# Master Batch Record (MBR) - Bulk

*Structured Word template with recording fields for general and product-specific GMP requirements*

## 1. Document Control

| | | | |
|---|---|---|---|
| Document No. | A0001 | Version | 1.0 |
| Effective Date | 01.03.2026 | Review Date | 01.01.2026 |
| Prepared By | MF Esua | Reviewed By | Macniell |
| Approved By | Mac | Supersedes | Not applicable |
| Product | Veracylglucan | Dosage Form | Tablets |
| Batch Size | 2500 Tablets | Theoretical Yield | 2500 |

## 2. Batch Identity, Scope, and Document Set Completeness

| Checks before start | Fill out information | Status | Signature/Date |
|---|---|---|---|
| Batch number, product code, strength, dosage form API identity verified | 3AB, 123, 40mg Tablets, Veracylg. | Yes / ~~No~~ | SM/24/03/26 |
| Manufacturing, packaging, testing, contract site(s) identified | ✓ | Yes / ~~No~~ | EM/24/03/26 |
| Current approved master manufacturing instructions available | ✓ | Yes / ~~No~~ | EM/24/03/26 |
| Current approved test methods and specifications available | ✓ | Yes / ~~No~~ | EM/24/03/26 |
| Current approved packaging instructions available (if applicable) | ✓ | Yes / ~~No~~ | EM/24/03/26 |
| Executed record issued from current approved master version | ✓ | Yes / ~~No~~ | EM/24/03/26 |
| All pages present, no unexplained blanks, legible entries | ✓ | Yes / ~~No~~ | EM/24/03/26 |
| Required signatures / initials / dates complete | ✓ | Yes / ~~No~~ | EM/24/03/26 |

## 3. Material Formula and Component List (BOM)

| Material (Lot No.) | Function | Std. Qty | Tolerance | Status | Signature /Date |
|---|---|---|---|---|---|
| Paracetamol (12D-00) | API | 100,0 kg | 95 – 100,0 kg | Released / ~~Q / Rej~~ | MES/24/03/26 |
| Microcrist.Cellulose (M1-00) | Excipient | 830,0 kg | 820 – 840,0 kg | Released / ~~Q / Rej~~ | MES/24/03/26 |
| NaHCO3 (N1-A0) | Excipient | 50,0 kg | 48 – 52,0 kg | Released / ~~Q / Rej~~ | MES/24/03/26 |
| Mg-Stearate (MG1-00) | Lubricant | 25,0 kg | 23 - 26 kg | Released / ~~Q / Rej~~ | MES/24/03/26 |
| SiO2 (SO-12D) | Disperser | 5,0 kg | 4 – 6,0 kg | Released ~~Q / Rej~~ | MES/24/03/26 |

## 4. Equipment and Utilities

| Equipment | ID | Status | General Requirement | Signature/Date |
|---|---|---|---|---|
| Mixer | AB | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES / 24/03/26 |
| Granulator | CD | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |
| Fluid bed dryer | EF | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |
| Tabletting machine | GH | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |
| Bulk container | IJ | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |
| Blistermashine | KL | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |
| HVAC | MN | Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |
| Rooms | OP | Clean / Cal. / Qualified | ~~Not overdue~~ / acceptable | MES 24/03/26 |

## 5. Pre-Execution Clearance

| Pre-Start Check | Status | Evidence / Reference | Signature/Date |
|---|---|---|---|
| Area / line clearance completed | Pass / ~~Fail~~ | 102 | St / 24/03/26 |
| Previous product / labels / documents removed | Pass / ~~Fail~~ | 103 | St 24/03/26 |
| Environmental conditions acceptable | Pass / ~~Fail~~ | 104 | St 24/03/26 |
| Operators trained / authorized | Pass / ~~Fail~~ | 105 | St 24/03/26 |
| Correct electronic system / MBR version in use | Pass / ~~Fail~~ | 106 | St 24/03/26 |
| No blocking deviation / maintenance issue | Pass / ~~Fail~~ | 107 | St 24/03/26 |

## 6. Master Process Steps and In-Process Recording

Use one row per manufacturing step. Add rows as needed for dispensing, synthesis, granulation, blending, drying, compression, filling, filtration, or packaging.

