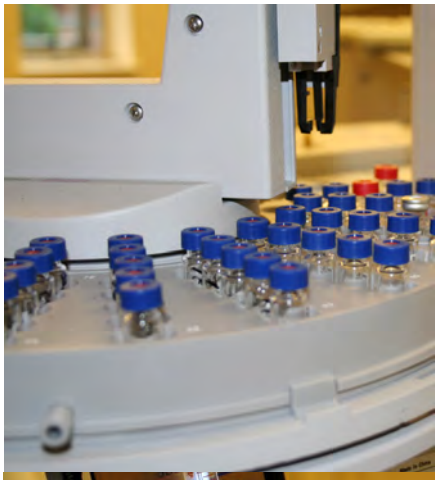

# Pharmaceutical Testing

Medicines are made to the strictest Quality Standards and controlled by Good Manufacturing Practice (GMP). Whilst we do not manufacture products at **RC Pharma** we do test pharmaceutical products in support of regulated manufacturing facilities, so analytical testing to GMP requirements is a significant part of our activity. Drug products must be fit for purpose and that includes freedom from contamination or deterioration. Some rubber or plastic-related chemicals may be leached or extracted from Medical Devices or packaging and end up in the drug matrix, and it is these extractables and leachables that fall into the category of contamination. Various specific analytical techniques at **RC Pharma** are used to test rubber products and drug products for target chemicals.

Typical types of GMP testing activity include leachables testing *ie* testing the drug matrix for specified compounds, extractables testing, *ie* testing extracts from delivery devices for specified compounds, Method Development and Method Validation. Validated methods are required, so these are either validated in-house or imported *via* Method Transfer from other accredited labs.

**RC Pharma's** capacity for pharmaceutical testing is supported by the latest state-of-the-art equipment. This includes GC-MS, GC-FID, GC-NPD, GC-HID, Headspace analysis, HPLC, LC-MS and IC.

Speciality Pharma analyses in line with GMP (Good Manufacturing Practice) include:

- Method development
- Method validation
- Leachables testing
- Extractables from rubber and plastic components
- Nitrosamines to CEN, FDA and BgVV / Bfr Standards
- PNA (or PAH) testing
- ACN monomer testing
- Formaldehyde (HCHO) analysis

As well as testing to client specific methods, we also offer a range of validated in-house analytical methods including:

- PNA (or PAH) testing to ISO 21461:2009 (under the REACH regulations)
- Residual ACN monomer (RAM) testing
- Nitrosamines and nitrosatable testing
- Formaldehyde (HCHO) analysis
- MBT, Irganox and BHT analysis

We specialise in extractrable and leachable analysis of OINDPs (orally inhaled and nasal drug products), nasal sprays, pMDIs (pressurized metered dose inhalers), dry powder inhalers, PODPs (parenteral and ophthalmic drug products), prefilled-syringes, container closure systems, SVPs (small volume parentrals) , LVPs (large volume parenterals). All work is carried out according to PQRI guidelines.

**For further information please contact one of our team:**
**info@rubberconsultants.com**
**+44 (0)1992 554657**

Rubber Consultants

TESTING • INNOVATION • SOLUTIONS
since 1984

RC Pharma, Brickendonbury, Hertford, SG13 8NL, UK
www.rubberconsultants.com e-mail: rcpharma@rubberconsultants.com
tel: +44 (0)1992 554657 fax: +44 (0)1992 504248