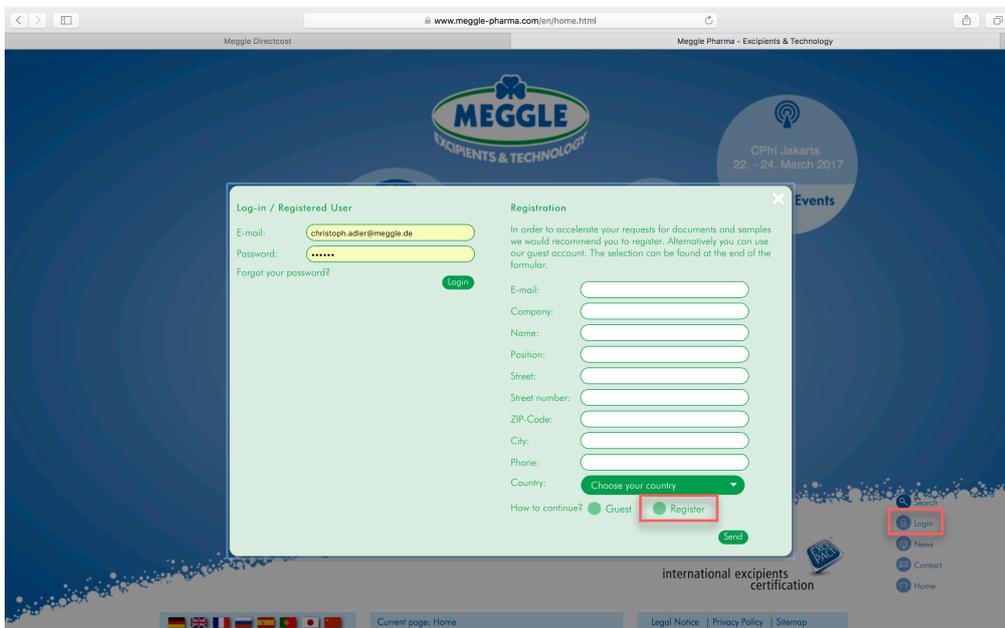
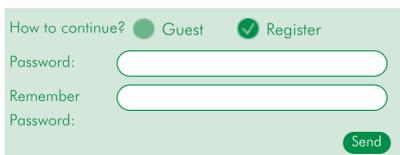


User Manual - DirectCost

DC - Optimize your tableting process

In order to get full access to MEGGLE's „DC-Tool“ please be so kind as to register.
<http://www.meggle-pharma.com> - click on  Login for the registration form.

Check the box „Register“ and choose your password.
 Repeat the password and finalize the registration step with the „Send“ button.

After the registration step you will find a green colored button for DirectCost. Click on this button to get full access to MEGGLE's optimization tool.



Top Navigation - Cockpit

In the levitating top navigation you will find all relevant information about your project. Furthermore we included a pull-down menu to manage your project. Detailed explanation you will find below.



Project title: Ibuprofen Tablets
 No. of tablets: 1,000,000 pcs.
 Batch size: 747.00 kg

Project title = is the name of your specific project.

No. of tablets = number of tablets you would like to produce.

Batch size = total quantity of material you need to process to produce the required number of tablets.



Start a new project / all input fields are cleared!



Save your project in the cloud. Your project will be stored under your account on our server.

Your benefit: You can re-start working on your project independently from your device.

Example: You start to work with your laptop on a certain project. Next day you need more flexibility in order to show your colleagues the first results - so you start the DC-Tool on your iPad and upload the project from the cloud. You only need a one time internet connection. Afterwards the tool is 100% offline capable.



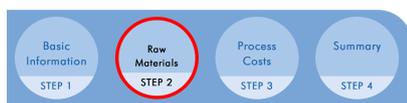
Upload your project from your local storage (HD)



Save your project on your local storage (HD)



Project report print preview page, which contains all data and results for your project.



Navigation-Bubbles for an easy switch between the different steps. Furthermore you will see due to color coding in which project steps you work at the moment.

