# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1 (Low Shear)

**Practical group No:** 11

## Batch Record Summary



| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/04/22 | VS 07 APR 2022. | | | | KS | | 07 APR 2022. |

7/4/22 7/4/22 7/4/22

# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1

**Practical group No:** 11

## 1 GMP PRE REQUISITES

### 1.1 Signatures

Before starting, read the whole document and populate the header information on every page and proceed to the signatures at the right locations for the beginning of the trial. Each page will also have to be signed during the trial and after the trial by the required persons.

### 1.2 Raw data recording

THE BATCH RECORD HAS TO BE FILLED WITH BLUE INK PENS AND THE QA VERIFICATION HAS TO BE DONE WITH A RED PEN

If you make a mistake when you record the raw data, you have to be clearly cross it (the mistake needs to be still legible), you put the date and you sign (if you have room you have even to explain the mistake)

Start date and time must all be completed.

### 1.3 Clean labels

You must start the trial or testing only if the manufacturing or testing equipment are CLEAN and have a "Clean" label partially stuck onto one part of the equipment. That "Clean" label must contain the following information:

- Equipment name
- Equipment code
- Name of the person who cleaned the equipment
- Date of cleaning
- Name of the person who verified the cleaning

Stick the CLEAN label in the appropriate section at the end of this batch record as an evidence that you used a clean equipment

### 1.4 Labeling

All the containers in contact with the powder need to be properly LABELLED BEFORE the powder is incorporated.
All the printings from printers need to be LABELLED BEFORE the measurement takes place

### 1.5 SAFETY

Wear gloves and masks at ALL TIMES
BEWARE OF THE BLADE!

### 1.6 WORKPLACE

YOUR WORKPLACE NEED TO BE CLEANED BEFORE YOU LEAVE THE LABORATORY

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/04/22 | VJ 07 APR 2022. | | | | K.S | | 07 APR 2022. |
| | | 7/4/2022 | 7/4/2022 | | 7/4/2022 | 7/4/2022 | | |

**DoE Trial No:** CP1

**Practical group No:** 11

## 2 PROTOCOL INFORMATION

CAREFULLY read the protocol and this batch record and fill the table below with the appropriate information

### 2.1 DoE trial

DOE Trial number : CP1(Lower Shear)

Fill the green cells with the appropriate values corresponding to the trial:

| factors | Factor 1 | Factor 2 | Factor 3 | Factor 4 |
|---|---|---|---|---|
| Name | Diluent type | Mgst quantity | Mixer type | |
| Matrix level (-1 or +1) | 0 | 0 | -1 | NA VS |
| Experimental level (real value | 1/2 Lactose 1/2 MCC | 1.5% | Low Shear | 07 APR 2022. |

### 2.2 Equipment required

| | Manufacture Equipment | Code No. | | Testing equipment | Code No. |
|---|---|---|---|---|---|
| 1 | Top load balance | ARC120 | 1 | Timers | NA. Yes |
| 2 | Low shear Mixer | 213-34 | 2 | Moisture content balance | 223-59 |
| 3 | Food dehydrator | 223-51 | 3 | Funnel | 223-59 |
| 4 | Granulator / Screener | 66549 | 4 | Tap density tester | 136-2 |
| 5 | Turbula | 060260 | 5 | Electromagnetic sieve shaker | 136-3 |
| 6 | Compression machine Shrek | NA | 6 | Analytical balance | 223-100 |
| 7 | | | 7 | Friability tester | 136-12 |
| 8 | NA TG 7/4/22 | | 8 | Hardness tester | 223-58 |
| 9 | | | 9 | Disintegration tester | 223-62 |

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/4/22 | VS 07 APR 2022. | Yumna | | Yumna | K. S | | 07 APR 2022. |

