

Annexure-I
In-Process Checks

Company Logo Here

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In-Process Checks

1. Tablet Manufacturing

☐ **Granulation Stage**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|--------------------|-----------------|--------|
| 1. | Appearance | Once in a batch | |
| 2. | Moisture | Once in a batch | |

☐ **Compression Stage**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|------------------------|----------------------------------|--------|
| 1. | Appearance | Every 15 minutes interval | |
| 2. | Average Weight | One hour interval | |
| 3. | Uniformity of Weight | One hour interval | |
| 4. | Hardness Test | One hour interval | |
| 5. | Friability Test | Every 2 hours interval | |
| 6. | DT Test | Startup & Every 5 hours interval | |
| 7. | Diameter/length Checks | One hour interval | |
| 8. | Thickness Checks | One hour interval | |

☐ **Coating Stage**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|-------------------------|--------------------------------------|--------|
| 1. | Appearance | At the end of the coating (one time) | |
| 2. | Average Weight | At the end of the coating (one time) | |
| 3. | Uniformity of Weight | At the end of the coating (one time) | |
| 4. | DT Test | At the end of the coating (one time) | |
| 5. | Diameter/ length Checks | At the end of the coating (one time) | |
| 6. | Thickness Checks | At the end of the coating (one time) | |

☐ **Tablet Packaging**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|------------------------------------|---------------------------|--------|
| 1. | Leak Test | One hour interval | |
| 2. | Blister strip counting | Every 30 minutes interval | |
| 3. | Environment condition (Temp. & RH) | Every 30 minutes interval | |
| 4. | Line setup check | 2 hours interval | |

2. Powder For Suspension

☐ **Blending Stage**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|--------------------|------------------|--------|
| 1. | Temperature | Specified in BMR | |
| 2. | Relative Humidity | Specified in BMR | |

☐ **Filling and Packaging Stage**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|--------------------|------------------|--------|
| 1. | Appearance | Every one hour | |
| 2. | Fill weight | Every one hour | |
| 3. | Leak test | Every one hour | |
| 4. | Relative Humidity | Specified in BMR | |
| 5. | Temperature | Specified in BMR | |

3. Encapsulation

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|----------------------|----------------------------------|--------|
| 1. | Appearance | Startup | |
| 2. | Average Weight | Every 30 minutes interval. | |
| 3. | Locking Length | Every 30 minutes interval. | |
| 4. | Uniformity of Weight | Startup & Every 2 hours interval | |
| 5. | DT Test | Startup & Every 5 hours interval | |

☐ **Capsule Packaging**

| Sl. No. | Name of the checks | Frequencies | Remark |
|---------|------------------------------------|---------------------------|--------|
| 1. | Leak Test | One hour interval | |
| 3. | Blister strip counting | Every 30 minutes interval | |
| 4. | Environment condition (Temp. & RH) | Every 30 minutes interval | |
| 6. | Line setup check | 2 hours interval | |