

INTRODUCTION

Custom Pharma Services specialises in the development and manufacture of placebo tablets to match your choice of active for use in clinical trials.

We are experts in providing a quality product which exceeds your expectations whilst delivering a cost-effective solution to ensure a timely delivery to your clinic.

HISTORY

Blinding was first introduced by Benjamin Franklin in 1784, where participants were literally blindfolded during experiments to shield them from knowledge in their assessments of the therapeutic claims made for applying mesmerism.

Whilst the use of blindfolds has become considerably less favourable today, the importance of blinding remains, and great consideration should be given to ensuring that the placebo is not just a 'sugar pill' and it truly matches the active in terms of shape, size, colour, texture, weight, taste and smell where appropriate.

AVOIDING RISK

It is not possible to simply purchase an 'off the shelf' placebo, and finding a contract manufacturer with suitable equipment and the expertise required who is willing to produce limited batch sizes of GMP product can be a challenge.

OUR APPROACH

At Custom, we adopt a standardized process when developing and manufacturing matching placebo tablets. The cost and scope of the project will be fixed and agreed up front, along with the timelines, allowing you to stay in control at all stages.

We will produce a feasibility report detailing the proposed placebo formulation and method of manufacturing for your approval ahead of conducting pilot trials to prove the concept using suitable dedicated tooling.

The tablets will then be manufactured and coated (if required) in our GMP pilot plant using bespoke small-scale equipment ideally suited to produce batches of a limited size.

The tablets can then be either bulk packed with an open label and shipped to a packing site of your choice, or Custom can co-ordinate clinical packing in accordance with your requirements.

The QC team at Custom will test and certify the batch, and our in-house QPs will provide the final release to packing or clinic.



Fig. 1.
Spot the difference!

Active (top) and placebo tablets showing a perfect colour match.¹

¹ Custom project reference D2017-018-DT

