# A CALIBRE SCIENTIFIC COMPANY



# Pharmaceutical Standards and Reagents



#### About Reagecon

Reagecon, part of the Calibre Scientific Group of companies is one of the largest producers of Physical and Chemical Standards. The company is based in an 8,000 sq. metre facility that includes a large suite of manufacturing, quality control and research and development laboratories in Shannon, Ireland with sales offices in Shanghai and North America, Europe and the UK through our Calibre Scientific sister companies. Reagecon employs 100 people, 50% are chemistry or science graduates and most are involved in the development, production, testing, quality control and sales & marketing of over 6,000 product references that we currently produce. We have a very active R&D programme and develop and bring to market many hundreds of new standards, every year.

All Reagecon manufactured products are underpinned by and demonstrate our position as a centre of excellence in the science of Metrology. Product is manufactured, tested, and certified under the applicable ISO/IEC 17025 (A2LA Ref: 6739.03) or ISO/IEC 17034 (A2LA Ref: 6739.01) accreditation or ISO/IEC 17025 (A2LA Ref: 6739.02) for Calibration, in one of our 20 specially equipped laboratories.

The resulting product is classified within one of 54 product families, these families are then grouped and promoted under 7 main product headings, as listed below:-

- Electrochemistry Standards
- Cation and Anion Standards
- Pharmacopoeia Reagents and Standards
- Physicochemical Standards
- Total Organic and Inorganic Carbon Standards
- Volumetric Solutions for Titration
- Customised Standards and Reagents





### Pharmaceutical Standards and Reagents

The testing and analysis of medicines for human and animal use, is one of the most important segments within the science of analytical chemistry. The equipment and technology being used is growing in sophistication and sensitivity. Similarly, the demand on analysts, to produce results that are correct and that can be proven to be correct is growing at an exponential rate. The provision of correct results and proof of that correctness requires that the standards and reagents used for calibration, quality control, method validation and instrument qualification needs to be of an extremely high quality, in particular, they need to be traceable, certified, be of known measurement uncertainty and be produced and tested in compliance with the stipulations of the major pharmacopoeias

Reagecon has responded to all of these technical challenges and demands, with our new range of Pharmaceutical Reagents and Standards. This range which can be accessed online contains many pages of up to date products, specifications, technical advice and is the most detailed and comprehensive collection of products, ever produced for the pharmaceutical industry. The range contains many rare and unusual standards and reagents, all of which are packed and delivered in easy to use and safe pack sizes. The contents of the range of products include the following:

#### Pharmacopoeias

- United States Pharmacopoeia (USP)
- European Pharmacopoeia (EP)
- Chinese Pharmacopoeia (ChP)
- Japanese Pharmacopoeia (JP)

These solutions have been developed as part of our ongoing Research and Development program and are only available from a small number of manufacturers worldwide. They bring you multiple benefits that include:

- Large reduction in the amount of time, expense and manpower required to prepare reagents and standards.
- Product consistency (independent, traceable, certificates of analysis), and tight specifications.
- Produced according to relevant Pharmacopoeia requirements.
- Manufactured using controlled processes. Batch certified to ensure lot-to-lot consistency and reproducibility of results.
- Such benefits give you the assurance and peace of mind that in-house preparations cannot provide.

#### **Cations and Anions**

Almost all of the major pharmacopoeias, have published regulations, pertaining to elemental impurities. Our range contains two sections relating to elemental impurities, one is a dedicated catalogue, that details the history, measurement methods, permitted daily exposure doses depending on ingestion route and available standards applicable to the measurement of elemental impurities.

The other section is a very comprehensive list of all of the single element and multi element standards for both cation and anion measurement applicable to many industries, including



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#### Total Organic Carbon (TOC)

Reagecon manufactures two main ranges of standards, that are specially formulated to comply with the regulations of the Pharmaceutical Industry.

The Premium Range is extensive, ultra-pure, has low measurement uncertainty, is highly specified and manufactured in a cleanroom environment using proprietary technology. A lot of the products are presented in suitable packaging for use on specific leading brand instruments.

The Quality Range of products are designed for situations, where less accuracy or sensitivity are required, such as effluent streams and are designed around typical discharge licence requirements.

