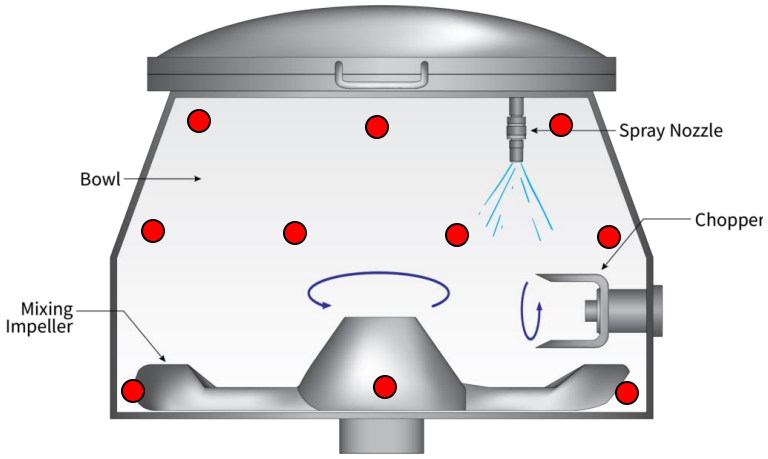
RAPID MIXER GRANULATOR



Role of Compressed Air in RMG: Purging air is supplied below from the Impeller to prevent stickiness in the granules to the impeller and also helps prevent contamination.

Pressure range: 5-6 kg

Note: As Compressed air comes in direct contact of granules hence user point of compressed air below impeller shall be qualified yearly as per ISO 8573.

Working Principle: The formation of granules occurs by rising, whirling and tumbling motion of the material. Dry mixing is done by adding all ingredients into the RMG by rotation of Impeller and Chopper at high speed. .

Ampere Load: End point can be defined by the formulator as a target particle size mean or distribution. Once the desired end point, the granule properties and subsequent tablet properties are very similar regardless of the granulation processing factors, such as impeller or chopper speed or binder addition rate. This is called "the principle of Equifinality".

Tests & Checks

- **Dry Mixing**
  1. Appearance of Dry Mix.
- **Wet Mixing**
  1. Appearance of Wet Mix
  2. Uniformity of Cohesive wet mass at all locations.
  3. Granules formation.
  4. Presence of Dry Powder lumps.

Acceptance Criteria

Assay of samples of allocations should be within the limit specified for products. RSD of all individual values of Assay should not be more than 2% Dry & Wet mixed mass should be uniform in all the locations of RMG and no dry powder lump should be present in any sample of wet mixed mass.

Critical Process Parameters:

- Mixing Time
- Chopper Speed
- Impeller Speed
- Binder Addition Speed
- Mixing Time

Critical Quality Attributes:

- Uniform Mixing
- Blend Uniformity
- Ampere Load

Sampling Locations for Performance Qualification:

1. **U1**= Upper Left / **U2**= Upper Center / **U3**= Upper Right
2. **M1**= Middle Left / **M2** = Middle Center 1 / **M3** = Middle Center 2 / **M4** = Middle Right
3. **L1**= Lower Left / **L2** = Lower Center / **L3** = Lower Right
4. **Composite Sample**
5. **Quantity of Sample:** Each sample of 3 times average weight
6. ● = Sampling Location