



Creation of Product Target and Strengths

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Introduction

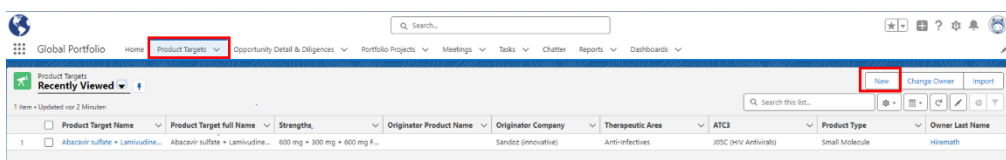
The documentation of originator's reference product in SANITY is termed as Product Target. Product Targets are defined by API (INN + Salt), Dosage Form, Strength, Therapeutic Area, ATC, Originator company, Brand name etc.

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.

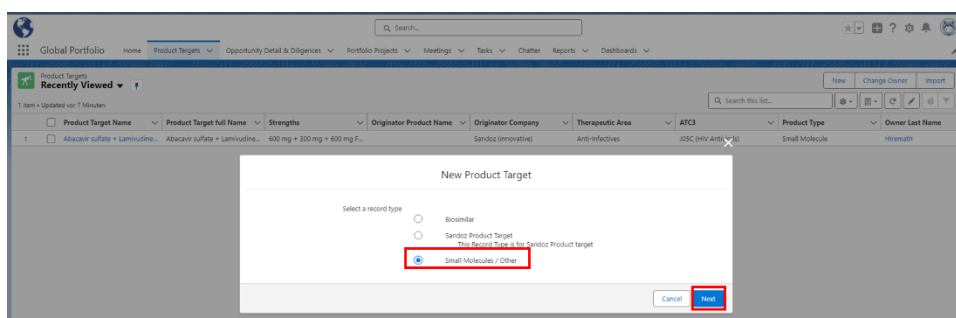
The main conceptual change is Dosage Form will be an attribute of Product Strength instead of attribute of API. This enables the recording of complex products with different Dosage Forms underneath one Product Target.

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--

* Therapeutic Area: --None--

* ATC1: --None--

ATC3: --None--

mandatory information

Product Core Substances

* Product Core Substance 1: Search Target API's...

[Add Core Substance](#)

[Cancel](#) [Save](#)

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

* Therapeutic Area: Alimentary

* ATC1: A (Alimentary Tract & Metabolism)

ATC3: --None--

Product Core Substances

* Product Core Substance 1: Sital

[Add Core Substance](#)

Search results for "Sita":

- Sitafloracin hydrate
- Sitafloracin
- Sitagliptin
- Sitagliptin
- Sitagliptin hydrochloride
- Sitagliptin
- Sitagliptin phosphate**
- Sitagliptin
- Sitaxentan sodium
- Sitaxentan

[Cancel](#) [Save](#)

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. Originator Product Name: Janumet

* Product Type: Small Molecule * Therapeutic Area: Alimentary

* ATC1: A (Alimentary Tract & Metabolism) ATC3: --None--

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. Originator Product Name: Janumet

* Product Type: Small Molecule * Therapeutic Area: Alimentary

* ATC1: A (Alimentary Tract & Metabolism) ATC3: --None--

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.

Sandoz OA | Logout

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

Product Target
Staglipitin phosphate + Metformin hydrochloride (Janumet)

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

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

Product Target full Name: Staglipitin phosphate + Metformin hydrochloride (Janumet) Originator Product Logo:

Product Target Name: Staglipitin phosphate + Metformin hydrochloride Therapeutic Area: Alimentary

Originator Company: Merck & Co. ATC1: A (Alimentary Tract & Metabolism)

Originator Product Name: Janumet ATC3: A (Alimentary Tract & Metabolism)

Pharm. compound number: SPRINT Product ID: BEAT ID: Category:

Product Type: Small Molecule

RUGA: Medical Device:

Product Comment:

Product Target APIs (2)

PTAP: 0000008101 Target API Name: Sitagliptin phosphate API Sequence: 1

PTAP: 0000008102 Target API Name: Metformin hydrochloride API Sequence: 2

[View All](#)

File (0)

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Or drop files

Pre-Launch Forecast Review Potential Allocation More

All Sandoz Pre-Launch Forecasts w or w/o Product Rights (ie unassigned 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

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.

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

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.

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.

Define Strengths and Dosage Forms

FCT

Innovative Strength ☐ Dosage Broad *Dosage Form Volume Volume Measure **Add API**

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

Define Strengths and Dosage Forms

FCT

Innovative Strength ☐ Dosage Broad *Dosage Form Volume Volume Measure **Add API**

Select API Total Amount of Base API Total Amount of API + SES Unit Include SES value in name ☐

Sitagliptin phosphate
Metformin hydrochloride

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

Define Strengths and Dosage Forms

Sitagliptin phosphate || 50mg || FCT

Innovative Strength ☐ Dosage Broad *Dosage Form Volume Volume Measure **Add API**

Quantity Total Amount of Base API Total Amount of API + SES Unit Include SES value in name ☐

Sitagliptin phospho... 50 55 mg

Define Strengths and Dosage Forms

Sitagliptin phosphate || 50mg || FCT

Innovative Strength ☐ Dosage Broad *Dosage Form Volume Volume Measure **Add API**

Quantity Total Amount of Base API Total Amount of API + SES Unit Include SES value in name ☐

Sitagliptin phospho... 50 55 mg

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.