STEP 1 / Basic Information

In the first step you can enter the basic information about your project. Some of these information will be displayed in the top navigation for a quick overview and orientation.

Project title: = is the name of your specific project.

No. of tablets: = number of tablets you would like to produce.

Currency: = you can choose between „EUR - €“ and „USD - \$“

Material loss - Wet Granulation
 Material loss - Direct Compression



Here you can adjust the typical/expected loss of material due to the manufacturing process. Typical values (5% WG - 3% DC)

STEP 2 / Raw Materials

In the second step you can enter all required raw materials (APIs + Excipients) for your formulation.

Enter the name of the API >> Enter the price / kg of the API >> Enter the required quantity (mg/tablet) of the API
Enter the name of the Excipient >> Price / kg of the Excipient >> Required quantity (mg/tablet) of the Excipient

-  = use this button to add the API to the list Active Ingredient(s)
-  = use this button to switch to the edit modus / now you can adjust again all figures.
-  = use this button to delete the API

| STEP 2 / Raw Materials | | | | | | | | | |
|------------------------------|------------|-------------------------------------|-------------|--|---|-------------------------------------|-------------|---|---|
| Active Ingredient(s) | | | | | | | | | |
| Price / kg | | mg / tablet | | | | | | | |
| 0 € / kg | | 0 mg | | | | | | | |
| What's the name of your API? | | | | | | | | | |
| Wet Granulation (WG) | | | | | Direct Compression (DC) | | | | |
| API | price / kg | WG | mg / tablet | Total weight [kg] | Total price [€] | DC | mg / tablet | Total weight [kg] | Total price [€] |
| Ibuprofen | 10,00 €/kg | <input checked="" type="checkbox"/> | 400 mg | 345,66 kg <small>Loss: 16,46 kg</small> | 3 456,60 € <small>Loss: 164,60 €</small> | <input type="checkbox"/> | 400 mg | 339,08 kg <small>Loss: 9,88 kg</small> | 3 390,76 € <small>Loss: 98,76 €</small> |
| Ibuprofen DC... | 12,00 €/kg | <input type="checkbox"/> | 400 mg | 345,66 kg <small>Loss: 16,46 kg</small> | 4 147,92 € <small>Loss: 197,52 €</small> | <input checked="" type="checkbox"/> | 400 mg | 339,08 kg <small>Loss: 9,88 kg</small> | 4 068,91 € <small>Loss: 118,51 €</small> |
| Sum: | | | | 345,66 kg <small>Loss: 16,46 kg</small> | 3 456,60 € <small>Loss: 164,60 €</small> | | | 339,07 kg <small>Loss: 9,87 kg</small> | 4 068,91 € <small>Loss: 118,51 €</small> |

Check the corresponding box if the API is used for Wet Granulation (WG) or Direct Compression (DC). Check both boxes if the API can be used in both manufacturing methods. The color coding provides a quick overview.

| Excipient(s) | | | | | | | | | |
|---|------------|-------------------------------------|-------------|---|--|-------------------------------------|-------------|---|--|
| Price / kg | | mg / tablet | | | | | | | |
| 0 € / kg | | 0 mg | | | | | | | |
| What's the name of your excipient beside lactose? | | | | | | | | | |
| Wet Granulation (WG) | | | | | Direct Compression (DC) | | | | |
| Excipient | price / kg | WG | mg / tablet | Total weight [kg] | Total price [€] | DC | mg / tablet | Total weight [kg] | Total price [€] |
| Granulac 200 | 2,50 €/kg | <input checked="" type="checkbox"/> | 300 mg | 259,25 kg <small>Total price: 12,35 kg Loss: 30,86 €</small> | 648,11 € <small>Loss: 30,86 €</small> | <input type="checkbox"/> | 0 mg | 0,00 kg <small>Loss: 0,00 kg</small> | 0,00 € <small>Loss: 0,00 €</small> |
| Tabletose 1... | 4,00 €/kg | <input type="checkbox"/> | 0 mg | 0,00 kg <small>Total price: 0,00 kg</small> | 0,00 € <small>Loss: 0,00 €</small> | <input checked="" type="checkbox"/> | 300 mg | 254,31 kg <small>Loss: 7,41 kg</small> | 1 017,23 € <small>Loss: 29,63 €</small> |
| X-PVP | 12,00 €/kg | <input checked="" type="checkbox"/> | 25 mg | 21,60 kg <small>Total price: 1,03 kg</small> | 259,25 € <small>Loss: 12,35 €</small> | <input checked="" type="checkbox"/> | 25 mg | 21,19 kg <small>Loss: 0,62 kg</small> | 254,31 € <small>Loss: 7,41 €</small> |
| Sum: | | | | 280,84 kg <small>Loss: 13,37 kg</small> | 907,36 € <small>Loss: 43,20 €</small> | | | 275,49 kg <small>Loss: 8,02 kg</small> | 1 271,54 € <small>Loss: 37,03 €</small> |

