [3-4Ci] / ml in 0.2N NaOH containing oxidant NaOCl 2-4mg/Ci. The different types of glass columns, needles, rubber stopper used were procured locally.

Kits for ^{99m}Tc compounds were available ex-stock in-house. In a few instances, carrier molybdenum solution in 3.5M NaOH, 150mg Mo / ml was prepared and directly mixed with the required quantity of fission molybdenum in order to maintain the ^{99}Mo activity to the desired level. Different types of need based special gadgets required for large scale processing of gel powder were designed and fabricated in-house.

An ionization chamber (NPL, UK) pre-calibrated with ^{137}Cs and Atom lab dose calibrator were used for the assay of radioactivity. Colorimetric spot tests for Zr, Al, Mo were carried out as limit tests.

2.1 Preparation of $ZrO^{99}MoO_4.xH_2O$ gel

The preparation of $Zr^{99}Mo$ gel is a multiple **step** complex operation. It involves quantitative precipitation reaction of sodium molybdate-^{99}Mo ($Na_2{}^{99}MoO_4$) solution (150mg Mo/ml), obtained by dissolving 135g irradiated MoO_3 powder in 3.5M NaOH solution, and zirconium oxychloride in water ($ZrOCl_2.8H_2O$) in the stoichiometric mole ratio of Mo: Zr :: 1:1.25**[9-11].** The pH of the precipitate thus obtained was adjusted to 4-5 with 4N NaOH solution. Then rapid filtration of the gel-like precipitate, drying of gel cake, disintegration with normal saline and washing to remove fine gel particles, re-drying to free flowing gel granules and transferring into glass column for use in generator.

Various stages of $Zr^{99}Mo$ gel processing (2x20g Mo conversion to ~120- 130g gel) carried out in the production facility are described below.

1. **Pooling of sodium molybdate-^{99}Mo solution in MPC-1:**

Different gadgets installed in MPC-1 are described below

a) Device for unloading and pooling of sodium molybdate-^{99}Mo solution

A special device has been designed and installed for unloading and pooling of sodium molybdate-^{99}Mo solution (2x66 ml equivalent to 20gMo) received in 2x100ml glass vial. The transfer to the pooling vessel is carried out under suction without decapping the seal thus providing highest level of safety and avoiding spillage of contents. 20 ml of 4 M NaOH solution is also transferred in the same pooling vessel in the same manner.

b) **Unscrewing device for opening of imported (n,f)^{99}Mocontainer**

A devoted system has been made of simple mechanism, reliable, partially motorized having pneumatic gripper to hold cap & body for unscrewing the fission product ^{99}Mo polypropylene container.

c) Pantograph mounted pipette assembly with external suction device: This device has been designed by modifying the available tong in such a way that multiple operations such as extraction of radioactive liquid, dispensing of any other liquid as per measured quantity can be achieved manually with ease.

2.Processing of $Zr^{99}Mo$ gel powder in MPC-2:

MPC-2 and MPC-3 processing plants have been specifically designed to accommodate complex chemical processing gadgets and the system for processing active gel and powder handling. Plants have enough waste storage space, lighting, ventilation and tong type manipulator. 100 mm lead shielding has been provided all around the plants using interlocking type lead bricks. Both the cells are connected & trolley movement provided for inter-cell transport

a) **Mixing -cum -reaction vessel:** This vessel is made up of glass and mounted on a stand. It has temperature controller, electrically operated mixing device with variable speed and inlet & outlet pipe.

Measured quantity of zirconium oxychloride solution (1100 ml, Conc: 23mg Zr/ml) pre-heated to ~80^0C is transferred to the reaction vessel with the help of masterflex peristaltic pump. After transferring zirconium oxychloride solution, the sodium molybdate-^{99}Mo solution is added slowly with constant stirring to form the viscous gel-like $Zr^{99}Mo$ precipitate at pH 4-5 and mixing is continued for 5 minutes.

b) **Filtration of $Zr^{99}Mo$ gel precipitate**

The Filter assembly works in-principle like buchner funnel with polypropylene filter cloth as the filtering medium but it is specially designed to suit process & maintenance requirement. It has provision for easy replacement of polypropylene filter cloth. Viscous gel-like $Zr^{99}Mo$ precipitate is transferred into two filtering assemblies (F-1 & F-2) with the help of a peristaltic pump and masterflex tubing and rapid filtration is achieved using oil-free, moisture-free diaphragm type vacuum pump. The filter assembly can be rotated through 180° to discharge gel cake using compressed air. ~500g gel cake is obtained by filtering ~1.5 litre gel slurry in ~10minutes.