4/7/22 4/7/22 4/7/22 7/4/2022

# Practical Batch Record- Wet Granulation- V04



**DoE Trial No:** CP1

**Practical group No:** 11

## 3 DISPENSING

**Start Date :** 7/4/22
**Start Time:** 9:45 am

| | | |
|---|---|---|
| **3.1** | Verify the bubble in the circle (tick the box at the right when OK and put initials) ☑ | YG. |
| **3.2** | Record the date at which the balance has been calibrated ☑ | YG |
| **3.3** | **Stick the CLEAN label** on the batch record and write with a marker on the plastic bag<br>• name of product, ☑<br>• TRIAL batch number ☑<br>• date ☑<br>• initials ☑<br>Open the plastic bag, roll the top and put on the top load balance<br>With a dedicated spoon or spatula weigh the excipients and record the amount in the table next page and print the ticket if available.<br>Close the plastic bag and put in the bigger batch plastic bag | Verified by YG. 7/4/22 9:45 am |

**End date :** 7/4/22

**End time:** 10:20 am

**Done by:**

VS.
7/4/22

**Comments:**

~~AA~~. YG. 7/4/22

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN<br>7/04/22 | VS<br>07 APR 2022. | Tnambo<br>9/7/22 | | Tnambo<br>7/4/22 | K.T<br>~~4/7/2022~~<br>7/4/2022 | | 07 APR 2022. |

# Practical Batch Record- Wet Granulation- V04



**DoE Trial No:** CP1

**Practical group No:** 11

| Material | | Material name | | % of the material in the formula (see protocol) | Quantity Required in g | Quantity weighed (recorded by scientist) | Quantity read (recorded by the QA manager) | Checked by (QA manager |
|---|---|---|---|---|---|---|---|---|
| Batch Number | Expiry date | Commercial name | Common name | | | | | |
| 10015653 | 12/22 | Pharmatose 200M | Lactose | 25 | 75.00 | 75.00 | 75.00 | YES |
| 561021913 | 06/22 | Avicel PH102 | Microcrystalline cellulose | 32.75 | 98.25 | 98.25 | 98.25 | YES |
| 10015653 | 12/22 | Pharmatose 200M | Lactose | 32.75 | 98.25 | 98.25 | 98.25 | YES |
| H1577236W0 | 04/21 | K30 | Povidone | 4 | 12.00 | 11.99 | 11.99 11.99 | YES |
| M5840 | 01/23 | AC-DI-SOL | Crosarmellose Sodium | 4 | 12.00 | 12.00 | VS 07 APR 2022 12.00 12.00 VS 07 APR 2022 | YES. |
| | | | | | | | | |
| | | | | | | | | |
| | | | | NA. YG. 7/4/22 | | | | |
| | | | | | | | | |
| 18042606 | NA. YG 7/4/22 | | Magnesium stearate (is weighed after the granule has been made and weighed) | 1.5 | ~~5.30~~ 4.9 | ~~5.32~~ 4.901 | 4.901 | YES |
| TOTAL | | TOTAL | | 100 | 300 | ~~5.320~~ 300.391 | 300.391 | YES |
| | | | | | | | | |

* WRONG VALUES USED FOR CALCULATION VS 07 APR 2022.

**BEFORE WEIGHING MAKE SURE THAT THE QUANTITIES CORRESPOND TO THE CORRESPONDING TRIAL FORMULA**

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/04/22 | VS 07 APR 2022. | Thumbs | | Thumbs | K.F | | 07 APR 2022 |
| | | 7/4/22 | | | 7/4/22 | 7/4/22 | | |

**QA signature and date and initials:**

VS 07 APR 2022.

# Practical Batch Record- Wet Granulation- V04



**DoE Trial No:** CP 1

**Practical group No:** 11

**MIXER USED :** Low Shear

**BEWARE THE SHARP BLADE IF YOU USE THE HIGH SHEAR MIXER**

## 4 STEP 1: DRY MIXING

Stick CLEAN label [NA VS 07 APR 2022]