Check the corresponding box if the Excipient is used for Wet Granulation (WG) or Direct Compression (DC). Check both boxes if the Excipient can be used in both manufacturing methods. The color coding provides a quick overview.

At the bottom of STEP 2 you will find a summary about the raw materials used for the different production methods.
Information: Total weight in mg >> Total amount of raw materials in kg >> Total price of raw material

| Summary Raw Materials | | | | | | | | | | | |
|---|----|--------------------------------|----|------------------------------|---|----------------|----|--------------------------------|----|------------------------------|---|
| Tablet weight: <small>without granulation liquid</small> | | Total amount of raw materials: | | Total price of raw material: | | Tablet weight: | | Total amount of raw materials: | | Total price of raw material: | |
| WG | | WG | | WG | | DC | | DC | | DC | |
| 725,00 | mg | 626,50 | kg | 4 363,96 | € | 725,00 | mg | 614,56 | kg | 5 340,45 | € |

STEP 3 / Process Costs

In the third step you are able to enter all your process parameter and process costs. On the left hand side you will find the typical process step for wet granulation arranged according to their typical sequence. The same logic you can find on the right hand side for the direct compression process.

HOW TO CREATE A NEW PROCESS STEP?

Between the different process step you will find these „plus buttons“. Click on this button to create a new process step at this certain position. 

A pop-up window will open in which you can choose the „type“ of process step you would like to add e.g. a screening, milling or granulation step.

Furthermore you can name the process step according to your requirements.

Finally you can determine if this process step is relevant for both production methods or only for one.

HOW TO DELETE A PROCESS STEP?

Between the different process step you will find these „minus buttons“. Click on this button to delete a process step at this certain position. 

HOW TO RENAME A PROCESS STEP?

In the headline of each process step you will find these „pencil symbols“. Click on this symbol to rename the process step according to your needs. 

HOW TO FADE IN THE PROCESS DETAILS?

For each process step it is possible to fade in or rather to fade out the details. This can be done with a „click“ on the ^ symbol. 

For each process step it is possible to fade in or rather to fade out the details. This can be done with a „click“ on the ^ symbol.

Raw Material Income Control ^

Average cost of API analysis:
150 €

Average cost of Excipient analysis:
100 €

Total analytical costs / Income control:
750,00 €

prev. step next step

Use data for DC >

All input fields colored in purple or orange must be filled by the user.

All calculation fields / information fields are shown greyed. You can influence these figures by adjusting the figures in the purple/orange input fields.

Navigation area:

With the buttons „prev. step“ and „next step“ you can jump back and forth. With the button „use data for DC“ you can transfer all taken input data from the wet granulation side to the direct compression side. Of course this is only valid for the certain process step.

EXPLANATION OF THE DIFFERENT PROCESS STEP:

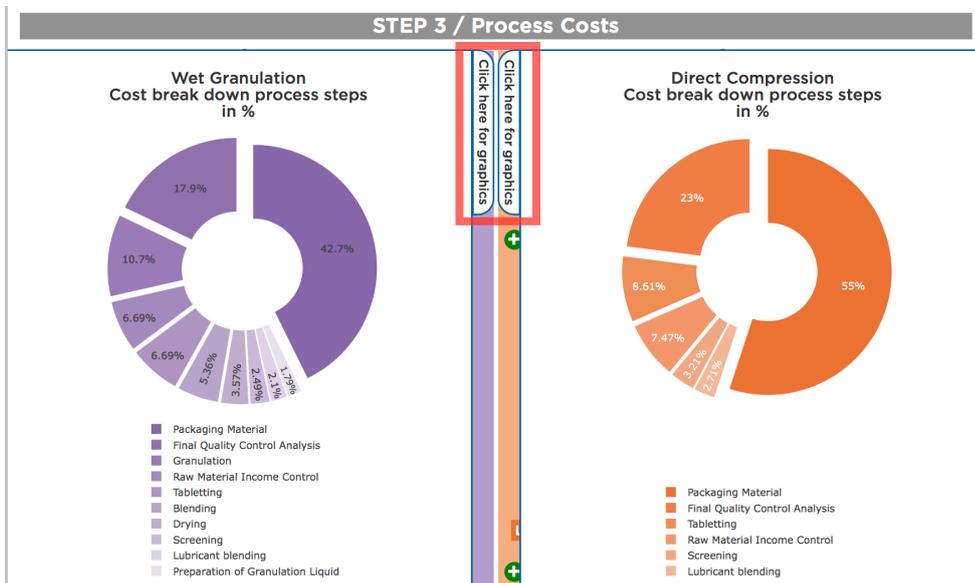
| | | | |
|--|---|--|--|
| <p>Raw Material Income Control ^</p> <p>Average cost of API analysis: Analysis cost per API in €</p> <p>Average cost of Excipient analysis: Analysis cost per Excipient €</p> <p>Total analytical costs / Income control: 0,00 €</p> <p>prev. step next step</p> <p>Use data for DC ></p> | <p>In the process step Raw Material Income Control:</p> <p>You can enter your analysis costs per API as well as your analysis costs per Excipient.</p> | <p>Screening ^</p> <p>Capacity per hour: How many kg can be screened? kg</p> <p>Total set up time: How many hours you need for setting up? h</p> <p>Final cleaning time: How long is your final cleaning? h</p> <p><input checked="" type="checkbox"/> Intermediate cleaning?</p> <p>Intermediate cleaning interval: Intermediate cleaning - every? h</p> <p>Intermediate cleaning time: How long does intermediate cleaning take? h</p> <p>Total cleaning time: 0,00 h</p> <p>Process time Screening: 0,00 h</p> <p>Cost rate per hour: Cost rate per hour? €</p> <p>Process costs Screening: 0,00 €</p> <p>prev. step next step</p> <p>Use data for DC ></p> | <p>In the process step Screening:</p> <p>Capacity of your screening equipment (kg / h).</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox</p> <p>What's your cleaning interval and how long you clean.</p> <p>What is your cost rate per hour for screening?</p> |
| <p>Final Quality Control Analysis ^</p> <p>Total cost of QC analysis: €</p> <p>prev. step next step</p> <p>Use data for DC ></p> | <p>In the process step Final Quality Control Analysis</p> <p>You can enter your total cost of QC analysis for your produced batch of tablets.</p> | | |

