

Creation of Product Target and Strengths

Contents

Introduction.....	2
Product Target creation	2
Product Strength creation	5
Sandoz Product Target creation (different Salt)	7
Sandoz Product Target creation (different Dosage Form).....	9

Introduction

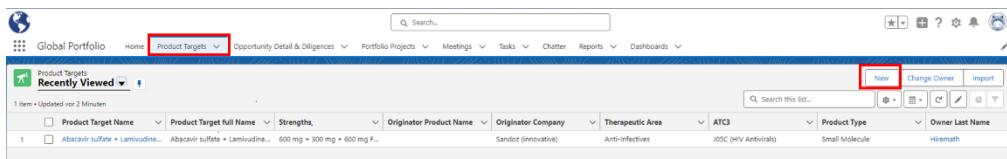
The documentation of originator's reference product in SANITY is termed as Product Target. Product Targets are defined by API (INN + Salt), Dosage Form, Strength, Therapeutic Area, ATC, Originator company, Brand name etc.

With the latest changes introduced in the Product Architecture, SANITY functionality has been enhanced to reflect complex products with different Dosage Forms and complex pack configurations.

The main conceptual change is Dosage Form will be an attribute of Product Strength instead of attribute of API. This enables the recording of complex products with different Dosage Forms underneath one Product Target.

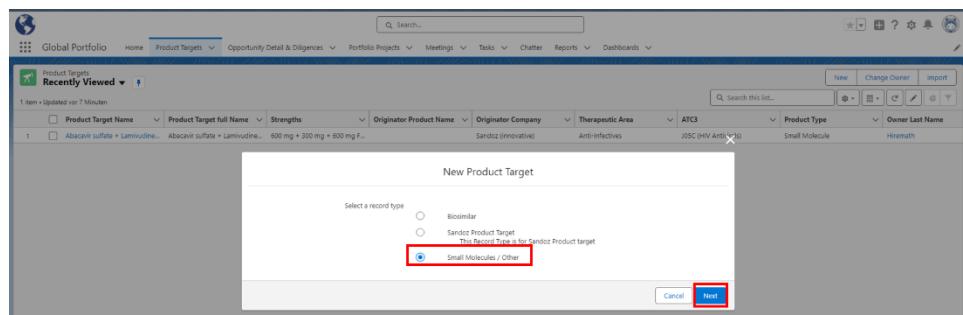
In this context, creation process of Product Target, Product Strength and Sandoz Product Target has been adopted. The detailed information is described below.

Product Target creation



Please go to the "Product Targets" tab in your navigation bar.

Please click on "New" button.



Please select the type of the Product Target you want to create.

New Product Target

Information

Product Target Name	Calculated upon save	Originator Company	optional	Originator Product Name	optional
* Product Type	--None--	* ATC1	--None--	* Therapeutic Area	--None--
ATC3	--None--	mandatory information			

Product Core Substances

* Product Core Substance 1	Search Target API's...	Cancel	Save
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Add Core Substance

Please add product information needed – “Product Type”, “ATC1” and “Therapeutic area” are mandatory information to provide. “Originator Company” and “Originator Product Name” – are optional.

New Product Target

Information

Product Target Name	Calculated upon save	Originator Company	Merck & Co.	Originator Product Name	Janumet
* Product Type	Small Molecule	* ATC1	A (Alimentary Tract & Metabolism)	* Therapeutic Area	Alimentary
ATC3	--None--				

Product Core Substances

* Product Core Substance 1	Sita	Cancel	Save
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Add Core Substance

Sita

Show All Results for "Sita"

- Sitaflloxacin hydrate
- Sitaflloxacin
- Sitagliptin
- Sitagliptin
- Sitagliptin hydrochloride
- Sitagliptin
- Sitagliptin phosphate
- Sitagliptin
- Sitaxentan sodium
- Sitaxentan

Please define Core Substance(s). Please choose the API from already existing API library. If you don't find the API you need, please contact API sourcing team to create the needed API.