c) **Transferring of wet gel cake**

A special purpose pneumatic powered material handling system (PPMHS) has been designed & developed for collecting radioactive gel cake, in a specially designed cake collection dish with a butterfly type valve, sequentially from two different filter stations F-1 & 2. The system can move to different pre-programmed stations such as microwave drying station and IR drying station with three-dimensional controlled movement.

d) **Drying gel cake using microwave oven [7-8,12-14]**

A domestic microwave oven was made amenable for remote operations and conditions such as duration and intensity for gel cake drying were optimized to prevent structural damage of gel.

With the help of PPMHS gel cake is placed into microwave oven and drying is carried out under optimized condition. Under optimized conditions, it took ~50 minutes to dry 500g gel cake to lumps ready for fragmentation by disintegration**.**

e) **Transferring of dried gel cake for disintegration**

The dried gel cake is transferred from microwave oven to another filter (F-3) by operating butterfly valve. The dried cake is positioned under a spray shower arrangement for fragmentation of the lumps into granules with normal saline solution. The effluent is collected in a glass receiver bottle under suction.

f) **IR drying to obtain free flowing gel powder**

The PPMHS moves the product granules in F-3 to the IR drying station and the product is dried under an IR lamp (250W) under suction to convert to free flowing gel granules. Finally after IR drying, the dried gel powder was transferred into a beaker through a wide mouth glass funnel and the total quantity of gel powder was measured using an electronic balance. The powder was then transferred in a bottle and taken to MPC-3.

The entire operation from sodium molybdate solution to free flowing ZrMo granules takes about 3 hours wherein 20g Mo is converted to ~60 g ZrMo granules.

3.$Zr^{99}Mo$ gel powder handling in MPC-3 [13-16]:

Glass column filling with gel powder and sealing:

Free flowing gel powder needs to be dispensed in individual glass columns in desired quantity and sealed. This is done with special purpose machine (SPM) designed and indigenously developed at BRIT having a highly accurate angular indexer (5 min accuracy) for positioning into six specified station. Each station has SPMs to accomplish specific activities as follows.

a) Powder dispenser-It is a device specially designed to dispense 5-6 g of powder accurately (+2.5%) by remote operation.

b) Pick & place for sintered disc loading-This device has been designed for auto pickup & accurate placement of sintered disc over the radioactive powder.

c) Pick & place for rubber bung loading -This device has been designed for auto pickup of rubber bung and insertion into column mouth.

d) Pick & place for aluminum closure loading- This device has been designed for auto pickup of aluminum closure placement over rubber closure.

e) Column crimping machine –This is a crimping machine specially designed for crimping column remotely.

f) Column washing machine -This is a device is designed for washing of column bed with saline. It has a simple mechanical design with provision for easy replacement.

4.Transferring of sealed gel column for generator assembling in MPC-4:

~11 -12 columns are filled with 5-6 g of gel powder each, sealed and then transferred from MPC-3 to MPC-4 with the help of a tong. The columns were then dropped with the help of a tong to a pre-assembled generator assembly, one by one and final assembling was done outside MPC-4.

Liquid waste handling: 3-4 L of liquid waste was generated per 20 g Mo processed. It is a white turbid liquid and comprises of filtrate of gel precipitate, dried product disintegration with saline waste, column bed washing and process vessel and tubing rinsing. This was collected in glass bottles placed in MPC-2 and MPC-3 and transferred to a HDPE carboy (10L) kept in the bottom compartment of MPC-2, by gravity, through pneumatic drain valves operated from outside switches. When allowed to stand undisturbed, the product fine solids settle down at the bottom of the carboy. The bottom compartment of MPC-2 and MPC-3 where the carboys are placed is provided with 4'' lead shielding on the front and rear side.

The liquid waste was left undisturbed for 6 months to 1 year in the storage area below MPC-2 and MPC-3. After prolonged storage, aliquots from each batch were assayed to determine the radioactive concentration (Bq/ml), identify and quantify presence of long-lived radionuclide contaminants etc. Thereafter the carboys were transferred to Waste Management Division, BARC for appropriate handling prior to disposal.