| | | |
|--|--|---|
| <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: center; margin: 0;">Blending ^</p> <p>Capacity of the blender: How many kg can be processed? <input type="text" value="0"/> kg</p> <p>Mixing time: Required time to prepare homogeneous blend <input type="text" value="0"/> h</p> <p>Total set up time: How many hours you need for setting up the equipment <input type="text" value="0"/> h</p> <p>Final cleaning time: How long is your final cleaning <input type="text" value="0"/> h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: <input type="text" value="0,00"/> h</p> <p>Process time Blending: <input type="text" value="0,00"/> h</p> <p>Cost rate per hour: Cost rate per hour? <input type="text" value="0"/> €</p> <p>Process costs Blending: <input type="text" value="0,00"/> €</p> <p style="text-align: center;"> <input type="button" value="prev. step"/> <input type="button" value="next step"/> </p> <p style="text-align: center;"><input type="button" value="Use data for DC >"/></p> </div> | <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: center; margin: 0;">Lubricant blending ^</p> <p>Capacity of the blender: How many kg can be processed? <input type="text" value="0"/> kg</p> <p>Mixing time: Required time to prepare homogeneous blend <input type="text" value="0"/> h</p> <p>Total set up time: How many hours you need for setting up the equipment <input type="text" value="0"/> h</p> <p>Final cleaning time: How long is your final cleaning <input type="text" value="0"/> h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: <input type="text" value="0,00"/> h</p> <p>Process time Blending: <input type="text" value="0,00"/> h</p> <p>Cost rate per hour: Cost rate per hour? <input type="text" value="0"/> €</p> <p>Process costs Blending: <input type="text" value="0,00"/> €</p> <p style="text-align: center;"> <input type="button" value="prev. step"/> <input type="button" value="next step"/> </p> <p style="text-align: center;"><input type="button" value="Use data for DC >"/></p> </div> | <p>In the process step „Blending“ and „Lubricant blending“:</p> <p>Capacity of your blender (kg / h).</p> <p>Mixing time = Required time to prepare homogeneous blend.</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox (Input fields explained in process step Screening)</p> <p>What is your cost rate per hour for screening?</p> |
| <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: center; margin: 0;">Preparation of Granulation Liquid ^</p> <p>Preparation time: Required time to prepare your granulation liquid <input type="text" value="0"/> h</p> <p>Total set up time: How many hours you need for setting up the equipment <input type="text" value="0"/> h</p> <p>Final cleaning time: How long is your final cleaning <input type="text" value="0"/> h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: <input type="text" value="0,00"/> h</p> <p>Process time granulation liquid: <input type="text" value="0,00"/> h</p> <p>Cost rate per hour: Cost rate per hour? <input type="text" value="0"/> €</p> <p>Process costs granulation liquid: <input type="text" value="0,00"/> €</p> <p style="text-align: center;"> <input type="button" value="prev. step"/> <input type="button" value="next step"/> </p> <p style="text-align: center;"><input type="button" value="Use data for DC >"/></p> </div> | <p>In the process step „Preparation Granulation Liquid“</p> <p>Required time to prepare your granulation liquid (h).</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox (Input fields explained in process step Screening)</p> <p>What is your cost rate per hour for the preparation of the granulation liquid?</p> | <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: center; margin: 0;">Granulation ^</p> <p>Capacity of granulation equipment: How many kg can be processed? <input type="text" value="0"/> kg</p> <p>Granulation time: Required time to prepare granulation <input type="text" value="0"/> h</p> <p>Total set up time: How many hours you need for setting up the equipment <input type="text" value="0"/> h</p> <p>Final cleaning time: How long is your final cleaning <input type="text" value="0"/> h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: <input type="text" value="0,00"/> h</p> <p>Process time Granulation: <input type="text" value="0,00"/> h</p> <p>Cost rate per hour: Cost rate per hour? <input type="text" value="0"/> €</p> <p>Process costs Granulation: <input type="text" value="0,00"/> €</p> <p style="text-align: center;"> <input type="button" value="prev. step"/> <input type="button" value="next step"/> </p> <p style="text-align: center;"><input type="button" value="Use data for DC >"/></p> </div> <p>In the process step „Preparation Granulation Liquid“</p> <p>Capacity of your granulator (kg / h).</p> <p>Required granulation time (h).</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox (Input fields explained in process step Screening)</p> <p>What is your cost rate per hour for the granulation?</p> |