**Start Date :** 7/4/22
**Start Time:** 10:30 am

| | | Verified by: |
|---|---|---|
| 4.1 | Put the ingredients in the order described in the mixer bowl IN A SANDWICH FORM, close the lid, put a plastic bag around the mixer to contain the powder and proceed with the mixing: NOT REQUIRED AS PER TA INSTRUCTION | |
| | • **½ of ½ or diluent\|: name of the diluent:** ☑ | |
| | • **Paracetamol** ☑ | YH. 7/4/22 |
| | • **Binder- name of the binder:** ☑ | |
| | • **Disintegrant- name of the disintegrant** ☑ | |
| | • **Remainder diluent: name of diluent:** ☑ | |
| | • **Speed (only for low shear mixer):** | |
| | • **Time: 3 min to be measured with a timer** | |
| | Stop the mixer | |

**End date :** 7/4/22

**End time:** 10:45 am

**Done by:** VS.

**Comments:**

NA
VS 07 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/04/22 | VS 07 APR 2022. | YG 7/4/22 | | YG. 7/4/22 | K.S 7/4/22 | | 07 APR 2022 |

**DoE Trial No:** CP 1

**Practical group No:** 11

## 5 STEP 2: GRANULATION

**Start Date :** 7/4/22
**Start Time:** 10:45 am

| | | Verified by: |
|---|---|---|
| 5.1 | In a measuring cylinder, measure the correct volume of water.<br>• **Volume of water:** 40mL ☑ | TH. 7/4/22 |
| 5.2 | When ready start the mixer and immediately start to slowly pipette the water into the powder<br>• **Speed (only for low shear mixer):**<br>• **Time of pouring the water : 30s (timer)** ☑<br><br>Continue to mix:<br>• **Time: 2.5 min (total of granulation 3 min)** ☑<br><br>Remove the granule from the mixer and spread it directly in the dryer. | Verified by:<br>TH. 7/4/22 |

**End date :** 7/4/22

**End time:** 10:50 am

**Done by:** VS.

**Comments:**

NA
VS
07 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN<br>7/04/22 | VS<br>07 APR 2022. | TG<br>7/4/22 | | TG<br>7/4/22 | K.T<br>7/4/22 | | 07 APR 2022. |

# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1

**Practical group No:** 11

## 6 STEP 3: DRYING

Stick CLEAN label ☑ NA - TG

Start Date : 7/4/22
Start Time: 10:55am

| | | |
|---|---|---|
| 6.1 | Lay pieces of large mesh cloth on each tray of the dryer and spread the wet granulation the cloth by layer and start the drying<br>• **Temperature: 75°C** ☑<br>• **Time: 20 min to start with** ☑ | Verified by:<br>YH. 7/4/22 |
| | End date : 7/4/22<br>End time: 11:15 am<br>Done by: VS. | Comments:<br>First moisture measurement was 3%, therefore dried for 40 mins (20 mins extra). |
| 6.2 | TEST: Moisture content<br>Stick the clean sticker ☑ NA TG.<br>• **IR balance**<br>• **Put ~~2.5~~ 5g of powder in the tray** ☑<br>• **Time: 3 min** ☑<br>• **110°C** ☑<br>• **Reading every min** | Result<br>1.1 % |
| | End date : 7/4/22<br>End time: 12:27 pm<br>Done by: VS. | Comments:<br>NA<br>VS<br>07 APR 2022. |

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN<br>7/04/22 | VS<br>07 APR 2022. | TG | | TG. | K.S | | 07 APR 2022. |

7/4/22 7/4/22 7/4/22

# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1

**Practical group No:** 11

## 7 STEP 4: SCREENING

Stick CLEAN label ☑ NA Y.G.

Start Date : 7/4/22
Start Time: 13:26 pm

| | | |
|---|---|---|
| 7.1 | Prepare the granulator according to the SOP. Place a large Plastic bag around the bottom of the granulator to recoup the screened granule and screen the granule until no more granule can pass through the mesh | Verified by: YH. 7/4/22 |

End date : 7/4/22
End time: 13:31 pm
Done by: VS.

Comments: NA VS 07 APR 2022.

## 8 STEP 5: LUBRICATION

Stick CLEAN label ☑ NA YG.

Start Date : 7/4/22
Start Time: 13:34 pm

**8.1** TEST: Yield: accurately weigh the dry granule on a top-load balance by taring another plastic bag and putting the bag containing the granules on the balance.