Recycling of gel generator assemblies:

Generators were supplied to all hospitals under the condition that they would return the spent generators to BRIT after their use. The main radioactive gel glass column, needles, secondary alumina column etc are removed from generator assembly, stored and disposed off appropriately and non-consumable hardware parts of the generator are hygeinized and reused.

Prior to processing day, each generator is assembled completely in a Laminar Flow Bench, a dummy empty column and secondary alumina column are inserted in place. An elution check is carried out using dil. acid solution (pH3-4) and an evacuated vial to ensure the integrity of all connections. The dummy column is replaced with the column containing radioactive gel powder in MPC- 4 after the processing has been completed.

In-process quality control checks were carried out to verify smooth functioning of each generator. The practicability of recycling and repeated use of generator non-consumable hardware part has been demonstrated to satisfaction.

Evaluation of performance of ^{99m}Tc gel generator

The 'Geltech' generator performance was ascertained in terms of continuity of eluent flow,

pH, clarity of eluate, ^{99m}Tc elution yield and ^{99}Mo breakthrough. The quality of pertechnetate eluate was evaluated as per pharmacopoeial specifications. The pharmaceutical purity aspects of sterility and apyrogenicity were checked by carrying out conventional sterility and BET tests on decayed eluates. Technetium compounds were formulated using pre-tested ready to use standard Tc-cold kits and evaluated.

2.2 Post-elution concentration (PEC) of ^{99m}Tc [17-20]

The concentration of ^{99m}Tc is possible only when there is no other macroscopic anion present in the eluate. The primary Zr^{99}Mo gel column, which contain high concentration of chloride anions, was conditioned by washing with 200ml of 1:1 v/v 0.05M NH_4OAc: AcOH, pH~5 followed by 50ml of DIW to remove chloride anions. The column effluents were checked for absence of chloride. ^{99m}Tc eluted in 10ml DIW was passed through acidic alumina bed (2g, 35x8mm) to trap ^{99m}Tc along with traces of co-eluted molybdate-^{99}Mo. The pertechnetate retained on alumina column was selectively re-eluted with ~3ml of normal saline. Thus a 3-fold increase in RAC of ^{99m}Tc was achieved without compromising the quality of pertechnetate. Same alumina column was washed with 5ml DIW for repeated use for concentration of ^{99m}Tc.

3.0 Results and Discussion

Table-I presents the data of batch production of the gel generators in the first year of operation.

The gel yield, both in terms of gel mass and radioactivity of ^{99}Mo, showed reasonable consistency from batch to batch. Typically, 80% utilization of ^{99}Mo activity processed was easily feasible. The elutions performed after ½ to 1 hour growth, as the in- process QC tests were used to evaluate elution yield, breakthrough of ^{99}Mo and radiochemical purity of pertechnetate. This provided a satisfactory index for product release for further use. In all, about 7-8 hours were required for the completion of the entire batch. The flow chart for production of gel generator is shown in **Fig.-1.**It is seen that there is a variation in the yield of gel mass. This could be due to the variation of cake discharge from the filter causing uneven distribution of gel cake mass on cake collection dish and subsequent drying in the microwave oven.

Performance characteristics of ^{99m}Tc gel generator

Elutions were smooth, rapid and completed in about 2 min. Clear eluates of pH 5-6 were always observed. The consistent results of over 75% yield of ^{99}Tc^{m}, $<10^{-3}$% ^{99}Mo breakthrough, >96% RC purity of pertechnetate, less than 10 ppm of Mo, Zr and Al in eluates, compatibility for formulating even sensitive ^{99m}Tc compounds etc. indicated satisfactory quality of pertechnetate and good quality images were reported by different users.

It has been found feasible to convert 40g of Mo into 120-130g Zr^{99}Mo gel powder in two cycles of 20g per batch to prepare 20-24 gel generators containing 1.5-2g Mo in each generator in an 8-hour shift. Market studies revealed that generators of activity of a minimum of 15-18GBq ^{99}Mo on Monday would be required by most user hospitals. The specific activity of indigenous produced (n,γ)^{99}Mo was in the range of 7.4-14.8GBq/g of Mo , there was a need to spike with (n,f) ^{99}Mo for preparing clinically useful generators of 15 GBq^{99}Mo generator on Monday. In case of non-availability of (n,f) ^{99}Mo, gel generators of 9.25 GBq ^{99}Mo on Monday were prepared using (n,γ)^{99}Mo alone containing larger quantity gel bed (3-4g Mo)to sustain regular supply of generator. The current production rate is 55 generators per month.