New Product Target

Information

Product Target Name	Calculated upon save
Originator Company	Merck & Co.
* Product Type	Small Molecule
* ATC1	A (Alimentary Tract & Metabolism)
ATC3	--None--
Originator Product Name	Janumet
* Therapeutic Area	Alimentary

Product Core Substances

- * Product Core Substance 1: Sitagliptin phosphate

Add Core Substance

Cancel Save

Please click on “Add Core Substances” button if your product consists of more than 1 API.

New Product Target

Information

Product Target Name	Calculated upon save
Originator Company	Merck & Co.
* Product Type	Small Molecule
* ATC1	A (Alimentary Tract & Metabolism)
ATC3	--None--
Originator Product Name	Janumet
* Therapeutic Area	Alimentary

Product Core Substances

- * Product Core Substance 1: Sitagliptin phosphate
- * Product Core Substance 2: Metfor

Add Core Substance

Cancel Save

Please follow the same process to record all the APIs needed in your Product Target.

Please click on “Save”.

Your Product Target has been created. You will be redirected to newly created Product Target, so that you can add additional details.

Sandbox QA | Logout

Global Portfolio Home Product Targets Opportunity Detail & Diligences Portfolio Projects Meetings Tasks Chatter Reports Dashboards

Product Target Sitagliptin phosphate + Metformin hydrochloride [Janumet]

Originator Company Merck & Co. Therapeutic Area Alimentary Product Type Small Molecule Strengths

New Assessment Polymorph Screening Pre-Dev Selection Decision

In order for NITY product structure to reflect the complex product landscape of SANDOZ, we have moved the dosage form information to the Product strength level. Please reach out to your Portfolio Operations Team for details.

Details Selections & Escalations Patents & Reg Strengths & Sndz Targets Packs & Units Forecasts BD & Scouting Quip

Product Target full Name	Sitagliptin phosphate + Metformin hydrochloride [Janumet]	Originator Product Logo
Originator Company	Merck & Co.	Alimentary
Originator Product Name	Janumet	ATC1 A (Alimentary Tract & Metabolism)
Pharm compound number		ATC3
Product Type	Small Molecule	SIPT Product ID
REGO		Category
Medical Device		
Product Comment		
Platforms		
COO - Global Platforms (PT)		STO - Technical Operating Units (PT)
COO - Development Platforms (PT)		
Selection Review Criteria		

Product Target APIs (2)

PTAPR-0000000101	Sitagliptin phosphate
Target API Name:	
API Sequence:	1
PTAPR-0000000102	Metformin hydrochloride
Target API Name:	
API Sequence:	2
View All	

Files (0)

Upload Files Or drop files

Pre-Launch Forecast Review Potential Allocation More

All Sandoe Pre-Launch Forecasts w or w/o Product Rights (6 unsigned BD)

You can see various details of Product Target in the “Details” tab in your Product Target. You will get the information about the API(s) in the “Product Target APIs” section located in the right side of your screen.

Product Strength creation

This screenshot shows the 'Product Targets' page for 'Sitagliptin phosphate + Metformin hydrochloride [Janumet]'. The 'Strengths & Sndz Targets' tab is highlighted with a red box. On the right, the 'Product Target APIs' section displays two entries: PTAPI-0000008101 (Target API Name: Sitagliptin phosphate, API Sequence: 1) and PTAPI-0000008102 (Target API Name: Metformin hydrochloride, API Sequence: 2). A message at the top states: 'In order for SANITY product structure to reflect the complex product landscape of SANDOZ, we have moved the dosage form information to the Product strength level. Please reach out to your Portfolio Operations Team for details.'

Please start from respective Product Target, which you want to create the Product Strength(s) for. Please go to “Strengths & Sndz Targets” tab to see if any strength is already existing.

This screenshot shows the 'Product Targets' page for 'Sitagliptin phosphate + Metformin hydrochloride [Janumet]'. The 'Manage Strength / Dosage' button is highlighted with a red box. The 'Product Target APIs' section on the right shows the same two entries as the previous screenshot. The left panel contains detailed product information, including 'Product Target full Name' (Sitagliptin phosphate + Metformin hydrochloride [Janumet]), 'Therapeutic Area' (Alimentary), 'Product Type' (Small Molecule), and 'Originator Company' (Merck & Co.).

Please click on “Manage Strength / Dosage” button to create new Product Strength(s)/ edit existing Product Strength(s).

This screenshot shows the 'Define Strengths and Dosage Forms' dialog box. The 'Add Strength' button is highlighted with a red box. The dialog box has fields for 'Dosage Broad' and 'Dosage Form', both of which are currently empty.

Here, you will be able to see/ edit already created Product Strength(s), only if the Product Strength(s) have not yet been used in any Opp D&D or Portfolio Project.

Please click on “Add Strength” to add a new Strength.

This screenshot shows the 'Define Strengths and Dosage Forms' dialog box. The 'Dosage Broad' and 'Dosage Form' fields are highlighted with a red box. Below them are dropdown menus for 'Select Dosage Broad' and 'Select Dosage Form', and a 'Volume' field with a 'Select Vol...' dropdown and an 'Add API' button.

Please define Dosage Broad and Dosage Form. In case of liquids, injectables (except lyophilizates, powders and implants), respiratory, patches, please put the denominator part of the strength in the Volume field and the unit in the Volume Measure field.

Please check “Innovative Strength” checkbox only if this is an innovative strength from Sandoz and does not belong to the originator.

The screenshot shows the 'Define Strengths and Dosage Forms' wizard. At the top, there are dropdown menus for 'Innovative Strength' (set to 'Ir oral solid'), 'Dosage Broad' (set to 'FCT - TABLET, FILM-C...'), 'Dosage Form' (set to 'FCT - TABLET, FILM-C...'), 'Volume' (empty), 'Volume Measure' (empty), and 'Select Vol...' (empty). Below these are buttons for 'Add API...', 'Close', 'Add Strength', 'Add Inert Strength', and 'Save'. A red box highlights the 'Add API...' button.

Please click on “Add API” to record the strength quantities per API.

The screenshot shows the 'Define Strengths and Dosage Forms' wizard with 'Sitagliptin phosphate' selected in the 'Select API' dropdown. The 'Total Amount of Base API' field contains '50'. The 'Total Amount of API + SES' field contains '55'. The 'Unit' dropdown is set to 'mg'. A red box highlights the 'Total Amount of Base API' field.

Important: Please record the respective strength quantity under respective API in the “Total Amount of Base API” field.

The screenshot shows the 'Define Strengths and Dosage Forms' wizard with both 'Sitagliptin phosphate' and 'Metformin hydrochloride' selected in the 'Select API' dropdown. The 'Total Amount of Base API' field for Sitagliptin phosphate contains '50'. The 'Total Amount of API + SES' field for Sitagliptin phosphate contains '55'. The 'Total Amount of Base API' field for Metformin hydrochloride contains '500'. The 'Total Amount of API + SES' field for Metformin hydrochloride contains '560'. The 'Unit' dropdown is set to 'mg'. A red box highlights the 'Total Amount of API + SES' field for Sitagliptin phosphate.

If the API you are recording has a salt, you can also record the amount of API + Salt in the field “Total Amount of API + SES”.

In this example – If the Sitagliptin (Base INN) amount is 50 mg and Sitagliptin Phosphate (including SES) amount is 55 mg, please record 50 (mg) in “Total Amount of Base API” field and 55 (mg) in the field “Total Amount of API + SES”.

If you want your strength amount to show Total Amount of API including SES (in this example 55 mg), please check the checkbox – “Include SES value in name”. Then the strength will be shown as 55 mg (including SES) instead of 50 mg.

Please click on “Add API” button and repeat the process if your product has multiple APIs.

The screenshot shows the 'Define Strengths and Dosage Forms' wizard with two entries. The first entry is for 'Sitagliptin phosphate' with 'Total Amount of Base API' as '50' and 'Total Amount of API + SES' as '55'. The second entry is for 'Metformin hydrochloride' with 'Total Amount of Base API' as '500' and 'Total Amount of API + SES' as '560'. The 'Unit' dropdown is set to 'mg'. A red box highlights the 'Add Strength' button at the bottom right.

Please click on “Add Strength” button to record another Product Strength. In this wizard, you can add as many Product Strengths as you want in one go.

