

Date of analysis : 07 Oct 2024

A. Product Information | Informasi Produk

| | |
|---|--------------------|
| Product Code <i>Kode Produk</i> | 1800000184 |
| Product Description <i>Deskripsi Produk</i> | Mitragyna Speciosa |
| Batch Number <i>Nomor Batch</i> | C24JZB020 |
| Date of Irradiation <i>Tanggal Iradiasi</i> | 07 Oct 2024 |
| Irradiation Process Number <i>Nomor Proses Iradiasi</i> | B2202410070569 |

B. Result of Analysis | Hasil Analisis

| No. | Parameter <i>Parameter</i> | Specification <i>Spesifikasi</i> | Result <i>Hasil</i> |
|-----|--|--|------------------------|
| 1. | Electron Beam Average Current (μA) <i>Rata-rata Arus Berkas Elektron</i> | As per specification <i>sesuai spesifikasi</i> | 1600 |
| 2. | Electron Beam Energy (MeV) <i>Energi Berkas Elektron</i> | As per specification <i>sesuai spesifikasi</i> | 10.24 |
| 3. | Calculated Minimum Dose (kGy) <i>Dosis Minimum Terhitung</i> | As Information <i>Sebagai informasi</i> | 5.4 |
| 4. | Calculated Maksimum Dose (kGy) <i>Dosis Maksimum Terhitung</i> | As Information <i>Sebagai informasi</i> | 5.9 |
| 5. | Chemical Indicator <i>Indikator Kimia</i> | Yellow to Red <i>Kuning ke Merah</i> | Yellow → Red |
| 6. | Minimum Process Target Dose (kGy) <i>Dosis Target Proses Minimum</i> | As Information <i>Sebagai informasi</i> | 5.0 |
| 7. | Maksimum Process Target Dose (kGy) <i>Dosis Target Proses Maksimum</i> | As Information <i>Sebagai informasi</i> | 5.9 |

Other Information | Informasi Lain

Process Target Dose 5 kGy

C. Approval | PersetujuanPrepared by | *Dipersiapkan Oleh*


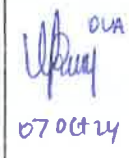
Name | *Nama* : Septi Winarni
Title | *Posisi* : QA Officer
Date | *Tanggal* : 09 Oct 2024

Reviewed & Approved by | *Disetujui Oleh*

Name | *Nama* : DERRY SUPPYADI
Title | *Posisi* : QA Manager
Date | *Tanggal* : 10 Oct 2024



E-BEAM IRRADIATION PROCESS RECORD – OEM PRODUCT

| I. GENERAL INFORMATION | | | | | |
|------------------------|-----------------------------------|--|--------------------------------|------------------|----------------------|
| No SO | : 1300000411 | PROCESS NUMBER STAMP B2202410070569 | | | |
| Internal Batch No | : C24JZB020 | | | | |
| Sterilization Date | : 07 Oct 2024 | | | | |
| Irradiation Purpose | : Preservation | | | | |
| Product Expired | : NA | | | | |
| Dosimeter Expired | : Jul 2029 | External Batch No | : NA | Customer Name | : PT Silah Meh Nuan |
| Dosimeter Quantity | : 8 pcs | Packaging Size | : 44 x 37 x 31 cm | Product Name | : Mitragyna Speciosa |
| Process Target Dose | : 5 kGy | Packaging Weight | : 25 kg | Product Quantity | : 200 CTN |
| Labeling | : <input type="checkbox"/> Radura | <input checked="" type="checkbox"/> Chemical Indicator | <input type="checkbox"/> Other | | |

| II. PARAMETER SETTING | | | | | |
|---------------------------|--|-------------------------------------|--------------|--|--|
| Process Parameter | Acceptance Criteria | Actual Value | Setting Time | Performed By | Verified By |
| Irradiation Process Path | <input type="checkbox"/> Single Side <input checked="" type="checkbox"/> Flipped | <input type="checkbox"/> Return | 15.10 |  07 Oct 24 |  07 Oct 24 |
| Power | <input type="checkbox"/> 10 kW <input checked="" type="checkbox"/> 15 kW | <input type="checkbox"/> Other..... | | | |
| Pulse per second | <input type="checkbox"/> 260 I/s <input checked="" type="checkbox"/> 360 I/s | <input type="checkbox"/> Other..... | | | |
| PFN Voltage | 19,6 kV | | | | |
| Average Beam Current | 1600 μ A \pm 5 % | 1611 μ A | | | |
| Conveyor Speed | 2,73 m/min \pm 3% | 2,72 m/min | | | |
| Peak of e-beam Current | 275 mA \pm 25 mA | 279 mA | | | |
| Klystron High Voltage | 130 V \pm 13 V | 132 V | | | |
| Peak of Microwave Power | 500 W \pm 25 W | 500 W | | | |
| Scan Current | 16 A \pm 0,1 A | 15,9 A | | | |
| Klystron ion pump | $\leq 1 \times 10^{-4}$ A | $0,0 \times 10^{-6}$ A | | | |
| e-source ion pump | $\leq 1 \times 10^{-4}$ A | $0,2 \times 10^{-6}$ A | | | |
| Accelerator tube ion pump | $\leq 1 \times 10^{-4}$ A | $0,6 \times 10^{-6}$ A | | | |
| Scan Box ion pump | $\leq 1 \times 10^{-4}$ A | $4,2 \times 10^{-6}$ A | | | |
| Cons. Temp. Water Inlet | 20 – 35°C \pm 0,5°C | 22,2 °C | | | |
| Cons. Temp. Water Outlet | 20 – 35°C \pm 0,5°C | 23,2 °C | | | |
| Cons. Temp. Water Flow | 18 m ³ /h \pm 1,8 m ³ /h | 18,0 m ³ /h | | | |
| Cool. Temp. Water Inlet | 20 – 35°C \pm 0,5°C | 24,1 °C | | | |
| Cool. Temp. Water Outlet | 20 – 35°C \pm 0,5°C | 26,0 °C | | | |
| Cool. Temp. Water Flow | 18 m ³ /h \pm 1,8 m ³ /h | 18,0 m ³ /h | | | |

