Chemistry, Manufacturing and Control Services

Tepnel Pharma Services

Tepnel Pharma Services an MHRA approved (cGMP), contract quality control laboratory provide the Chemistry, Manufacturing and Control (CMC) services for all phases of drug development, ensuring that your product meets the Regulators requirements.

Our licence/certification covers manufacturing operations and importation of medicinal products, specifically Quality Control testing; Microbiological: sterility and non-sterility testing, Chemical/Physical testing and Biological testing.

Manufacturing and Control is the accumulation of important information required around manufacturing processes, product characteristics and product testing which must be defined in order to ensure that the product is **safe, effective and consistent** between batches.

The CMC section is a very important part of a pharmaceutical clinical trial or marketing application and there are several guidance documents available to assist:

- ICH Q2(R1) Validation of Analytical Procedures: Text and Methodology.
- ICH Q3C(R6) Impurities: Residual Solvents.
- ICH Q6A Specification: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.

Testing requirements of ICHQ6A

ICH Q6A, breaks down the requisite CMC testing into two categories, Universal Testing and Specific Testing. Universal tests are considered generally applicable to all new drug substances and products whilst Specific tests may be considered on a case by case basis for drug substances and/or drug products (see table below).[1] The experience and data accumulated during the development of a new drug substance or product should form the basis for setting the specifications for the specific tests.

Universal Tests		Specific Tests
New Drug Substances	New Drug Products	New Drug Substances
Description:	Description:	Physicochemical properties
Identification	Identification	Particle size
Assay	Assay	Polymorphic forms
Impurities	Impurities	Tests for chiral new drug substances
		Water content
		Inorganic impurities
		Microbial limits

The specific tests for new drug products has been adopted to deal with the specific dosage forms of solid oral drug products, liquid oral drug products, and parenterals (small and large volume). It is recognised that other dosage forms exist and the increase in biological and advanced therapies mean that different characteristics and parameters have evolved and as such the concepts of ICHQ6A should be used:

Tablets (coated and uncoated) and hard capsules	Oral liquids	Parenteral Drug Products
Dissolution	Uniformity of dosage units	Uniformity of dosage units
Disintegration	pH	pH
Hardness/friability	Microbial limits	Sterility(6)
Uniformity of dosage units	Antimicrobial preservative content	Endotoxins/ Pyrogens
Water content	Extractables	Particulate matter
Microbial limits	Alcohol content	Water content(7)
	Dissolution(1)	Antimicrobial preservative content
	Particle size distribution(2)	Antioxidant preservative content
	Redispersibility	Extractables
	Rheological properties(3)	Functionality testing of delivery systems
	Reconstitution time(4)	Osmolarity
	Water content(5)	Particle size distribution
	Antioxidant preservative content	Redispersibility(8)
		Reconstitution time

(1) for oral suspensions and dry powder products for resuspension.

(2) for oral suspensions.

(3) for relatively viscous solutions or suspensions.

(4) for dry powder products which require reconstitution.

(5) for oral products requiring reconstitution.

(6) All parenteral products should have a test procedure and acceptance criterion for evaluation of sterility.

(7) for non-aqueous parenterals, and for parenteral products for reconstitution.

(8) for injectable suspensions which settle on storage (produce sediment).

CMC Testing at Tepnel Pharma Services

Since our advent in 1972, the staff at Tepnel Pharma Services have focussed on both the chemical and microbiological aspects of CMC support. During our time as an Official Medicines Control Laboratory on behalf of the Medicines Testing Scheme, a significant amount of analytical time was spent testing pharmaceutical products using the aforementioned Universal and Specific tests.

This wealth of experience has carried on into the current day and Tepnel Pharma Services, working with a select number of approved partners continues to focus on providing quality control analytical services to pharmaceutical companies developing and manufacturing solid oral drug products, liquid oral drug products, and parenterals (small and large volume).

Our extensive knowledge and understanding of Pharmacopoeial science extends our capabilities, enabling us to also test:

- Drug Formulations with an analysis of those components intended to appear in the formulation and those which may not appear, but which are used in the manufacturing process e.g. excipients, raw materials, solvents and the API itself.
- The stability of the drug formulation and packaging to ensure that it remains compliant during the period of use.
- The development and validation of analytical methodology that complies with regulatory guidelines.

For all your microbiological testing requirements and further information on Tepnel Pharma Services please contact:

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Together we are better

References.
1. ICH Q6A Specification: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances