DFE pharma | C2F

Closer to the Formulator
A Center of Excellence by DFE Pharma

Closer to the Formulator (C2F)
A Center of Excellence by DFE Pharma

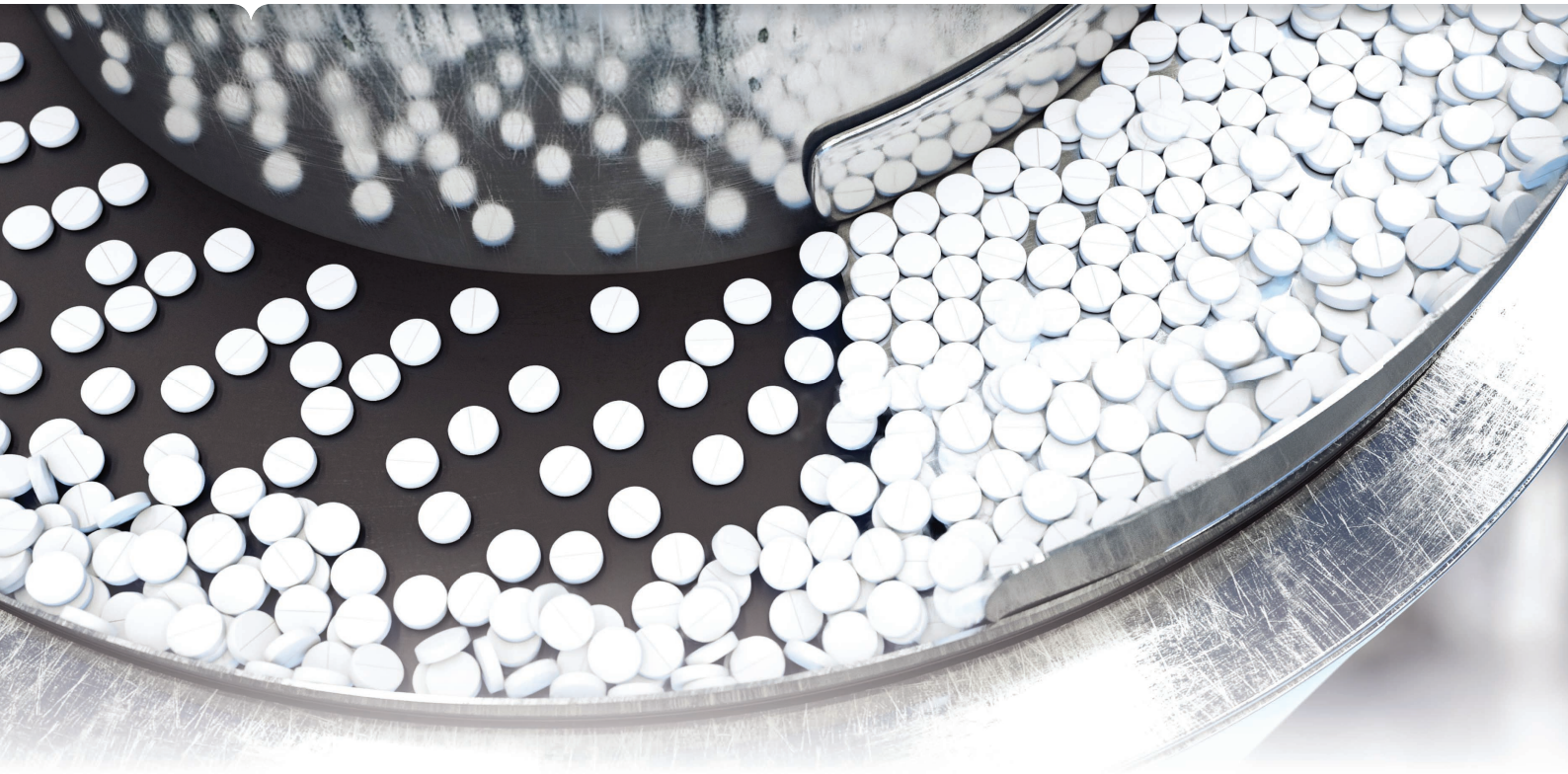
DFE Pharma is a global leader in pharma- and nutraceutical excipient solutions. We develop, produce and supply high-quality functional excipients for use in the pharmaceutical, biopharmaceutical, and nutraceutical industries for respiratory, oral solid dose (OSD), ophthalmic and parenteral formulations. Our excipients are used in numerous medicinal and nutraceutical products, including COVID-19 vaccines and treatments.

Our excipients play an essential role as fillers, binders, disintegrants, and in stabilizing active ingredients for release predictably and effectively into the patients' system. With more than a century of experience and around 450 people worldwide, we are serving over 5,000 customers in 100+ countries worldwide.

C2F: Bridging excipient excellence and formulation expertise

The new Center of Excellence “Closer to the Formulator” (C2F) by DFE Pharma helps pharmaceutical companies to shorten the time from a concept to a finished commercial product through expertise in all phases of pharmaceutical development. The services offered by this new state-of-the-art facility, are mainly focused on Oral Solid Dosage (OSD) forms, comprising all types of pre-registration work including development, intermediate scale-up, and technology transfer.