| III. PROCESS PARAMETER MONITORING (PRE-HEATING) | | | | | | | | | | | |
|---|---------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Start Time | | | | | | | | | | | |
| Process Parameter | Acceptance Criteria | Time | | | | | | | | | |
| | | I (A) | V (V) | I (A) | V (V) | I (A) | V (V) | I (A) | V (V) | I (A) | V (V) |
| e-source Filament | I \leq 3,3 A | | | | | | | | | | |
| | V \leq 12 V | | | | | | | | | | |
| Klystron Filament | I \leq 50 A | | | | | | | | | | |
| | V \leq 7,5 V | | | | | | | | | | |
| Thyratron Filament | I \leq 100 A | | | | | | | | | | |
| | V \leq 6,3 V | | | | | | | | | | |
| Thyratron H2-Pressure | I \leq 7,0 A | | | | | | | | | | |
| | V \leq 6,3 V | | | | | | | | | | |
| End Time | | | | | | | | | | | |

E-BEAM IRRADIATION PROCESS RECORD – OEM PRODUCT

| IV. PROCESS PARAMETER MONITORING (OPERATING) | | | | | | | |
|--|--|---|--|--|---|--|--|
| Start Time | | : 15.17 | | | | | |
| Process Parameter | Acceptance Criteria | Time | | | | | |
| | | 16.17 | | | | | |
| Pulse Per Second | ≤ 420 I/s | 360 I/s | | | | | |
| Average Beam Current | 1600 μA ± 5 % | 1588 μA | | | | | |
| PFN Voltage | 19,6 – 19,7 kV | 19,7 kV | | | | | |
| Conveyor Speed | 2,73 m/min ± 3% | 2,71 m/min | | | | | |
| Peak of E-beam Current | 275 mA ± 25 mA | 278 μA | | | | | |
| Klystron High Voltage | 130 V ± 13 V | 132 V | | | | | |
| Peak of Microwave Power | 500 W ± 25 W | 500 W | | | | | |
| Scan Current | 16 A ± 0,1 A | 15,9 A | | | | | |
| Klystron Ion Pump | ≤ 1 x 10 ⁻⁴ A | 0,0 x 10 ⁻⁶ A | | | | | |
| e-source Ion Pump | ≤ 1 x 10 ⁻⁴ A | 0,2 x 10 ⁻⁶ A | | | | | |
| Accelerator Tube Ion Pump | ≤ 1 x 10 ⁻⁴ A | 1,0 x 10 ⁻⁶ A | | | | | |
| Scan Box Ion Pump | ≤ 1 x 10 ⁻⁴ A | 7,4 x 10 ⁻⁶ A | | | | | |
| Cons. Temp. Water Inlet | 20 – 35°C ± 0,5°C | 21,9 °C | | | | | |
| Cons. Temp. Water Outlet | 20 – 35°C ± 0,5°C | 23,0 °C | | | | | |
| Cons. Temp. Water Flow | 18 m ³ /h ± 1,8 m ³ /h | 18,0 m ³ /h | | | | | |
| Cool. Temp. Water Inlet | 20 – 35°C ± 0,5°C | 28,6 °C | | | | | |
| Cool. Temp. Water Outlet | 20 – 35°C ± 0,5°C | 30,6 °C | | | | | |
| Cool. Temp. Water Flow | 18 m ³ /h ± 1,8 m ³ /h | 18,0 m ³ /h | | | | | |
| End Time | | : 16.50 | | | | | |
| Total Master Box Quantity Processed | | : 200 CTN | | | | | |
| | | Performed by | | | Verified by | | |
| Sign | |  ABS 07 Oct 24 | | |  alt 07 Oct 24 | | |
| Note | | | | | | | |
| NA | | | | | | | |

E-BEAM IRRADIATION PROCESS RECORD – OEM PRODUCT

| V. CHEMICAL INDICATOR CHECK (YELLOW TO RED) | | | | |
|---|-------------|---------|-------------------------------------|-------------------------------------|
| Chemical Indicator (Qty) | Color (Qty) | | Performed By | Verified By |
| | Yellow | Red | | |
| 200 pcs | NA | 200 pcs | <i>[Signature]</i> 14m 07 Oct 24 | <i>[Signature]</i> DIA 07 Oct 24 |
| VI. PROCESS VERIFICATION | | | | |
| Process Performed by | | | Process Verified by | |
| <i>[Signature]</i> AND 07 Oct 24 | | | <i>[Signature]</i> DIA 07 Oct 24 | |

