

# Practical Batch Record- Wet Granulation- V04

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DoE Trial No: Exp 3.

Practical group No: 11

## Batch Record Summary

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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	VJ	Y.G.		Y.G.	K.J		J.S.
7/04/22	07 APR 2022.				7/4/22	7/4/22	7/4/22	07 APR 2022

# Practical Batch Record- Wet Granulation- V04

DoE Trial No: Exp 3  
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	VS	TG	TG	K-T			Daily 02 APR 2022

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## 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 : Exp 3

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

factors	Factor 1	Factor 2	Factor 3	Factor 4
Name	Diluent Type	Mass Quantity	Matrix type	NA
Matrix level (-1 or +1)	-1	1	-1	
Experimental level (real value)	Lactose	1%	Low shear	

TG.

7/4/22

### 2.2 Equipment required

Manufacture	Equipment	Code No.	Testing equipment	Code No.
1	Top load balance	ARC120	1 Timers	APR VS 07 APR 2022
2	Low Shear mixer	213-34	2 Moisture content balance	223-59
3	Food dehydrator (SunBeam)	223-51	3 Funnel	223-59
4	Granulator / Sieve	66549	4 Top 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		TG. 7/4/22	8 Hardness tester	223-58
9	NA	7/4/22	9 Disintegration tester	223-62

TG.

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	VJ		
7/04/22		07 APR 2022	YG.			K.T		07 APR 2022

7/4/22

7/4/22

7/9/22

# Practical Batch Record- Wet Granulation- V04

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DoE Trial No: Exp 3

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Start Date : 7/4/22

Start Time: 10:05 am

Verified

Verified by

YG.

## 3 DISPENSING

3.1 Verify the bubble in the circle (tick the box at the right when OK and put initials)

3.2 Record the date at which the balance has been calibrated

3.3 Stick the CLEAN label on the batch record and write with a marker on the plastic bag

- name of product,
- TRIAL batch number
- date
- initials

Open the plastic bag, roll the top and put on the top load balance

With a dedicated spoon or spatula weigh the excipients and record the amount in the table next page and print the ticket if available.

Close the plastic bag and put in the bigger batch plastic bag

End date : 7/4/22

End time: 10:30 am

Done by:

VN. & YG. & SK.

Comments:

YG. 7/4/22

MA

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	YG 07 APR 2022		YG 7/4/22	IC.T 7/4/22			TW 07 APR 2022

7/4/22

7/4/22

7/4/22

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Material		Material name		% of the material in the formula (see protocol)	Quantity Required in g	Quantity weighed (recorded by scientist)	Quantity read (g) (recorded by the QA manager)	Checked by (QA manager)
Batch Number	Expiry date	Commercial name	Common name					
10015653	12/22	Pharmatose 200M	Lactose	25.0	75.00	75.01	75.01	YES
561021913	06/22	Avicel PH102	Microcrystalline cellulose	0.0	0.00	0.00	0.00	YES
10015653	12/22	Pharmatose 200M	Lactose	66.0	195.00	195.00	195.00	YES
M5840	01/23	AC-DI-SOL	Croscarmellose Sodium	4.0	12.00	12.01	12.01	YES
41577236W0	04/21	K30	Povidone	4.0	12.00	12.01	12.01	YES
			NA	Y6. 7/4/22				
18042606	AA. 76. 7/4/22	Mg St.	Magnesium stearate (is weighed after the granule has been made and weighed)	2	6.36	6.3610	5.3610g	YES
<b>TOTAL</b>		<b>TOTAL</b>		100	306	5.3610 AA. 76. 299.391	299.391	YES
			NA	Y6. 7/4/22				

\* WRONG CALCULATION USED  
VS 07 APR 2022.

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

QA signature and date and initials:

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
					Y6	K.F		
VN 7/04/22	VS 07 APR 2022	YG.					lally 07 APR 2022.	

VS  
07 APR 2022.

