

# MON.TEK

## <sup>99</sup>Mo/<sup>99m</sup>Tc Generator

### PRODUCT DATA

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Element                | Molybdenum-99                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Mother Nuclide         | Sodium Molybdate ( $\text{Na}^{99}\text{MoO}_4$ ) 5-50 GBq / Generator (Mo-99 radioactivity at calibration date)                                                                                                                                                                                                                                                                                                                                                                                                              |
| Daughter Nuclide       | Sodium ( $^{99m}\text{Tc}$ ) pertechnetate (obtained from $^{99}\text{Mo}/^{99m}\text{Tc}$ generator system.)                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Half-life              | 6.02 hours                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Shelf Life             | 21 days from the date of production for the generator<br>12 hours from elution time                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Calibration Activities | 5 - 50 GBq Mo-99                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Packaging              | Generator set <ul style="list-style-type: none"> <li>• 1 unit <math>^{99}\text{Mo}/^{99m}\text{Tc}</math> radionuclide generator in the special package</li> <li>• Sterile 0.9 NaCl solution 10 ml or 5 ml (5 vial per each) in cardboard box packages.</li> <li>• 2x5 units of sterile evacuated vials in a cardboard box</li> <li>• 10 units of elution label for vial and 10 units of label for lead shield</li> <li>• 10 units of swap containing 70% isopropyl alcohol</li> <li>• Patient Information Leaflet</li> </ul> |





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## <sup>99</sup>Mo/<sup>99m</sup>Tc Generator

### SPECIFICATIONS

|                            |                                                                              |
|----------------------------|------------------------------------------------------------------------------|
| Appearance                 | Clear, colorless solutions                                                   |
| Radiochemical Purity       | Minimum 95% of total Tc-99m radioactivity                                    |
| Identification             | The most prominent gamma photon of technetium-99m has an energy of 0.141 MeV |
| Eluate                     | Sodium Pertechnetate ( <sup>99m</sup> Tc) Injection (Fission)                |
| Iodine-131 (impurity A)    | <sup>131</sup> I/ Total Radioactivity ≤ 5% $\times 10^{-3}$                  |
| Molybdenum-99 (impurity B) | <sup>99</sup> Mo/ Total Radioactivity ≤ 0.1%                                 |
| Ruthenium-103 (impurity C) | <sup>103</sup> Ru/ Total Radioactivity ≤ 5% $\times 10^{-3}$                 |

### SPECIFICATIONS

|                                      |                                                             |
|--------------------------------------|-------------------------------------------------------------|
| Beta emitting impurities             | <sup>89</sup> Sr/ Total Radioactivity ≤ 6% $\times 10^{-5}$ |
| Strontium-89 (impurity D)            | <sup>90</sup> Sr/ Total Radioactivity ≤ 6% $\times 10^{-6}$ |
| Gamma impurities/Total Radioactivity | ≤ 0.01%                                                     |
| Alpha impurities/Total Radioactivity | ≤ 1% $\times 10^{-7}$                                       |
| Aluminum                             | ≤ 5 ppm                                                     |
| Bacterial Endotoxins (LAL)           | ≤ 0.25 IU / mL                                              |
| pH                                   | 4.0 – 8.0                                                   |
| Sterility                            | Sterile                                                     |

