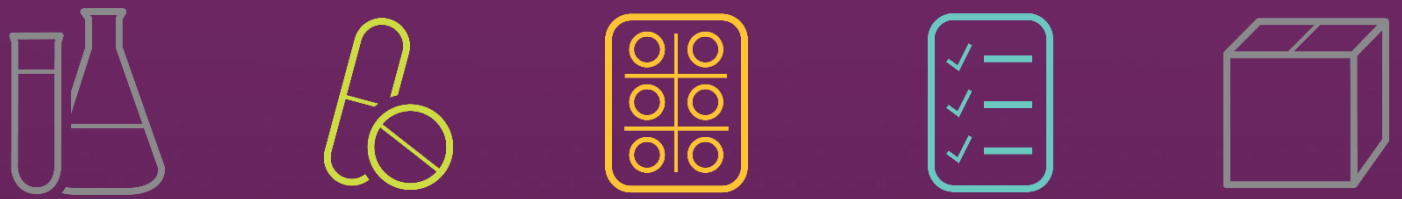
Custom Pharma Services



CUSTOM
Pharma Services

END-TO-END SUPPORT SINCE 1979

CUSTOM Pharma Services

FROM CLINICAL TO COMMERCIAL

- Based in Brighton & Hove, UK and established in 1979
- Holders of MIA, MIA (IMP), MS, ManA (Veterinary Medicines)/GMP certificates issued by MHRA
- Specialists in tablets, capsules, powders and modified release formulations
- Licensed to manufacture controlled drugs, hormones, IMPs, Specials and veterinary medicines
- Experts in low dosage (sub-mg) formulations

CUSTOM Pharma Services

cGMP COMPLIANT, UP-TO-DATE CAPABILITIES

One-stop-shop, whether you are

- establishing a commercial supply for a new product
- transferring an existing product
- have a need to update/remediate an established drug
- seeking opportunities and resources in generics, Specials or veterinary medicines

CUSTOM Pharma Services

cGMP COMPLIANT, UP-TO-DATE CAPABILITIES

- 4,000 m^2 packaging facilities
- 1,700 m^2 temperature monitored facilities
- Up to 50M+ blister packs per year
- Variety of packaging options to suit your needs – blister, pot and bulk
- Open label clinical packaging
- Serialisation

CUSTOM Pharma Services

EXPERIENCE

We have a 40+ year depth and breadth of experience providing access to a wide range of conventional and specialized oral solid dosage capabilities and capacity delivering a reliable and high quality service you need to achieve your goals.

CUSTOM Pharma Services

FORMULATION AND PROCESS EXPERTS

- Formulation development including QbD and DoE
- Tech Transfer of established products
- Remediation of challenging processes/products
- Feasibility planning up front to ensure a transparent development pathway
- GMP pilot plant with dedicated experienced Technicians and Formulation Scientists: tablet blending/granulating and compression, fluid bed drying, capsule filling, coating and oven drying

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FORMULATION DEVELOPMENT - COMMERCIAL

Custom's philosophy is to "develop once & develop it right" in order to reduce the time to market and the overall costs, avoiding risky short cuts and pitfalls that lead to costly delays.

Pre-formulation screening

- Solubility/stability assessment
- Excipient screening
- API properties for process-ability

Formulation Development

- Solid dose forms: tablets, film coating & tablet printing, hard capsules, powders, powders for oral solution (PfOS)
- Immediate and modified release expertise
- Dry and wet granulation/tray dry/fluid bed dry

CUSTOM Pharma Services

ANALYTICAL EXPERTS

- Analytical method development, remediation and optimization service
- Teams specializing in QC, Raw Materials, Development and Stability operating under a single Quality Management System (QMS)
- Stability work for commercial and as a stand-alone service
- Stability programme management, stability storage service and analysis in line with ICH Q1a guidelines

CUSTOM Pharma Services

FROM CLINICAL TO COMMERCIAL

- Analytical methods developed and validated to support your trial
- Early-stage formulation development and technical batches with stability studies to help future proof your concept
- Bespoke placebo-to-match development and manufacturing at clinical scale
- QP certification services

CUSTOM Pharma Services

PROJECT MANAGEMENT

Our project management team will ensure that a multi disciplinary team supports your project and ensures we provide a…

Flexible

Agile and

Streamlined approach to deliver on

Time and meet your expectations

CUSTOM Pharma Services

Health / Safety and The Environment

Custom Pharma have developed a 5 year health and safety strategy to ensure we maintain a strong commitment to health and safety and our environment.

Effective health and safety management is a key component of Custom's ability to provide and maintain excellent services.

Custom Pharma is committed to :

- **Ensuring** a safe and healthy environment
- **Recognising** the impact the company's work may have on others and the world around us
- **Upholding** Custom's reputation as an employer committed to the safety and health of our people, customers, suppliers, and visitors
- **Focusing** on continuous improvement of Custom's health and safety management through our goals and the behaviours underpinning our safety culture
- **Understanding** and minimising the impact of our activities on our environment including our carbon footprint

CUSTOM Pharma Services

Mettler Quantos

AUTOMATED DRUG-IN-CAPSULE MICRODOSING

CUSTOM Pharma Services

CLINICAL & PRODUCT DEVELOPMENT

Selection of dosing heads to suit the physical characteristics of your API

RFID chip ensures full traceability and maximum yield

Safe, precise, **accurate** dosing using dedicated capsule holders

CUSTOM Pharma Services

UNDER ONE ROOF (UxR)

- New manufacturing site is being built
- We're bringing all of our services under one "roof" (=in one industrial area)
- 200% capacity increase for formulation development and clinical manufacturing
- High potency products from gram scale to 50kg (per granule sub-lot), could be as much as 400kg as sub-lot multiples
- Solid oral dose up to 150kg sub-lot for general manufacturing

New facility

Our current Brighton site

CUSTOM Pharma Services

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www.custompharma.co.uk

MHRA
Regulating Medicines and Medical Devices

ACHIEVEMENT AWARD
WORKPLACE CONDITIONS ASSESSMENT

LIVING WAGE EMPLOYER
BRIGHTON & HOVE

INVESTORS IN PEOPLE

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