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

# Practical Batch Record- Wet Granulation- V04

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DoE Trial No: Exp 3

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MIXER USED :

Low shear Mixer

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

## 4 STEP 1: DRY MIXING

Stick CLEAN label

NB VS  
07 APR

Start Date : 7/4/2022

Start Time: 10:50 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:

- **½ of ½ or diluent|: name of the diluent:**
- **Paracetamol**
- **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**



YG.



7/4/22



Stop the mixer

End date : 7/4/22

Comments:

End time: 11:05 am

Done by:

VN. & SK.

NA

TG. 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 7/10/22	VS 07 APR 2022	YG. 07 APR 2022		YG. 7/4/22	YG. 7/4/22	IC-S 7/4/22	Check signature Date/sign 7/4/22	Harsh 07 APR 2022

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<b>5 STEP 2: GRANULATION</b>		<b>Start Date :</b> 7/4/22 <b>Start Time:</b> 11:05 am
5.1	In a measuring cylinder, measure the correct volume of water. <ul style="list-style-type: none"> <li>Volume of water: <u>40mL</u> <input checked="" type="checkbox"/></li> </ul>	Verified by: YG. 7/4/22
5.2	When ready start the mixer and immediately start to slowly pipette the water into the powder <ul style="list-style-type: none"> <li>Speed (only for low shear mixer):</li> <li>Time of pouring the water : 30s (timer) <input checked="" type="checkbox"/></li> </ul> Continue to mix: <ul style="list-style-type: none"> <li>Time: 2.5 min (total of granulation 3 min) <input checked="" type="checkbox"/></li> </ul> Remove the granule from the mixer and spread it directly in the dryer.	Verified by: 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 7/4/22	VN 07 APR 2022.	VN 07 APR 2022.	YG.	YG. 7/4/22	K J			Y G 07 APR 2022.

7/4/22

7/4/22

8/9/22

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<b>6 STEP 3: DRYING</b> Stick CLEAN label <span style="border: 1px solid red; padding: 2px;">NA</span> VS 07 APR 2022.		<b>Start Date :</b> 7/4/22 <b>Start Time:</b> 1:10 pm
<b>6.1</b> <ul style="list-style-type: none"> <li>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           <ul style="list-style-type: none"> <li>Temperature: 75°C <input checked="" type="checkbox"/></li> <li>Time: 20 min to start with <input checked="" type="checkbox"/></li> </ul> </li> </ul>	Verified by: YG 7/4/22	
	<b>End date :</b> 7/4/22 <b>End time:</b> 1:35pm <b>Done by:</b> YG	Comments:  NA YG 7/4/22
<b>6.2</b> <ul style="list-style-type: none"> <li>TEST: Moisture content           <ul style="list-style-type: none"> <li>Stick the clean sticker <span style="border: 1px solid red; padding: 2px;">NA</span> VS 07 APR 2022.</li> <li>IR balance <input checked="" type="checkbox"/></li> <li>Put 2.5g of powder in the tray <input checked="" type="checkbox"/></li> <li>Time: 3 min <input checked="" type="checkbox"/></li> <li>110°C <input checked="" type="checkbox"/></li> <li>Reading every min <input checked="" type="checkbox"/></li> </ul> </li> </ul>	Result  1.70%	
<b>End date :</b> 7/4/22 <b>End time:</b> 1:50pm <b>Done by:</b> VN	Comments:  NA 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 7/4/22	VS 07 APR 2022.	YG.		YG 7/4/22	RS			YH 07 APR 2022

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## 7 STEP 4: SCREENING

Stick CLEAN label ~~NA~~ VS 07 APR 2022.

Start Date : 7/4/22

Start Time: 2:30pm

- 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:

TG. 7/4/22

End date : 7/4/22

End time: 2:40 pm

Done by: VN & TG.

Comments:

TG. 7/4/22

## 8 STEP 5: LUBRICATION

Stick CLEAN label ~~NA~~ VS 07 APR 2022.