The screenshot shows the 'Define Strengths and Dosage Forms' section. It lists two dosage forms: 'FCT - TABLET, FILM-COATED || 50mg + 500mg || FCT' and 'FCT - TABLET, FILM-COATED || 100mg + 1000mg || FCT'. Each form has its quantity, total amount of base API, unit, and a checkbox for 'Include SES value in name'. The second dosage form is highlighted with a red border.

Please repeat the process for every strength. Please select the Proper Dosage Broad and Dosage Form for each Product Strength, as for complex products, Dosage Broad and Dosage Form might be different.
 Please click on "Save" button after you are done adding/ changing all Product Strength(s).
 Important: Please make use of the button "Add Inert Strength" if the product has any inert strength. For example – Some oral contraceptives like Estradiol valerate + Dienogest (NATAZIA) pack has 2 white inert tablets (contains no hormones) in the blister.

The screenshot shows the 'Strengths & Sndz Targets' tab. It lists two product strengths: 'FCT - 50 mg + 500 mg' and 'FCT - 100 mg + 1000 mg'. The right panel contains sections for 'Product Target APIs' and 'Files'.

Please go to "Strengths & Sndz Targets" tab to see the newly created Product Strength(s).

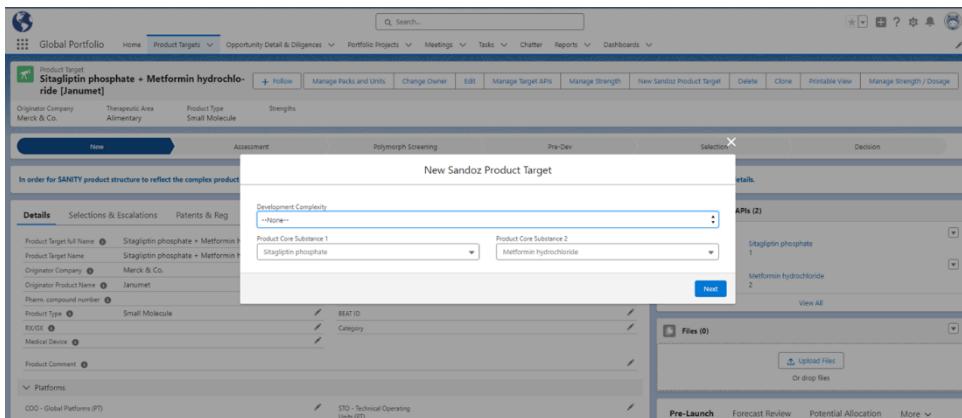
Sandoz Product Target creation (different Salt)

When Sandoz wants to develop a product with a different Dosage Form and/ or Salt than the Originator Product, a Sandoz Product Target needs to be created. The created Sandoz Product Target will always be linked to the reference Originator Product Target.

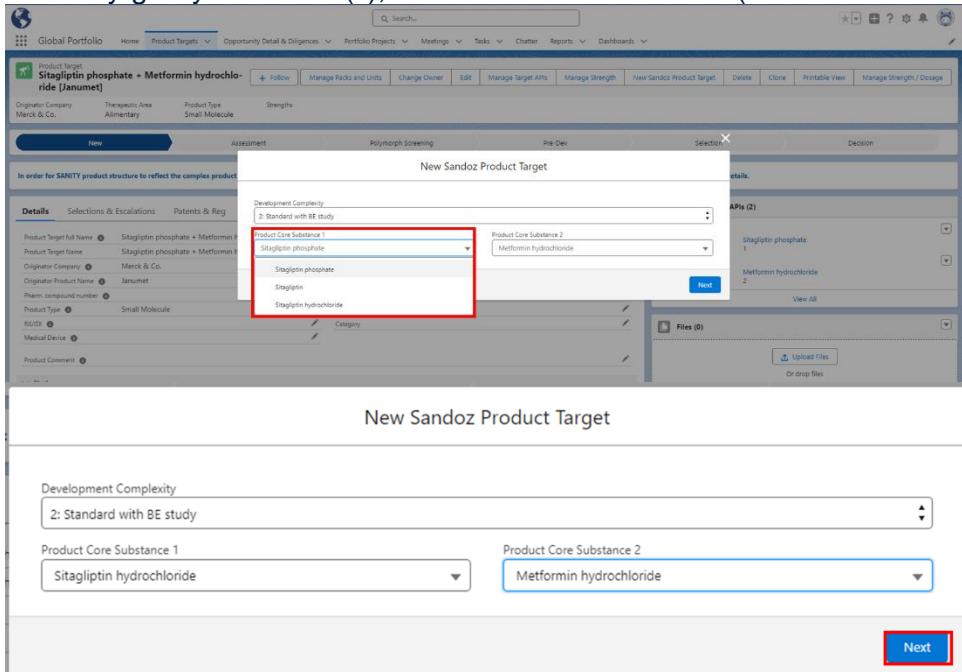
At first, we will show you an example of a Sandoz Product Target with a different salt.

The screenshot shows the 'New SDZ Product Target' button in the 'Strengths & Sndz Targets' tab. The right panel contains sections for 'Product Target APIs' and 'Files'.

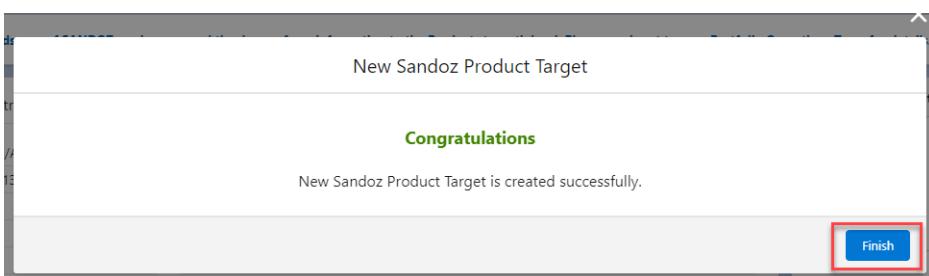
Please go to the reference Product Target in SANITY and Start from reference Product Target.
 Please click on the button "New SDZ Product Target".



Please choose the Development Complexity from the given dropdown if you already know the information. Please select the API(s) in the field(s) – “Product Core Substance x” and choose the correct API(s). SANITY will automatically give you the API(s), which have the same INN (with same or different salt).



In this example, we chose Sitagliptin hydrochloride instead of Originator's Sitagliptin Phosphate. Once you are done with choosing the correct API(s), please click on “Next” button.



Please click on “Finish” button to close the wizard.

All Strengths are shown below, both Innovator strengths and any strengths for Sandoz dosage forms.

Product Strengths (2)

Strength Link	Dosage + Strength	API Combination	Innovative Str
1 FCT - 50 mg + 500 mg	50 mg + 500 mg FCT	Sitagliptin phosphate + Metformin hydrochloride	<input type="checkbox"/>
2 FCT - 100 mg + 1000 mg	100 mg + 1000 mg FCT	Sitagliptin phosphate + Metformin hydrochloride	<input type="checkbox"/>

Product Targets (2)

Product Target Name	Strengths
1 Sitagliptin hydrochloride + Metformin hydrochloride	50 mg + 500 mg TAB, 100 mg + 1000 mg TAB
2 Sitagliptin phosphate + Metformin hydrochloride TAB	

Product Target APIs (2)

PTAPI-0000008101	Target API Name: Sitagliptin phosphate
PTAPI-0000008102	Target API Name: Metformin hydrochloride

Files (0)

Pre-Launch Forecast Review Potential Allocation In-Market

All Sandoz Pre-Launch Forecasts w or w/o Product Rights (ie unsigned BD)

We can't draw this chart because there is no data.

To find created Sandoz Product Target, please go to “Strengths & Sndz Targets” tab. Now you can add Product Strength(s) as needed for the newly created Sandoz Product Target.

Sandoz Product Target creation (different Dosage Form)

As stated earlier, when Sandoz wants to develop a product with a different Dosage Form and/ or Salt than the Originator Product, a Sandoz Product Target needs to be created. The created Sandoz Product Target will always be linked to the reference Originator Product Target.

In this step, we will show you an example of a Sandoz Product Target with same salt but different Dosage Form.

All Strengths are shown below, both Innovator strengths and any strengths for Sandoz dosage forms.