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#### **Conductivity Standards**

Reagecon is the world's largest producer of conductivity standards and is credited with the invention of low-level aqueous standards. The company is still the only producer worldwide with the capability to manufacture and stabilise these products at such low levels of conductivity. This low range of standards includes  $1.3\mu$ S  $\pm$  0.05 $\mu$ S/cm, the lowest aqueous conductivity standard available.

#### pH Buffer Solutions

Reagecon's pH buffer standards are directly traceable to the IUPAC pH scale by an unbroken chain of traceability. Reagecon achieve this traceability through a series of comparisons, with the key reference materials being Standard Reference Materials (SRMs) manufactured by NIST. The product offering in this range, represents the largest range available from any supplier.





#### **Dissolution Media**

Reagecon offers an extensive range in two formats: Ready to use, which eliminates all preparatory steps in the users laboratory and Concentrates, which only require one preparation step, thus saving shipping costs and space.





#### **Buffered Eluents**

These aqueous and non-aqueous high quality buffer systems minimise variations of mobile phase pH, leading to dramatically improved selectivity, retention, peak, shape and reproducibility. They offer the following benefits:

- Significant reduction in the amount of time and expense required to prepare them in house – "lean labs"
- Produced according to relevant
  Pharmacopoeia requirements no
  deviation in materials or methodology
- Manufactured under controlled processes and batch certified to ensure lot-to-lot consistency and reproducibility of results



#### Titration

Largest range of acid/base, oxidation/reduction, precipitation and complexometric titrants and indicators available from any supplier worldwide. Aqueous and non-aqueous titrants available in a large range of pack sizes. Large range of indicators also available.

#### Osmolality

Reagecon manufactures a range of Osmolality Standards for ease of use when calibrating all types of Osmometers, irrespective of brand. All Osmolality standards are manufactured using high purity raw materials in accordance with European and United States Pharmacopoeia guidelines, where appropriate.





## Other families of standards available from Reagecon for the Pharmaceutical Industry:

#### Colour

Reagecon offers the full range of ASTM, Saybolt, Platinum-Cobalt (Hazen), Gardner, European Pharmacopeia and United States Pharmacopeia Colour Standards for use with ASTM, APHA, ACS, European and United States Pharmacopeia standard methods.

#### Density

Reagecon's Density Standards Premium range are manufactured in accordance with ASTM D1480 for testing of Density or Relative Density by Bingham Pycnometry. Reagecon's Quality range of Density Standards are manufactured in accordance with ASTM D4052 for testing of Density, Relative Density and API Gravity of Liquids using Digital Density Meters. The products can be used for calibration, quality control, method validation or instrument qualification where appropriate.

#### **Melting Point**

Reagecon's Melting Point Standards include materials that range in melting point value from +47°C to +335°C. These products are tested using a reference Melting Point apparatus that is calibrated to give traceability to the ITS-90 Temperature Scale.

#### **Refractive Index**

Reagecon manufactures Refractive Index (RI) Standards using both Sucrose and Solvents as raw materials. The products represent excellent value for users. These products are used either to calibrate Refractometers or as Quality Control Solutions during refractive index measurement.

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#### Spectrophotometry

Reagecon's Spectrophotometry Standards are suitable for use on all UV-VIS Spectrophotometers. The range of standards includes: Linearity, Wavelength, Stray Light, Bandwidth and Resolution Standards.

#### Turbidity

Reagecon's range of Turbidity Standards for Ratio and Non-ratio instruments are extremely accurate, NIST traceable and US EPA approved. We also offer Turbiform<sup>™</sup> Stabilised Formazin Standards.

#### Viscosity

Reagecon's Viscosity Standards are certified, accurate and traceable. Products can be used for calibration, control, verification, qualification or method validation of Kinematic and Dynamic Viscosity Measurement Instruments (manual and automatic).

#### **Customised Products**

Reagecon employs in excess of 60 graduate or post graduate chemists that possess a wide range of skill sets and experience. Because of this broad array of capabilities, we have been producing customised reagents and standards for many years. The reason, both technical and commercial, for outsourcing these products are compelling, so for whatever needs you may have please contact your relationship manager or sales@reagecon.ie







For further information or enquiries, please contact us

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