Start Date : 7/4/22

Start Time: 2:40pm

- 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.

90.7%

Calculate the quantity of lubricant that is needed knowing that the lubricant is  $\frac{2}{5}$ % of the total formula

Equation:

$$2\% \times 268.04g = 5.36g$$

- Quantity of Mg Stearate required?

\* WRONG  
DECIMAL  
PLACE USED.

V8 07 APR 2022.

Verified by:

TG. 7/4/22

Verified by:

5.3610  
\* 5.36g

TG. 7/4/22

5.3610  
\* 5.36g

Verified by

TG.

End date : 7/4/22

End time: 2:50 pm

Done by: SK.

Comments:

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
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

V8  
07 APR 2022.

TG.

7/4/22

TG

K.S

7/4/22

  
07 APR 2022

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8.2	<p>Put the dry granule in the glass jar then add the Mg Stearate. Put the glass jar in the Turbula. Start the mixing.</p> <ul style="list-style-type: none"> <li>Speed: 72 rpm <input checked="" type="checkbox"/></li> <li>Time: 3min <input checked="" type="checkbox"/></li> </ul>	Verified by: Y.G. 7/4/22
	<p>End date: 7/4/22 End time: 3:05 pm Done by: VS &amp; SK</p> <p>Comments:</p> <p>MA TG. 4+ 7/4/22</p>	
8.3	<p>TEST: Flowability: weigh 50 g of lubricated powder.</p> <p>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.</p> <p>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.</p> <ul style="list-style-type: none"> <li>Flow time in s (no decimal places)</li> </ul>	<p>Weight 50.01g</p> <p>Result 2 s</p>

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.	Y.G.		Y.G.	L.T			L.T. 07 APR 2022.

7/4/22

7/4/22

7/4/22

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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.

Volume (ml)	V0	V10	V500	V1250	(V2500)
Density (g/ml)	82 mL	78 mL	73 mL	69 mL	69 mL
	0.61 g/mL	0.64 g/mL	0.68 g/mL	0.72 g/mL	0.72 g/mL

Calculate the Carr index:

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

\* WRONG  
DECIMAL  
PLACES  
USED

VS 07 APR 2022

Verified by:

\* 10.981  
10.98

End date : 7/4/22

End time: 4:20 pm

Done by: VS, VN.

Comments:

NA YG. 7/4/22

SK.

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.	YG.		YG	K.S			W.H. 07 APR 2022.

7/4/22

7/4/22

7/4/22

# Practical Batch Record- Wet Granulation- V04

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8.5

TEST: particle size:  
 Measure the weight of each screen:

	bottom	125µm	180 µm	355 µm
Mass in g	282.32	299.70	297.60	314.37

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	288.85	310.34	306.13	327.93

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

	bottom	125 µm	180 µm	355 µm
%	33.4	21.5	17.7	27.4

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

End date : 8/4/22

Comments:

End time: 12:10pm

YG . 8/4/22

Done by: VN & VS.

NA

## 9 STEP 6: TABLETTING

Stick CLEAN label

Start Date : 7/4/22

Start Time: 3:50pm

Verified by:

YG.

8/4/22

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

Stop the machine when the powder volume is low.

End date 7/4/22

Comments:

End time: 4:10pm

NA

YG . 8/4/22

Done by: SK .

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 08 APR 2022.	YG.		YG. 08 APR 2022.	KT			WILL 08 APR 2022.