Product Strengths (2)

Strength Link	Dosage + Str...	API Combination	Innovative ...	GMD Status
1 FCT - 50 mg + 500 mg	50 mg + 500 mg KCT	Sitagliptin phosphate + Metformin hydrochloride	<input type="checkbox"/>	Draft
2 FCT - 100 mg + 1000 mg	100 mg + 1000 mg F...	Sitagliptin phosphate + Metformin hydrochloride	<input type="checkbox"/>	Draft

Product Targets (1)

Product Target Name	Strengths
1 Sitagliptin hydrochloride + Metformin hydrochloride	

Product Target APIs (2)

PTAPI-0000008101	Target API Name: Sitagliptin phosphate
PTAPI-0000008102	Target API Name: Metformin hydrochloride

Files (0)

Pre-Launch Forecast Review Potential Allocation More

All Sandoz Pre-Launch Forecasts w or w/o Product Rights (ie unsigned BD)

We can't draw this chart because there is no data.

Please go to the reference Product Target in SANITY and Start from reference Product Target. Please click on the button “New SDZ Product Target”.

New Sandoz Product Target

Development Complexity

-None--

Product Core Substance 1

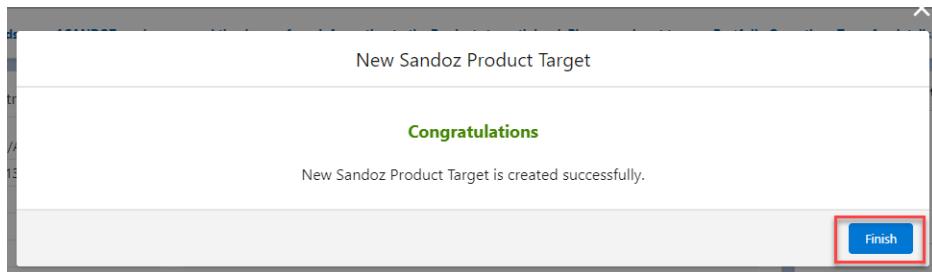
Sitagliptin phosphate

Product Core Substance 2

Metformin hydrochloride

Next

Please choose the Development Complexity from the given dropdown if you already know the information. Please keep the API(s) unchanged as you want to create a Sandoz Product Target with same salt. Once you are done with this step, please click on “Next” button.



Please click on “Finish” button to close the wizard.

To find created Sandoz Product Target, please go to “Strengths & Sndz Targets” tab.

Now, to add Product Strength(s) with different Dosage Form for this particular Sandoz Product Target, please go to the Sandoz Product Target and click on “Manage Strength / Dosage” button.

Here, you will be able to see/ edit already created Product Strength(s) (connected to this particular Sandoz Product Target), only if the Product Strength(s) have not yet been used in any Opp D&D or Portfolio Project.

Please click on “Add Strength” to add a new Strength.

Please define Dosage Broad and Dosage Form. In case of liquids, injectables (except lyophilizates, powders and implants), respiratory etc. products, please put the denominator part of the strength in the “Volume” field and the unit in the “Volume Measure” field.

In this example, we are showing you the use case where, Sandoz wants to develop a Tab (Tablet) instead of Originator’s FCT (Film Coated Tablet).

Please check “Innovative Strength” checkbox only if this is an innovative strength from Sandoz and does not belong to the originator.

Please click on “Add Strength” button to record another Product Strength corresponding to this particular Sandoz Product Target. In this wizard, you can add as many Product Strength(s) (corresponding to this particular Sandoz Product Target) as you want in one go (as described in the Product Strength creation section).

Please repeat the process for every Product Strength(s) you want to create.

Please click on “Save” button after you are done adding all Product Strength(s) corresponding to this particular Sandoz Product Target.

Product Strengths Name	Strength Amount	Innovative Strength	Product Target	Product Strength
1 PS - 0009012	50 mg + 500 mg	<input type="checkbox"/>	Sitagliptin phosphate + Metformin hydrochloride TAB	50 mg + 500 mg
2 PS - 0009013	100 mg + 1000 mg	<input type="checkbox"/>	Sitagliptin phosphate + Metformin hydrochloride TAB	100 mg + 1000 mg

To see all the Product Strength(s) you have created, please go to the particular Sandoz Product Target, click on “Strengths & Sndz Targets” tab and hover-over/ click on “Product Strengths (Sandoz Product Target)” related list.