TABLE OF <sup>99m</sup>Tc ACTIVITIES OBTAINED FROM MON.TEK <sup>99</sup>Mo/<sup>99m</sup>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 45 |         | MON.TEK 50 |         |
|------|-----------|--------|------------|--------|------------|--------|------------|--------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|------------|---------|
|      | mCi       | MBq    | mCi        | MBq    | mCi        | MBq    | mCi        | MBq    | mCi        | MBq     | mCi        | MBq     | mCi        | MBq     | mCi        | MBq     | mCi        | MBq     | mCi        | MBq     |
| -6   | 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 | 4.950      | 183.150 | 5.521      | 204.277 |
| -5   | 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 | 3.812      | 141.026 | 4.251      | 157.287 |
| -4   | 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  | 2.935      | 108.590 | 3.273      | 121.101 |
| -3   | 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  | 2.260      | 83.614  | 2.520      | 93.240  |
| -2   | 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  | 1.740      | 64.383  | 1.940      | 71.780  |
| -1   | 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  | 1.340      | 49.575  | 1.494      | 55.278  |
| 0    | 113       | 4.181  | 225        | 8.325  | 340        | 12.580 | 455        | 16.835 | 570        | 21.090  | 685        | 25.345  | 800        | 29.600  | 915        | 33.855  | 1.032      | 38.173  | 1.150      | 42.550  |
| +1   | 87        | 3.219  | 173        | 6.401  | 261        | 9.657  | 350        | 12.950 | 438        | 16.206  | 527        | 19.499  | 616        | 22.792  | 704        | 26.048  | 794        | 29.393  | 886        | 32.782  |
| +2   | 67        | 2.479  | 133        | 4.921  | 201        | 7.437  | 269        | 9.953  | 337        | 12.469  | 406        | 15.022  | 474        | 17.538  | 542        | 20.054  | 612        | 22.633  | 682        | 25.234  |
| +3   | 52        | 1.924  | 102        | 3.774  | 155        | 5.735  | 207        | 7.659  | 260        | 9.620   | 312        | 11.544  | 365        | 13.505  | 417        | 15.429  | 471        | 17.427  | 525        | 19.425  |
| +4   | 40        | 1.480  | 79         | 2.923  | 119        | 4.403  | 159        | 5.883  | 200        | 7.400   | 240        | 8.880   | 281        | 10.397  | 321        | 11.877  | 363        | 13.419  | 404        | 14.948  |
| +5   | 31        | 1.147  | 60         | 2.220  | 92         | 3.404  | 123        | 4.551  | 154        | 5.698   | 185        | 6.845   | 216        | 7.992   | 247        | 9.139   | 279        | 10.332  | 311        | 11.507  |
| +6   | 24        | 888    | 46         | 1.702  | 70         | 2.590  | 94         | 3.478  | 118        | 4.366   | 142        | 5.254   | 166        | 6.142   | 190        | 7.030   | 215        | 7.956   | 240        | 8.880   |
| +7   | 18        | 666    | 36         | 1.332  | 54         | 1.998  | 73         | 2.701  | 91         | 3.367   | 109        | 4.033   | 128        | 4.736   | 146        | 5.402   | 166        | 6.126   | 185        | 6.845   |
| +8   | 14        | 518    | 27         | 999    | 42         | 1.554  | 56         | 2.072  | 70         | 2.590   | 84         | 3.108   | 98         | 3.626   | 113        | 4.181   | 127        | 4.717   | 142        | 5.254   |
| +9   | 11        | 407    | 21         | 777    | 32         | 1.184  | 43         | 1.591  | 54         | 1.998   | 65         | 2.405   | 76         | 2.812   | 87         | 3.219   | 98         | 3.632   | 109        | 4.033   |
| +10  | 8         | 296    | 16         | 592    | 24         | 888    | 33         | 1.221  | 41         | 1.517   | 50         | 1.850   | 58         | 2.146   | 67         | 2.479   | 76         | 2.797   | 84         | 3.108   |
| +11  | 6         | 222    | 12         | 444    | 19         | 703    | 25         | 925    | 32         | 1.184   | 38         | 1.406   | 45         | 1.665   | 51         | 1.887   | 58         | 2.154   | 65         | 2.405   |
| +12  | 5         | 185    | 9          | 333    | 14         | 518    | 19         | 703    | 24         | 888     | 29         | 1.073   | 34         | 1.258   | 39         | 1.443   | 45         | 1.658   | 50         | 1.850   |
| +13  | 4         | 148    | 7          | 259    | 11         | 407    | 15         | 555    | 19         | 703     | 22         | 814     | 26         | 962     | 30         | 1.110   | 35         | 1.277   | 38         | 1.406   |
| +14  | 3         | 111    | 5          | 185    | 8          | 296    | 11         | 407    | 14         | 518     | 17         | 629     | 20         | 740     | 23         | 851     | 27         | 983     | 29         | 1.073   |
| +15  | 2         | 74     | 4          | 148    | 6          | 222    | 9          | 333    | 11         | 407     | 13         | 481     | 15         | 555     | 18         | 666     | 20         | 757     | 22         | 814     |

\*Elution Activity is the activity obtained from a generator eluted at 8 A.M by at least 5 ml sodium chloride 9 mg/ml (0.9%) solution for injection that is not eluted during 24 hours.

\*\* The activities to be obtained are the 90-110% of the given activity amounts.

## About Monrol



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