91.7%

Calculate the quantity of lubricant that is needed knowing that the lubricant is 0.5% of the total formula
Equation:

~~Yield X 1.5%~~ mass of screened granules X 1.5% = mass Mgst required.

Verified by: YH.

- **Quantity of Mg Stearate required?** 5.3202 ~~5.32g~~ YG. 8/4/22
- **Quantity weighed:** 5.3201 ~~5.32g~~ YG. 8/4/22

Verified by YH. 7/4/22

End date : 7/4/22
End time: 13:48 pm
Done by: VS & YG

Comments: NA VS 07 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/04/22 | VS 07 APR 2022. | YG 7/4/22 | | YG 7/4/22 | K.S 7/4/22 | | 07 APR 2022. |

# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1

**Practical group No:** 11

| | | |
|---|---|---|
| 8.2 | Put the dry granule in the glass jar then add the Mg Stearate. Put the glass jar in the Turbula. Start the mixing.<br>• **Speed: 72 rpm** ☑<br>• **Time: 3min** ☑ | Verified by:<br>YH.<br>4/4/22 |
| | **End date :** 7/4/22<br>**End time:** 14:03 pm<br>**Done by:** VS. | **Comments:**<br>NA<br>VS 07 APR 2022 |
| 8.3 | TEST: Flowability: weigh 50 g of lubricated powder.<br>Put the funnel in a stand above a 250 ml measuring cylinder that is specific to the tap density tester. Stop the hole of the funnel with your thumb and pour the 50 g of powder in the funnel.<br>Remove your thumb at the exact same time as you activate the timer and stop the timer when the 50 g have gone through the funnel. Make sure not to touch the cylinder if possible when determining the volume.<br>• **Flow time in s (no decimal places)** | Weight<br>50.15 g<br>Result<br>25 |
| | **End date :** 7/4/22<br>**End time:** 14:40<br>**Done by:** VS. & SK. | **Comments:**<br>NA<br>VS 07 APR 2022 |

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN<br>7/04/22 | VS<br>07 APR 2022. | YG.<br>7/4/22 | | YG.<br>7/4/22 | K.S<br>7/4/22 | | 07 APR 2022. |

# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1

**Practical group No:** 11

**8.4** TEST: tapped density: record the bulk volume in the measuring cylinder

Cover the measuring cylinder with a metal foil, but not covering the graduated lines on the cylinder. Fit the measuring cylinder in the tapped density tester and set 10 taps according to USP 2. Record the volume after 10 taps and record the powder volume in the table below.
Set the machine for having the following number of taps records and record the volumes in the table below

Pour the powder in the mesh for particle sizing and then clean the cylinder with a cloth (mesh) and pen.

| | V0 | V10 | V500 | V1250 | (V2500) |
|---|---|---|---|---|---|
| **Volume (ml)** | 116 | 94 | 90 | 85 | 85 |
| **Density (g/ml)** | 0.43 | 0.53 | 0.56 | 0.59 | 0.59 |

Calculate the Carr index:

$$C = 100\frac{V_{10} - V_{500}}{V_{10}}$$

Result: 4.26

Verified by: YH. 7/4/22

**End date :** 4/7/22

**End time:** 16.01pm

**Done by:** VS. & VN. & YG.

**Comments:** N/A, VN 7/04/22

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 7/04/22 | VS 07 APR 2022. | YG 7/4/22 | | YG 7/4/22 | K.S 7/4/22 | | 07 APR 2022. |

# Practical Batch Record- Wet Granulation- V04

**DoE Trial No:** CP1

**Practical group No:** 11

**8.5** TEST: particle size:

Measure the weight of each screen:

| | bottom | 125µm | 180 µm | 355 µm |
|---|---|---|---|---|
| **Mass in g** | 282.16 | 299.60 | 297.61 | 314.38 |

Set up the sieve shaker and pour the tapped powder into the top screen and run the test:

- **Time: 10 min** ☑
- **Vibration: 20** ☑

Record the weights of each screen containing the powder and **KEEP each fraction in separate labeled plastic bags;**

| | bottom | 125 µm | 180 µm | 355 µm |
|---|---|---|---|---|
| **Mass in g** | 302.10 | 308.90 | 310.61 | 321.12 |

Calculate the difference and the percentage of powder in each particle size:

| | bottom | 125 µm | 180 µm | 355 µm |
|---|---|---|---|---|
| % | 40.7 | 19.0 | 26.5 | 13.8 |

Clean cylinder with mesh and pen before handing it to other group.