Define Strengths and Dosage Forms

Sitagliptin phosphate - Metformin hydrochloride || 50mg - 500mg || FCT

Innovative Strength ☐ Dosage Broad *Dosage Form Volume Volume Measure **Add API**

Quantity Total Amount of Base API Total Amount of API + SES Unit Include SES value in name ☐

Sitagliptin phospho... 50 55 mg

Quantity Total Amount of Base API Total Amount of API + SES Unit Include SES value in name ☐

Metformin hydroch... 500 500 mg

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.

Define Strengths and Dosage Forms

Sitagliptin phosphate + Metformin hydrochloride || 50mg + 500mg || FCT

Imprecise Strength: ☐ **Dosage Broad:** **Dosage Form:** **Volume:** **Volume Measure:** ☐ **Include SES value in name:** ☐

Quantity: **Total Amount of Base API:** **Total Amount of API + SES:** **Unit:** ☐ **Include SES value in name:** ☐

Quantity: **Total Amount of Base API:** **Total Amount of API + SES:** **Unit:** ☐ **Include SES value in name:** ☐

Sitagliptin phosphate + Metformin hydrochloride || 100mg + 1000mg || FCT

Quantity: **Total Amount of Base API:** **Total Amount of API + SES:** **Unit:** ☐ **Include SES value in name:** ☐

Quantity: **Total Amount of Base API:** **Total Amount of API + SES:** **Unit:** ☐ **Include SES value in name:** ☐

Add Strength **Add Inert Strength** **Save**

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.

Strengths & Sndz Targets

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 Target APIs (2)

PTAP-0000008101
Target API Name: Sitagliptin phosphate
API Sequence: 1

PTAP-0000008102
Target API Name: Metformin hydrochloride
API Sequence: 2

Files (0)

Upload Files

Or drop 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.

New Sandoz Product Target

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:**

Product Target Name: Sitagliptin phosphate + Metformin hydrochloride **Therapeutic Area:** A (Alimentary Tract & Metabolism)

Originator Company: Merck & Co. **ATC1:**

Originator Product Name: Janumet **ATC2:**

Pharm. compound number:

Product Type: Small Molecule **BD&S ID:**

INDU:

Medical Device:

Product Comment:

Platforms

COO - Global Platforms (PT):

SDO - Development Platforms (PT):

Selection Review Criteria:

Product Target APIs (2)

PTAP-0000008101
Target API Name: Sitagliptin phosphate
API Sequence: 1

PTAP-0000008102
Target API Name: Metformin hydrochloride
API Sequence: 2

Files (0)

Upload Files

Or drop files

Pre-Launch **Forecast Review** **Potential Allocation** **More**

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

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.

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.

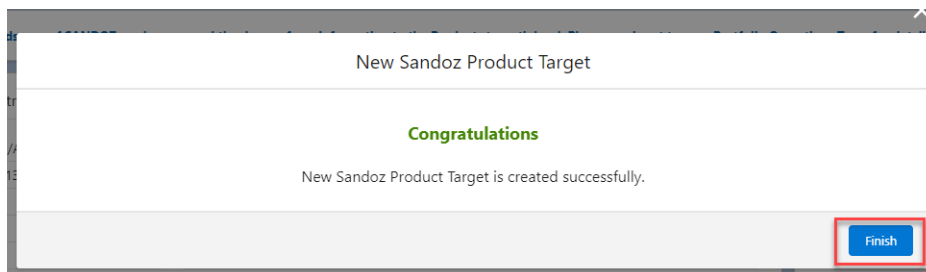
Sandoz Product Target creation (different Dosage Form)

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.

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 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.

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"/>

[View All](#)

Sandoz specific Product Targets are shown below

Product Targets (2)

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

[View All](#)

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

Product Target
Sitagliptin phosphate + Metformin hydrochloride

Note that this is a Sandoz Product Target which varies from the Originator Product.

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.

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

Product Target Full Name: Sitagliptin phosphate + Metformin hydrochloride
Product Target Name: Sitagliptin phosphate + Metformin hydrochloride
Medical Device: ☐

Product Target: Sitagliptin phosphate + Metformin hydrochloride
SPRINT Product ID:

Related Originator Product Details

Originator Product Type: Small Molecule
Originator Therapeutic area: Alimentary
ATC1:
ATC2:

IP Information

Global Patent Attorney:
Latest Executive summary:
Date:
IP Executive Summary:

Early Stage Details

Opportunity Priority:
PD Strategy Comment:

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.

Define Strengths and Dosage Forms

TAB

Imitative Strength: ☐

Dosage Broad:

Dosage Form: **TAB - TABLET**

Volume:

Volume Measure:

[Add API](#) [Add Strength](#) [Add Inert Strength](#) [Save](#)

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 Target: **Sitagliptin phosphate + Metformin hydrochloride TAB**

Originator Company: [Redacted] Therapeutic Area: [Redacted] Product Type: [Redacted] Strengths: 50 mg + 500 mg TAB, 100 mg + 1000 mg TAB

Note that this is a **Sandoz Product Target** which varies from the Originator Product.

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.

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

This information is not available on Sandoz Product Target records

Related List Quick Links

- Product Lists (0)
- Product Strengths (Sandoz Product Target) (2)**
- Country Default LoE Dates (0)
- Product Target History (1)
- Files (0)

Product Strengths (Sandoz Product Target)

2 items • Updated a few seconds ago

	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

View All

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.