RECP Best Practices Catalogue

Process Optimisation and Transition to Direct Compression

Developed within the framework of MED TEST II

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

switchmed

The SwitchMed Programme is funded by the European Union

Best Practice - Process Optimisation and Transition to Direct Compression

SECTOR:	**Chemical and Phamaraceutical**
Branch:	Manufacture of basic pharmaceutical products
CATEGORY	Process control or modification
APPLICABILITY	Process

COMPANY SIZE	600

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Description of the Problem (Base Scenario):	Manufacturing a generic drug (dental antibiotic) requires mixing active ingredients and excipients. Hot water is then added to these ingredients. Wetting is started manually so as to carry out wet granulation. Then the drying stage follows (heating to 50° C for about one hour). From there a wet calibration is conducted (open mesh rack : 7.5 mm mesh openings). Drying is carried out at 50° C in order to achieve a residual humidity between 3 and 6%. The problem occurs during drying. The product becomes glued on the Glatt dryer and at the mixer. There is an approximate 2 kg of loss after the calibration phase with 100 kg batches.
Description of the Solution	Investigate and carry out direct compression tests, given the high microcrystalline cellulose content. As a result, the wet granulation step can be avoided. Time savings (currently, it is a slow and expensive manufacturing process with risk of degradation for the fragile active ingredient). Significant savings with the elimination of the wet granulation step.

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Economic Gains	€ 10,000/year (for 20 production batches of 100 kg each)
Environmental Gains	There is less water used (absence of the wet granulation step) and more energy savings with the elimination of the granulation and drying steps. Diminished pollutant load for solid waste.
Health and Safety Impact	Reduced amount of hazardous pharmaceutical waste.

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Capital Investments & Financial Indicators	No Investment Time for Return on Investment: Immediate
Supplier Information	-
Other Aspects	2% improvement in Production performance
Implementation	A trial was conducted and an AMM (Marketing authorisation) application form was prepared and filed with the Ministry of Public Health.

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