VERIFIED BY
08 APR 2022.

**End date :** 08/04/2022
**End time:** 11:42 a.m.
**Done by:** VS.

**Comments:** NA
VS. 08 APR 2022.

## 9 STEP 6: TABLETTING

Stick CLEAN label

**Start Date :** 7/4/22
**Start Time:** 3:50pm

**9.1** Proceed with tableting on the Shrek machine. Produce at least 200 tablets at the set COMPRESSION FORCE.

Stop the machine when the powder volume is low.

Verified by:
VS
08 APR 2022.

**End date :** 7/4/22
**End time:** 4:10pm
**Done by:** SK.

**Comments:** NA V.S 8/4/22

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 8/04 | VS 08 APR 2022. | TG. 8/4/22 | | TG. 8/4/22 | K.T 8/4/2022 | | 08 APR 2022. |

**DoE Trial No:** CP1

**Practical group No:** 11

**9.2** TEST: Mass/Hardness: On an analytical balance, weigh each 10 tablets individually and place them back in the well plate.
Measure the hardness and thickness of the tablets in the tablet holder in order to get the mass, the hardness and the thickness of each individual tablet.

Verified by: VS 8/4/22

| | Tablet 1 | Tablet 2 | Tablet 3 | Tablet 4 | Tablet 5 |
|---|---|---|---|---|---|
| Mass (balance with 4 decimal places) in mg | 0.5118 | 0.5079 | 0.5316 | 0.5032 | 0.5015 |
| Hardness (hardness tester) (N) | 24.799 | 25.449 | 21.652 | 22.524 | 19.242 |
| Thickness (Caliper) (mm) | not required as per video protocol | N/A, VN 8/04/22 | | | |
| | Tablet 6 | Tablet 7 | Tablet 8 | Tablet 9 | Tablet 10 |
| Mass (balance with 4 decimal places) in mg | 0.5165 | 0.5098 | 0.5116 | 0.5076 | 0.5149 |
| Hardness (N) | 23.935 | 20.409 | 18.922 | 20.073 | 15.997 |
| Thickness (mm) | not required as per video protocol | N/A, VN 08/04/22 | | | |

**End date :** 8/04/22
**End time:** 10.55 am
**Done by:** VN

**Comments:** N/A VN 8/04/22

**9.3** TEST: Disintegration time: place 3 tablets in the basket holes in 2 baskets and place the disks on top of each tablet. Start the disintegration test according to the pharmacopeia. Record the time at which the tablet is disintegrated (small lumps are considered disintegrated) –

Verified by: VS 8/4/22

| | Tablet 1 | Tablet 2 | Tablet 3 | Tablet 4 | Tablet 5 | Tablet 6 |
|---|---|---|---|---|---|---|
| Disintegration time (s) | 1:16 | 1:16 | 1:16 | 1:16 | 1:16 | 1:16 |

**End date :** 8/04/22
**End time:** 10.40 am
**Done by:** VN

**Comments:** N/A VN 8/04/22

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 8/04 | VS 08 APR 2022. | YG. 8/14/22 | | YG 8/14/22 | K.S 8/4/2022 | | 08 APR 2022. |

# Practical Batch Record- Wet Granulation- V04



**DoE Trial No:** CP1

**Practical group No:** 11

| | | |
|---|---|---|
| 9.4 | TEST: friability:<br>• **accurately weigh approximately 6.5 g of tablets (4 g if average weight of individual tablet is more than 650 mg)** ☑<br>• **Run the test at 100 rotations (type in 100)** ☑<br>Remove the tablets from the wheel, dedust them and weigh them again. Calculate the friability in % = (before-after)/before x 100 | Verified by:<br>YH.<br>08/04/2022 |

| | Before | After | Friability % |
|---|---|---|---|
| Mass (g) | 6.6061 | 6.1827 | 6.4% |