The pH adjustment of gel cake drying is the most important parameter to be maintained for processing gel generator. Depending upon the pH, both the transitional metal forms multiple polymeric species in aqueous solutions and produce quantitative precipitate of $Zr^{99}Mo$ gel and subsequent drying give amorphous gel powder with varying water molecules **[10-11].**

PEC of ^{99m}Tc provides ~ 3-fold increase in RAC of ^{99m}Tc. This is found adequate for few radiopharmaceuticals, which require pertechnetate of moderate to high RAC (e.g. Tc-MDP for bone scanning, Tc-MIBI for myocardial perfusion studies) of ^{99m}Tc. The duration of this concentration process was ~3 minutes. Generators containing upto 17GBq ^{99}Mo in 5-6g $Zr^{99}Mo$ gel column were prepared and radioactive concentration of ^{99m}Tc upto 1.6GBq /ml was obtained on the first day of use (3- days post production) **[18].**

We have thus demonstrated the uninterrupted production and supply of 'Geltech' generator initially on fortnightly basis and thereafter weekly basis successfully. The adaptation of the simple concentration procedure of pertechnetate into zirconium molybdate-^{99}Mo gel generator is a novel outcome for a user-friendly, closed system operation at hospital end. A cost effective and environment-friendly initiative of recycling of spent generators has been demonstrated to satisfaction.

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Table-1: TYPICAL PRODUCTION DATA OF *Geltech* GENERATORS

	B. No	Date	Activity handled GBq [Ci]	(n, f) + (n, γ)	Mo (g)	Product Quantity (g)	Generators produced	Tc^{99m} activity on Monday GBq (mCi)
Jan	19	13th	370[10@]	10+0	10	31.6	5	14.6(396)
	20	27th	407[11@]	11+0	15	49.4	9	20.2(546)
Feb	21	13th	444[12@]	12+0	15	51.8	8	21(567)
	22	24th	499[13.5]	11.3+2.2	18	57.9	8	13.7(372)
Mar	23	10th	755[20.4]	16.6+3.8	20	51.5	9	19.4(525)
	24	24th	433[11.7@]	11.7+0	15	44.7	8	15(405)
Apr	25	7th	485[13.1@]	13.1+0	20	79.4	10	13.8(374)
	26	21st	625[16.9]	11.2+5.7	20	72.3	10	16(435)
May	27	5th	270 [7.3$]	0+7.3	20	64.2	4(Jumbo)	16.8(454)
	28	19th	688[18.6]	11.7+6.9	20	64.7	10	22.7(615)
June	29	2nd	681[18.4]	11.4+7.0	20	74.1	11	17(460)
	30	16th	692[18.7]	11.1+7.6	20	67	12	20.7(560)
July	31	1st	592[16]	8.7+7.3	20	60.4	11	17.5(473)
	32	14th	585[15.8]	11+4.8	17	55.3	10	23(620)
	33	28th	699[18.9]	11.5+7.4	20	62	11	25.5(664)
Aug	34	11th	589[14.3@]	14.3+0	18	54.8	10	19.8(536)
	35	25th	659[17.8]	11.1+6.7	20	67.9	12	19.2(521)
Sept	36	8th	784[21.2]	13.8+7.4	20	63.9	12	22.6(610)
	37	22nd	684[18.5]	11.2+7.3	20	67	12	20.7(560)
Oct	38	6th	659[17.8]	11.9+5.9	20	69.8	11	17(458)
	39	20th	244[6.6$]	0+6.6	20	73.9	6(Jumbo)	11.5(310)
Nov	40	3rd	662[17.9]	11.3+6.6	20	65	10	19.4(525)
	41	17th	670[18.1]	11.8+6.3	20	61.9	10	26.3(710)
Dec	42	1st	662[17.9]	11+6.9	20	63	11	22.7(614)
	43	15th	370[10]	2.1 +7.9	20	70	12	12.2(330)
	44	29th	692[18.7]	11.3+7.4	20	59.6	11	21.4(580)
Total	**26**						**252**	