| | | | |
|---|--|---|---|
| <p>Drying</p> <p>Capacity of drying equipment: How many kg can be produced? kg</p> <p>Drying time: Required time to dry the granules? h</p> <p>Total set up time: How many hours you need for setting up the equipment? h</p> <p>Final cleaning time: How long is your final cleaning? h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: 0,00 h</p> <p>Process time Drying: 0,00 h</p> <p>Cost rate per hour: Cost rate per hour? €</p> <p>Process costs Drying: 0,00 €</p> <p>prev. step next step Use data for DC ></p> | <p>In the process step „Drying“</p> <p>Capacity of your drying equipment (kg).</p> <p>Required drying time (h)</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox (Input fields explained in process step Screening)</p> <p>What is your cost rate per hour for drying?</p> | <p>Tabletting</p> <p>No. of tablets to be produced: 0 pcs.</p> <p>Tabletting speed: How many tablets can be produced per hour? pcs./h</p> <p>Total set up time: How many hours you need for setting up the equipment? h</p> <p>Final cleaning time: How long is your final cleaning? h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: 0,00 h</p> <p>Process time Tabletting: 0,00 h</p> <p>Cost rate per hour: Cost rate per hour? €</p> <p>Process costs Tabletting: 0,00 €</p> <p>prev. step next step Use data for DC ></p> | <p>In the process step „Tabletting“</p> <p>No. of tablets will be taken for STEP 1 - Basic information.</p> <p>How many tablets you can produce per hour (pcs./h)</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox (Input fields explained in process step Screening)</p> <p>What is your cost rate per hour for the tabletting?</p> |
| <p>Packaging Material</p> <p>No. of tablets to be packed: 0 pcs.</p> <p>Packaging speed: How many tablets can be packed per hour? pcs./h</p> <p>Total set up time: How many hours you need for setting up the equipment? h</p> <p>Final cleaning time: How long is your final cleaning? h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: 0,00 h</p> <p>Process time Packaging: 0,00 h</p> <p>Cost rate per hour: Cost rate per hour? €</p> <p>No. of tablets per package: How many tablets can be packed in one package? pcs.</p> <p>Price per packaging unit: What is the combined price per unit? €</p> <p>Costs packaging material: 0,00 €</p> <p>Process costs Packaging: 0,00 €</p> <p>prev. step next step Use data for DC ></p> | <p>In the process step „Packaging Material“</p> <p>No. of tablets will be taken for STEP 1 - Basic information.</p> <p>How many tablets you can pack per hour (pcs./h)</p> <p>Set up time - how many hours you need for setting up the equipment.</p> <p>How long will it take to clean your equipment (final cleaning)</p> <p>In case you have intermediate cleaning tick the checkbox (Input fields explained in process step Screening)</p> <p>What is your cost rate per hour for the packing?</p> <p>How many tablets you can pack in one packaging unit?</p> <p>Price per packaging unit?</p> | <p>Miscellaneous Step</p> <p>Capacity of equipment: How many kg can be produced? kg</p> <p>Required time of action: How many hours you need for the action? h</p> <p>Total set up time: How many hours you need for setting up the equipment? h</p> <p>Final cleaning time: How long is your final cleaning? h <input type="checkbox"/> Intermediate cleaning?</p> <p>Total cleaning time: How long do you clean your equipment? h</p> <p>Process time: 0,00 h</p> <p>Cost rate per hour: Cost rate per hour? €</p> <p>Process costs: 0,00 €</p> <p>prev. step next step Use data for DC ></p> | <p>In the process step „Miscellaneous Step“</p> <p>If you would like to add an additional process step, these miscellaneous step can be used and adjusted to your requirements.</p> <ul style="list-style-type: none"> - Capacity input field (kg) - Processing input field (h) - Set up time (h) - Cleaning time (h) - Intermediate cleaning - Cost rate per hour |