4/7/22

4/7/22

1/7/22

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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 8/04/22
	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5		
Mass (balance with 4 decimal places) in mg	0.6786	0.6709	0.6706	0.6514	0.6661		
Hardness (hardness tester) (N)	104.996	105.912	100.086	90.118	96.717		
Thickness (Caliper) (mm)							
NIA, VN 8/04/22	not required as per video protocol						
	Tablet 6	Tablet 7	Tablet 8	Tablet 9	Tablet 10		
Mass (balance with 4 decimal places) in mg	0.6562	0.6766	0.5197	0.6137	0.6698		
Hardness (N)	89.835	104.447	19.976	83.619	95.888		
Thickness (mm)							
NIA, VN 8/04/22	not required as per video protocol						
End date : 8/04/22	Comments:						
End time: 11:49 am	NA						TG. 8/14/22
Done by: VN							
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 8/14/22
	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5	Tablet 6	
Disintegration time (s)	5:51	5:51	5:53	5:46	5:45	5:41	
End date : 8/04/22	Comments:						
End time: 10:50 Am	NA						TG. 8/14/22
Done by: VN							

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 8/04/22	VS 08 APR 2022	YQ		YQ 8/14/22	K. J			J. S. 08 APR 2022

8/14/22

8/14/22

8

8/14/22

# Practical Batch Record- Wet Granulation- V04

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9.4	TEST: friability:				Verified by:							
	<ul style="list-style-type: none"> <li>accurately weigh approximately 6.5 g of tablets (4 g if average weight of individual tablet is more than 650 mg) <input checked="" type="checkbox"/></li> <li>Run the test at 100 rotations (type in 100) <input checked="" type="checkbox"/></li> </ul>	<p>Remove the tablets from the wheel, dedust them and weigh them again. Calculate the friability in % = (before-after)/before x 100</p> <table border="1"> <thead> <tr> <th></th> <th>Before</th> <th>After</th> <th>Friability %</th> </tr> </thead> <tbody> <tr> <td>Mass (g)</td> <td>4.0163 4.02 NA.</td> <td>3.5106</td> <td>12.6</td> </tr> </tbody> </table> <p>TG</p>					Before	After	Friability %	Mass (g)	4.0163 4.02 NA.	3.5106
	Before	After	Friability %									
Mass (g)	4.0163 4.02 NA.	3.5106	12.6									
<p><b>End date:</b> 8/4/22    <b>Comments:</b> NA. TG. 8/4/22</p> <p><b>End time:</b> 10:50am</p> <p><b>Done by:</b> VS.</p>												

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 8/04/22	VJ 08 APR 2022	TG 08 APR 2022		TG	bj			lmtt 08 APR 2022

8/14/22

8/14/22 8/4/22

# Practical Batch Record- Wet Granulation- V04

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Temp 3

Practical group No:

11

## 10 STEP 7: TABLETTING GAMLEN

Stick CLEAN label

Start Date :

Start Time:

- 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) wrote on wrong page, VN, 104122	104.946	105.912	100.086	90.118
Tensile strength (MPa)				
FORCE/ DEPLACEMENT recorded				
EJECTION FORCE				

Verified by:

**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

NA

VS 08 APR 2022.

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
				VS 03 APR 2022.				

APR 2022.

# Practical Batch Record- Wet Granulation- V04

DoE Trial No: Exp3  
 Practical group No: 11

	End date :	Comments:
	End time:	NA VS 08 APR 2022.
	Done by:	* NOT REQUIRED AS PER VIDEO PROTOCOL.

## 11 GENERAL COMMENTS ON THE BATCH

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
VN 08/04/22	VS 08 APR 2022.	VS 08 APR 2022.	NA VS 08 APR 2022.	VS 08 APR 2022.	NA VS 08 APR 2022.	VS 08 APR 2022.	VS 08 APR 2022.	VS 08 APR 2022.

# Practical Batch Record- Wet Granulation- V04

DoE Trial No: EXP

Practical group No: 11

## 12 CLEAN LABELS

CLEAN LABELS:

NA  
VS  
08 MAR 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 MAR 2022.				

# **Practical Batch Record- Wet Granulation- V04**

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**DoE Trial No:** Expt 3

Practical group No: 11

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

Practical Batch Record- Wet Granulation- v04

**DoE Trial No:**

Exhibit A3

# Practical group No:

11

NA

15

08 APR 2022