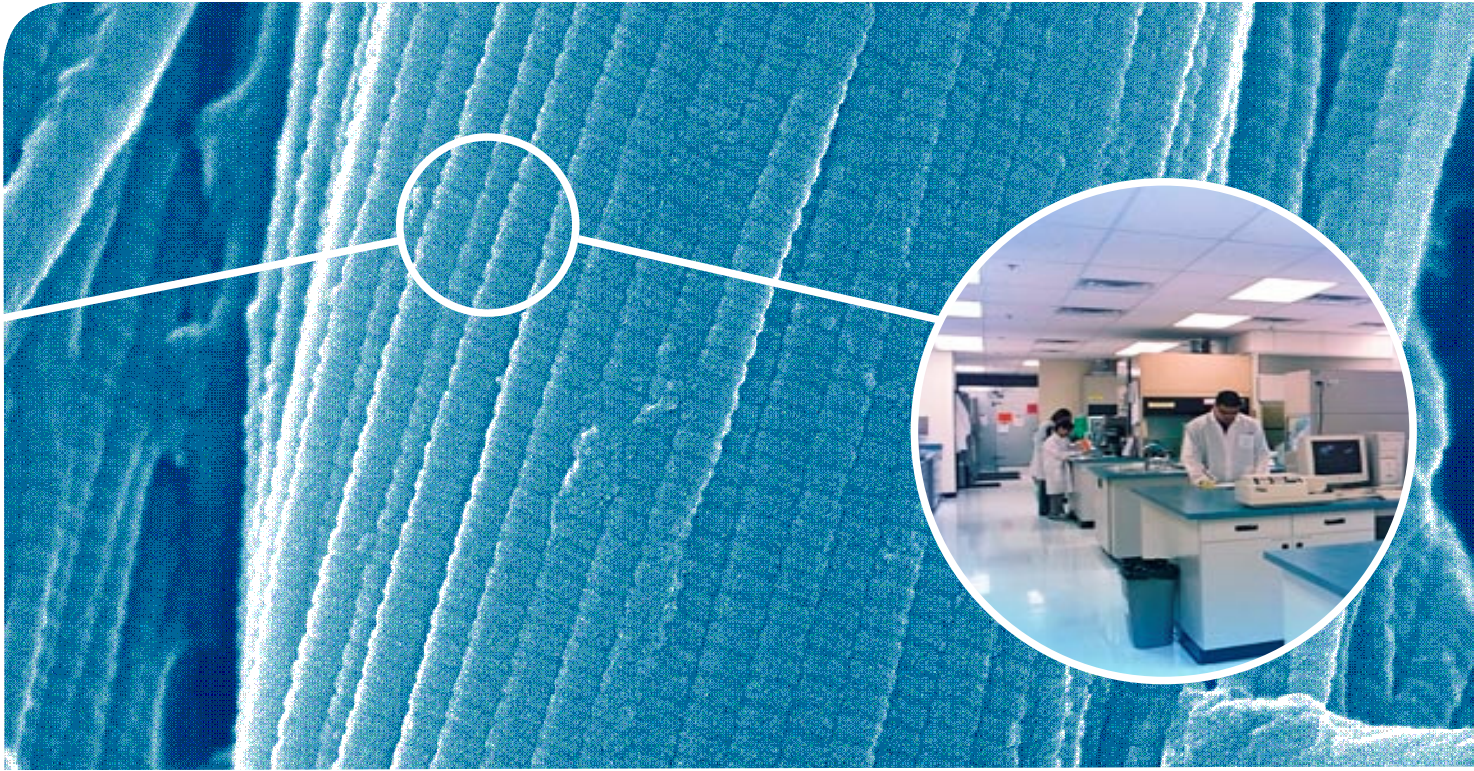


# Collagen Analysis

## Healthcare Applications

**Intertek**

Valued Quality. Delivered.



Collagen is fibrous structural protein which has found increasing application in healthcare and personal care applications including wound care, burns care, orthopaedic graft products, tissue matrices, cosmetic surgery and as an ingredient in skin and hair care products.

There is a rapidly growing interest in the processing and characterisation of collagen as developers find new applications. A good understanding of the collagen material and process residuals are key to successful product development.

Intertek's specialist biomaterial scientists deliver high quality analytical services to facilitate your product development, authorisation and manufacturing. Services include:

- Biochemical and Chemical Collagen characterization: e.g.
  - Collagen content (hydroxyproline determination)
  - Amino acid analysis
- Physical characterisation and imaging via SEM, TEM and optical microscopy
- Impurity profiling e.g. Process residuals quantification e.g. antibiotics or surfactants
- Determination of relevant biological species e.g. GAGs, total protein content
- ICH Stability Studies and cGMP QC Testing Services
- Extractables and Leachables
- Management System Certification
- Notified Body Reviews for the Medical Device Directive

## Quality

The laboratory has been inspected by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for GLP and GMP compliance and by the US Food and Drug Administration (FDA) for cGMP compliance in relation to customer's pharmaceutical manufacturing license.

# Collagen Analysis

Valued Quality. Delivered.



## Chemical Characterisation

- Concentration, Purity (hydroxyproline content)
- Moisture Content
- Amino Acid Analysis
- Peptide Mapping
- Carbohydrate Analysis

## Physical Characterisation

- Shrink Temperature (DSC) - Insoluble samples
- Viscosity (Mainly soluble samples)
- TEM - Soluble or Insoluble samples
- SEM - Electron Micrograph (native banded 640 Å structure for fibrils)
- Mechanical testing (e.g. tensile strength)
- Light Microscopy
- Surface Characterisation

## Technology

- Mass Spectrometry (ESI-MS, LC-MSMS)
- Gas Chromatography (GC-MS, HS GC-MS, Pyrolysis)
- HPLC and UPLC (UV, RI, ELSD, MS)
- Ion Chromatography with electrochemical detection (HPAEC-PAD)
- Spectroscopy (FTIR, Nr IR, UV-vis, Fluorescence)
- Trace Metals Analysis by ICP-MS, ICP-OES

## Biochemical Characterisation

- % Type I collagen/Total Protein
- % Other Types Collagen
- SDS-PAGE Analysis
- Total DNA (ppm or %)
- Total Lipid content
- Trypsin Resistance
- Collagenase Resistance
- GAGs Levels (total and each type)

## Impurities profile

- Heavy Metal Analysis
- Additives (cross-linkers, lubricants, drugs, sterilents)
- Process Residuals (antibiotics, detergents, etc)
- Endotoxin Level
- Bioburden

- Trace Organic and Inorganic
- Analysis Techniques Bio-safety Level II Facility
- Classical Organic and Inorganic Analysis
- Trace Metals analysis by ICP-MS, ICP-OES
- Microscopy (optical microscopy, SEM (cryo and high resolution), Transmission Electron Microscopy TEM)
- UV/Vis Molar Extinction Coefficient

## Tissue Scaffold Characterisation

- Collagen Analysis & Processing Residuals Analysis (e.g. detergents, antibiotics)
- Biomaterial characterisation (alginates, polysaccharides, collagen, chitosan)
- Polymer Analysis (e.g. molecular weight, residual solvents)
- Polymer / Ceramic composite analysis (e.g. trace metals analysis)
- Mechanical / physical / thermal testing of scaffolds

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## Get in touch.

Your business knows no boundaries - and neither does ours. Whatever your target market, Intertek's global network of experts is ready to help you reach it. For more information email [ASGenquiries@intertek.com](mailto:ASGenquiries@intertek.com) or call **+44 (0)161 721 5247**.