STEP 3 - PROCESS COSTS / GRAPHIC FEATURES

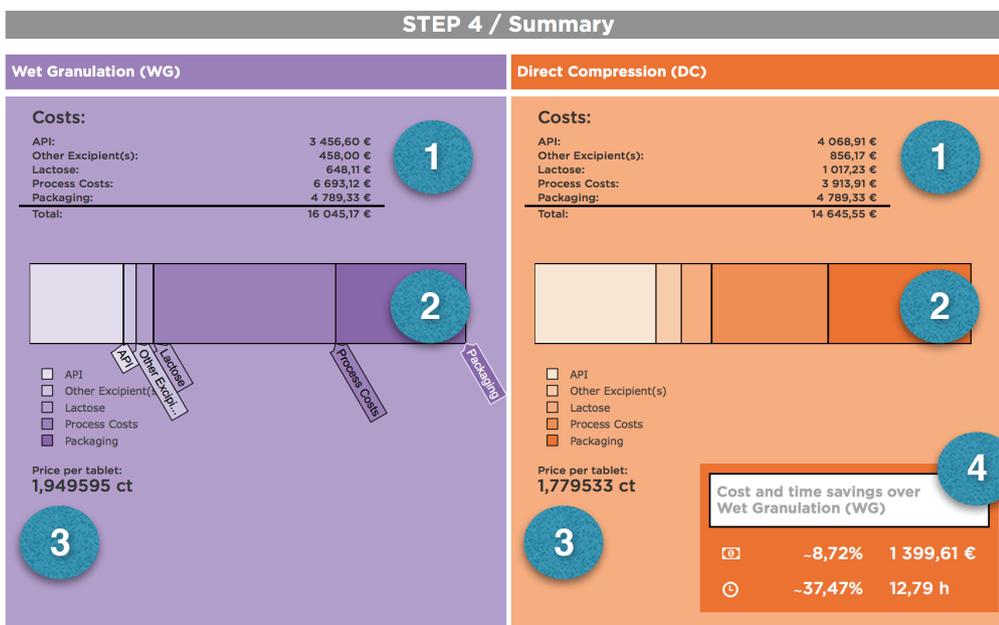
On the left side in section „wet granulation“ as well as on the right side in section „direct compression“ you will find so called slide in buttons „Click here for graphics“ in order to give you a diagram about the cost breakdown of the single process step. These diagrams will be updated on the fly. This means if you adjust your figures you will see the impact in the diagram immediately. Give it a try.



STEP 4 / Summary

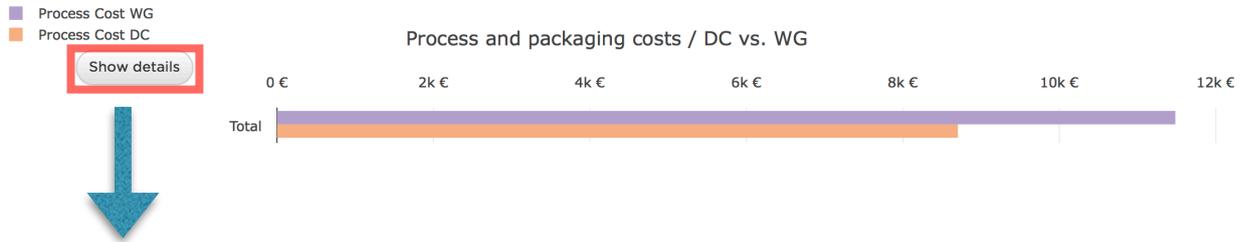
In the last step „Summary“ you will see if a switch to direct compression is advisable due to increased efficiency. Furthermore you need to consider savings in process- and packaging time!

- 1 In the first table you will find the costs for the different components of your formulation e.g. the costs for the API >> costs for Other Excipient(s) >> costs for Lactose >> Process costs >>Packaging costs. These figures will be updated on the fly. This means if you adjust your figures in STEP 1-3, you will see the impact immediately. Give it a try.
- 2 In the middle part of the summary you will find the graphic presentation of the figures mentioned in point 1.
- 3 At the bottom of the summary you will find the information about the price per tablet.
- 4 This info box shows you the cost and time savings of direct compression over wet granulation. This means how much money and time you can save by using direct compression (€/ \$ + %).



In the bottom part of STEP 4 you will get two additional graphs.

The first graph compares the process and packaging costs of the two different production methods. If you hover of the colored bars, the exact numbers are shown. If you click on the button „Show details“ you can see the detailed cost report.



The second graph compares the process and packaging time of the two different production methods. If you hover of the colored bars, the exact numbers are shown. If you click on the button „Show details“ you can see the processing times per position.

“Time is money“ therefore please carefully check possible savings in this area.

