Manufacturing of SDF:

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| **Stage** | **Quality variable** | **Output Quality Attributes** |
| Dispensing | Material ID | Assay (API content) |
| Weight Accuracy |
| Milling & Sieving | Particle Size |
| Mill Speed | Content Uniformity |
| Blending | Blending Uniformity |
| Mixing Time |
| Granulation | Granule Size |
| Moister % | Dissolution |
| Binder amount |
| Drying | Inlet Temperature |
| Outlet Temperature |
| Drying time | Hardness |
| Sizing | - |
| Lubrication | - |
| Compression | Hardness |
| Weight | Moisture content |
| Tablet Thickness |
| Punch Speed |
| **Coating** | Spray Rate |
| Inlet Temperature | Friability |
| Coating weight |
| Packaging | Humidity |
| Sealing Strength |

**Conditional dependencies in SDF manufacturing**

Let`s separate all our parameters in three groups:

* Manufacturing process parameters
* Intermediate quality variables
* Final CoA parameters

**Manufacturing process parameters**

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| --- | --- |
| **Variable** | **Direct Influence** |
| API and Excipient properties | Granule size, blend uniformity |
| Dispensing accuracy | Assay, content uniformity |
| Milling setting | Granule size, blend uniformity |
| Blending time and speed | Blend uniformity |
| Granulation parameters (binder amount, granulation time) | Granule size, moisture content |
| Drying parameters | Moisture content, moisture content (final) |
| Compression force and speed | Weight variation, content uniformity |
| Coating parameters (spray rate, temp) | Moisture content, moisture content (final) dissolution |
| Packaging humidity | Moisture content (final) |

**Intermediate quality variables**

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| --- | --- |
| **Variable** | **Directly Influence** |
| **Granule size** | Blend uniformity, hardness, dissolution |
| **Blend uniformity** | Assay, content uniformity |
| **Moisture content** | Hardness, dissolution, Moisture content (final) |
| **Tablet weight variation** | Assay, content uniformity |

**CoA output attributes**

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| --- | --- |
| **CoA Attribute** | **Influenced By** |
| **Assay (API content %)** | Dispensing accuracy, blend uniformity, tablet weight variation |
| **Content Uniformity** | Blend uniformity, compression force, granule size, tablet weight variation, Dispensing accuracy |
| **Hardness** | Granule size, moisture content, compression force |
| **Dissolution** | Granule size, moisture content, coating parameters |
| **Moisture Content (final)** | Drying parametres, coating, packaging humidity, moister content |