| Step No. | Process Step | Target | Theoretical Limit | Actual | Acceptance Criteria | Comments / Exceptions | Signature/Date |
|---|---|---|---|---|---|---|---|
| 1 | Dispensing | All components weighed in the right quantities acc. with the section 3 | s. section 3 | ✓ | Within Theoretical limits | ✓ | St / 24/03/26 |
| 2 | Mixing/Compounding | -Homogeneous | N/A | / | Homogeneous white powder | ✓ | St / 24/03/26 |
| 3 | Granulation | Particle sizes distribution | 250 – 850µm | 500 - 700 µm | Meeting granules particle size specification | ✓ | St / 24/03/26 |
| 4 | Drying | Lost on Drying | 3 – 5% | 4% | Within Theoretical limits | ✓ | St 24/03/26 |
| 5 | Tabletting | Hardness | 60 – 80 N | 70 N | Within Theoretical limits | ✓ | St 24/03/26 |

## 7. In-Process Controls (IPC)

| IPC Parameter | Stage | Frequency | Target | Limits | Result | Signature/Date |
|---|---|---|---|---|---|---|
| Assay/Content | Granules | N/A | 100 % | 95 – 100 % | 98% | ME 24/03/26 |
| LOD | Granules | N/A | 5% | 4 - 6% | 4% | ME 24/03/26 |
| Weight | Tabletting | 15 - 30 min | 500 mg | 450 - 550 mg | 500 mg | ME 24/03/26 |
| Hardness | Tabletting | 30 – 60 min | 60 N | 50 - 70 N | 65N | ME 24/03/26 |
| Thickness | Tabletting | 30 – 60 min | 5 mm | 4 - 6 mm | 5mm | ME 24/03/26 |
| Friability | Tabletting | Start/end of batch | 0,5% | 0 - 1,0% | 0.5% | ME 24/03/26 |
| Desintrigation | Tabletting | Start/Middle/End | 10 min | 5 - 15 min | 10 min | ME 24/03/26 |
| Appearance | Tabletting | Continuous | White | N/A | White | ME 24/3/26 |

## 8. Yield and Reconciliation

| Stage | Theoretical | Range / Limit | Actual | Reconciliation / Investigation Note | Signature / Date |
|---|---|---|---|---|---|
| Dispensing | 100% | 95 – 100 % | 100% | ✓ | ME 24/03/26 |
| Compounding | 100% | 98 - 100 % | 100% | ✓ | ME 24/03/26 |
| Drying | 100% | 95 – 100 % | 98% | ✓ | ME 24/03/26 |
| Compression/Tableting | 100% | 98- 100 % | 100% | ✓ | ME 24/03/26 |
| Packaging | 100% | 95 – 100 % | 98% | ✓ | ME 24/03/26 |
| Final yield | 100% | 95 – 100 % | 100% | ✓ | ME 24/03/26 |

## 9. Sampling and QC Link

| Sample/Material | Qty | Parameter | Specification | Result | Signature/Date |
|---|---|---|---|---|---|
| Paracetamol | 5 g | - Assay<br>- impurities<br>- H2O<br>- Appearance<br>- Identity | - 95 – 100%<br>- 0.1 – 2 %<br>- 1 – 3 %<br>- White powder<br>- IR - Spectrum | - 98%<br>- 1,5%<br>- 2%<br>- White<br>- passed | ST 24/03/26<br>ST 24/03/26<br>ST 24/03/26<br>ST 24/03/26<br>ST 24/03/26 |
| Microcrist.Cellulose | 2 g | - Appearance<br>- Identity | - White powder<br>- IR - Spectrum | | |
| NaHCO3 | 1g | - Appearance<br>- Identity<br>- PH | - White powder<br>- IR – Spectrum<br>- 7-8 | | ME |
| Mg-Stearate | | - Identity | - IR - Spectrum | passed | |
| SiO2 | | - Identity | - IR - Spectrum | passed | 24/03/26 |

## 10. Deviations, OOS/OOT, Nonconformances, and Change Control Impact

| Ref. No. | Issue / Event | Status | Impact on Batch | Signature /Date |
|---|---|---|---|---|
| 1 Dev- 01 | Mixing time was longer as required 1 hr instead of 45 min. | | | |
| 2 Dev-02 | Clean hold time of compounding container was exceeded | | | |

## 12. Primary Packaging

| Packaging Check | Target | Actual | Evidence / Reference | Signature/Date |
|---|---|---|---|---|
| Packaging instruction / artwork version | Available | | DC | |
| Line clearance before start | Done | | CD | |
| Coding: batch / expiry / serialization | Done | | EF | 24/03/26 |
| Printed component reconciliation | Done | | EF | |
| Seal / closure / count / print check | Done | | EG1 | |
| Final pack examination | Done | | G1 | |