The C2F offerings can provide pharmaceutical companies with multiple advantages as, for example, it aims to significantly lower the number of development cycles and aspires to reduce formulation costs, when launching a medicine. Thanks to C2F capabilities, pharmaceutical companies, and formulators benefit from faster access to the market with high-quality products, robust formulations & processes, higher success rate and improved efficiency.



From concept to commercial: End to end formulation development, lab and application support

Through C2F, we share our formulation development advice on selection of type & grade of excipients, their ratios in the formulation and optimum manufacturing processes. All developments are based on Quality by Design principles including statistical Design of Experimentations.

The services are spread across various oral solid dosage forms such as immediate release tablets, chewable tablets, capsules, powders, granules, etc. We also support development of specialized dosage forms such as orally disintegrating tablets, effervescent tablets, sublingual tablets, minitablets, etc and both matrix and diffusion controlled Modified Released formulations. The facility also houses a full suite of analytical tools to characterize the physical / chemical quality attributes of powder blends and tablets. Stability studies as per ICH conditions are also feasible to support formulation development. With our excipient expertise and process capabilities we also support achieving cost/process efficiencies through projects involving process conversion from wet granulation to direct compression.

Active Pharmaceutical Ingredients (APIs)

At our C2F, we are capable of using APIs belonging to OEL I-III categories. For those projects involving APIs within the OEL IV-V categories, we can operate with model APIs used for speed, flexibility & cost benefits

Excipients

We work with a broad portfolio of excipients (including 3rd party), not limited to DFE Pharma's portfolio alone. At C2F facility we formulate with all categories of excipients and their different grades.

We provide our expertise and support in technical and analytical solutions across all lifecycle stages of the formulation development process including any specific need within the formulation development or intermediate scale-up, all resulting in higher levels of success as well as faster launch to market. Thanks to the formulation equipment and analytical capabilities available at C2F facilities, we can develop batches with varying capacities meeting your formulations goals. This will serve to provide our customers with all necessary data to reproduce it at their manufacturing site at big scale.

Both Asia-dedicated and worldwide support in the registration and approval of new products, including user-friendly documentation and interpretation of regulations.

A smooth process from your formulation goal to successful scale-up

1. Confidentiality: all projects are treated with total exclusivity and always in a confidential way.
2. Innovative idea: help to develop new ideas and to address any challenge, following the latest industry trends and suggesting how to improve products and processes.
3. Project proposal: taking into accounts all the requirements and goals by the customer, a comprehensive and detailed proposal for the project is prepared, but also flexible to be adjusted to any needed change.
4. Project agreement: once our proposal meets all the requirements, the final project and quote are agreed with the customer.
5. Project development: we start the development process to deliver the final product. During all this progression, monthly meetings are held to update the customers and integrate their wideas.
6. Report: Final findings are shared in summary and full report format, including methodology, used test methods and results. Through our technology transfer support, we secure customers can reproduce successfully the process in their manufacturing site.

State-of-the-art lab facilities in an exceptional location, the Genome Valley at Hyderabad

The cutting-edge 1200 sq meters laboratory facilities of the C2F center are equipped with the latest technology and staffed by highly experienced scientists. The equipment covers an instrumented tablet press, an automated capsule filling machine, a tablet coater, a blister packaging machine, stability chambers, and state-of-the-art analytical equipment.

The C2F center is based in Genome Valley, Hyderabad (India), the largest pharma and life sciences hub in Asia. It is a privileged location, where many major Indian and global (bio)pharmaceutical companies are present, as well as worldwide renowned research institutions and best-in-class supporting specialized infrastructure. This vibrant R&D cluster drives collaboration and innovation among some of the global key players in the pharmaceutical industry.

Equipment & Instruments available at Closer to the Formulator (C2F), a Center of Excellence by DFE Pharma

Formulation Equipment	Analytical Equipment
High Shear Mixer Granulator (HSMG)	High Performance Liquid Chromatography (HPLC)
Fluid Bed Processor	Fourier-Transform Infrared Spectroscopy (FT-IR)
Fourier-Transform Infrared Spectroscopy (FT-IR)	Laser Diffraction Particle Size Analyzer
Laser Diffraction Particle Size Analyzer	UV/Vis Spectrophotometer
UV/Vis Spectrophotometer	Dissolution Apparatus (Auto Sampler)
Dissolution Apparatus (Auto Sampler)	Stability Chambers as per ICH requirements
Powder Flow Tester	Low Humidity Stability chamber (25°C ± 2°C/40% RH ± 5%)

Formulation Equipment	Analytical Equipment
Rotary Compression Machine (D and B Tooling)	
Automatic Tablet coating machine	
Automatic Capsule Filling Machine (Powders, Pellets and Tablets in capsules)	
Automatic Blister Packing machine (PVC, PVDC, PVC/PE/PVDC, Alu-Alu Blisters)	

To know more about how C2F services can support your company, please reach us at *c2f@dfepharma.com*

Your medicines, our solutions. **Moving to a healthier world.**

For more information, please visit *dfepharma.com* or follow us at: