



# Using the Gansons Nauta™ Mixer to Improve Process Efficiency for Synthesis of an Active Pharmaceutical Ingredient (API)

## Background

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Active Pharmaceutical Ingredient (API) intermediates are chemical compounds that form the basis for manufacturing active ingredients. One needs to be cautious while working with these crystalline intermediates as slight changes in their temperature and pressure can bring about polymorphic transitions and cause detrimental changes in the final product.

## Challenge

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A leading chemical manufacturer was facing challenges during the mixing stage of a product owing to the presence of an API intermediate (methoxy naphthalene based) with a sensitive physical nature. The client was using a ribbon blender to mix the intermediate during API synthesis. However, the crystal properties of this intermediate were affected during the blending stage which led to changes in compaction and colour of the final product.

## Project Goal

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The main aim was to prevent any polymorphic changes during mixing to the final product.

## Gansons Solution

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Gansons proposed conducting trials using the Gansons Nauta™ mixer to overcome the above-mentioned challenges. The Gansons Nauta™ mixer has a unique screw flight agitator which lifts the material from the bottom to the top and moves it in a



clockwise direction. Its characteristic gentle mixing action prevents damage to heat sensitive materials.

## Results

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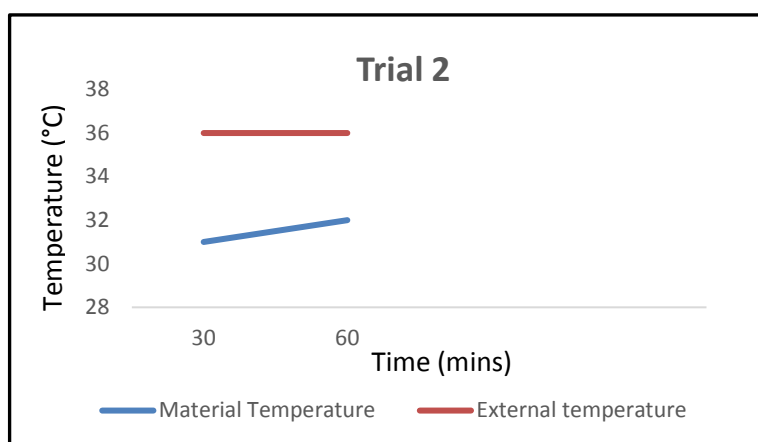
Two mixing trials were conducted for manufacturing API in the Gansons Nauta™ DBXE 300R model with 150 kilograms of material in each batch. In the initial trial, compaction properties (lump formation was observed) and colour of the product were altered after mixing for 120 minutes. This phenomenon occurred due to the generation of dead spots in the Nauta™ mixer where the material exhibits a high propensity to be degraded by heat. Hence, to prevent this occurrence, the rpm of the screw was reduced from 60 to 25 in the second trial.

No changes in physical properties of the intermediate were observed during the second trial (Figure 1). When the Gansons Nauta™ mixer was operated with a full load, there was no tripping or abnormal noise observed. In addition, there was no significant change in temperature of the product up to 60 minutes (Figure 1). Additionally, the product demonstrated homogeneous colour after 30 minutes with no further change in product colour after this time.

The final product from Trial 2 was suspended under heavy weight for 15 days to estimate the changes in crystal properties and no alteration in the same was noted by the client. Hence, the process was successfully completed in the Gansons Nauta™ mixer with around 40% reduction in process time compared to the ribbon blender.



Figure 1: Time dependent changes in temperature for Trial 2 product in Gansons Nauta™ mixer



Around 30% reduction in energy consumption was observed for mixing the intermediate in the Gansons Nauta™ equipment compared to the ribbon blender. Furthermore, negligible heat generation was observed in the same owing to low energy consumption in the process.

## Conclusion

The Gansons Nauta mixer generated little shear during the mixing process and caused minimum damage to sensitive material compared to horizontal blenders. Thus, the Gansons Nauta™ mixer successfully retained the crystal properties of sensitive API intermediate during API synthesis making a more suitable mixer for these types of applications.

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