@ (n,f) produced Mo^{99} alone

$ (n,γ) produced Mo^{99} alone, jumbo columns containing 9-10 g gel powder were supplied

GEL GENERATOR PRODUCTION FLOW DIAGRAM

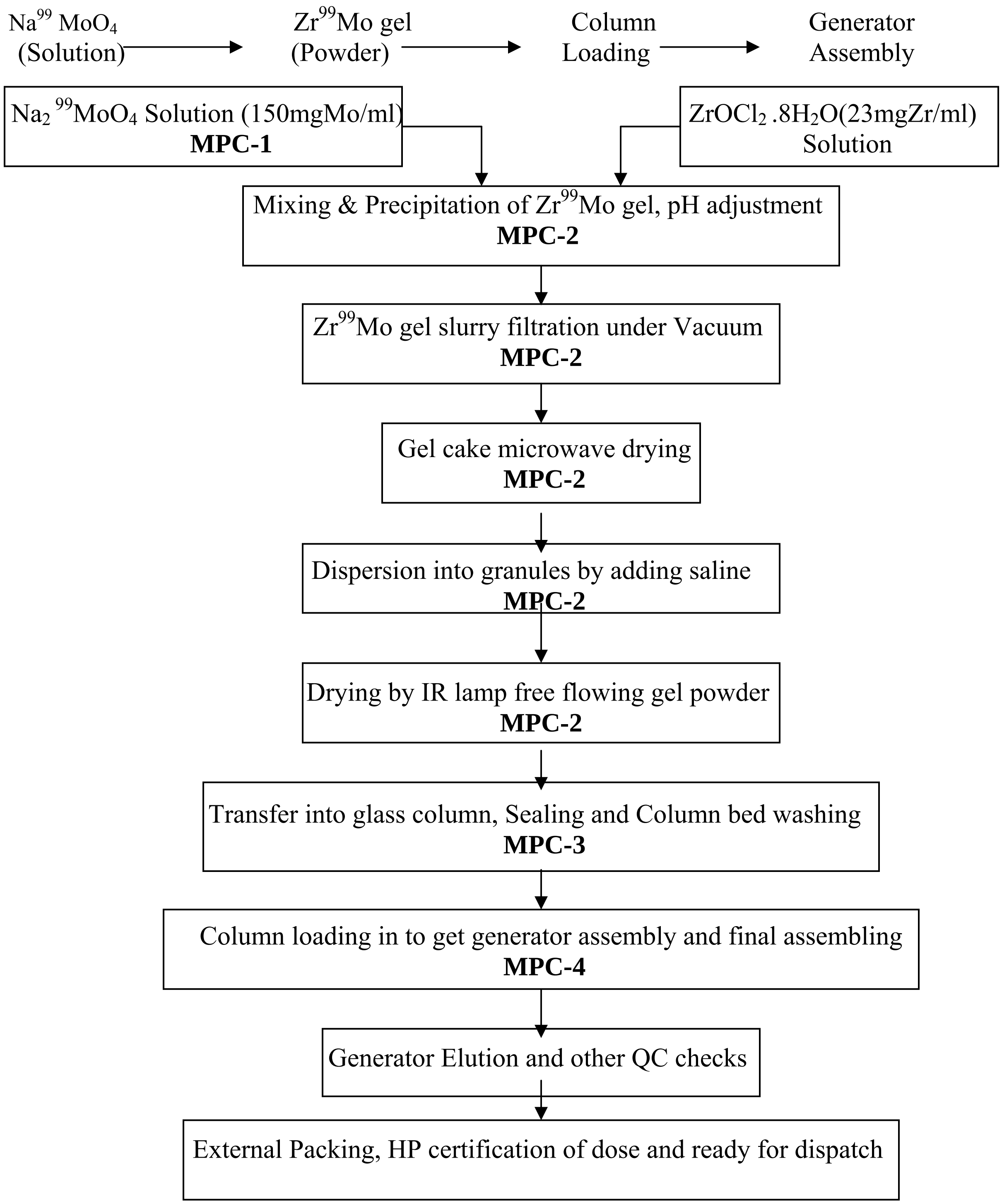

FIG-1

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