**End date:** 08/04/2022

**End time:** 11 : 08

**Done by:** VS.

**Comments:**

NA

YS 08 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | VN 8104 | VS 08 APR 2022. | YG 8/4/22 | | YG 8/4/22 | K.S 8/4/2022 | | 08 APR 2022. |

**DoE Trial No:** CP1

**Practical group No:** 11

## 10 STEP 7: TABLETTING GAMLEN

Stick CLEAN label

**Start Date :**
**Start Time:**

Verified by:

**10.1** **On the Gamlen tablet press,** produce 4 tablets with the granule

- **Mass of each tablet: 200mg**
- **Compaction force: 500kg**

Test: hardness of 4 tablets from the whole granule :
Measure the corresponding hardness and tensile strength. Record the force versus displacement curve and the ejection force and calculate tensile strength

| | Tablet 1 | Tablet 2 | Tablet 3 | Tablet 4 |
|---|---|---|---|---|
| **Mass (mg)** | | | | |
| **Hardness (N)** | | | | |
| **Tensile strength (MPa)** | | | | |
| **FORCE/ DEPLACEMENT recorded** | | | | |
| **EJECTION FORCE** | | | | |

NA VS 08 APR 2022.

**10.2** **On the Gamlen tablet press,** produce 4 tablets with the fractions of PARTICLE SIZE TEST

- **Mass of each tablet: 200mg**
- **Compaction force: 500kg**

Test: hardness of 4 tablets from the whole granule :
Measure the corresponding hardness and tensile strength. Record the force versus displacement curve and the ejection force and calculate tensile strength

| | Tablet 1 BOTTOM | Tablet 2 125microns | Tablet 3 180 microns | Tablet 4 355 microns |
|---|---|---|---|---|
| **Mass (mg)** | | | | |
| **Hardness (N)** | | | | |
| **Tensile strength (MPa)** | | | | |
| **FORCE/ DEPLACEMENT recorded** | | | | |
| **EJECTION FORCE** | | | | |

* NOT REQUIRED AS PER VIDEO PROTOCOL VS 08 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | | | NA VS 08 APR 2022. | | | | | |

**DoE Trial No:** CP1

**Practical group No:** 11

| | | |
|---|---|---|
| | **End date :**<br>**End time:**<br>**Done by:** | **Comments:**<br>N/A<br>VJ 08 APR 2022. |

* NOT REQUIRED AS PER VIVEK PROTOCOL.

## 11 GENERAL COMMENTS ON THE BATCH

N/A
VJ
08 APR 2022.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Signature prior to the trials Date/sign** | Project Manager | QA Manager | Scientists | **Signature during the trials Date/sign** | Scientist1 | Scientist2 | **Check signature Date/sign** | QA Manager |
| | | VJ<br>08 APR 2022. | | | | | | 08 APR 2022. |

DoE Trial No: CP6

Practical group No: 11

## 12 CLEAN LABELS

CLEAN LABELS:

NA
VS
08 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | | | NA VS 08 APR 2022. | | | | | |

# Practical Batch Record- Wet Granulation- V04

| | |
|---|---|
| **DoE Trial No:** | CP |
| **Practical group No:** | 11 |

NA
YJ
08 APR 2022.

| **Signature prior to the trials Date/sign** | Project Manager | QA Manager | Scientists | **Signature during the trials Date/sign** | Scientist1 | Scientist2 | **Check signature Date/sign** | QA Manager |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

| DoE Trial No: | CP |
|---|---|
| Practical group No: | 11 |

NA
VJ
04 APR 2022.

| Signature prior to the trials Date/sign | Project Manager | QA Manager | Scientists | Signature during the trials Date/sign | Scientist1 | Scientist2 | Check signature Date/sign | QA Manager |
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