

Pharmaceuticals and Bio-based products

What is the aim?

Organic substances may be very weak against oxidative degradation mechanisms; therefore the stability of pharmaceutical raw materials and formulations, industrial and life science materials from novel biological sources may be poor and challenging. To process successfully even complex product formulations, one may be concerned about the quality of incoming raw materials, semi-finished and finished goods, logistic conditions and the shelf life resulting from all these different factors.

This leaflet shall highlight some application examples in the field of life science, pharmaceuticals and biotechnology; and it shall help you to understand the benefits of the label-free testing approach of the ACL Instruments technology solutions.

Chemiluminescence testing

The technology of ACL Instruments is a valuable asset to analyse, score or predict anti-oxidative effects, pro-oxidative effects, freshness or aging characteristics of organic substances and products (e.g. lipids, antioxidants, aromes, packaging materials, additives, active ingredients etc.).

The oxidation of organic substances by oxygen is normally caused by a radical chain reaction which may consist of several intermediate reactions. However, peroxidation is responsible for the creation of excited states in most cases.

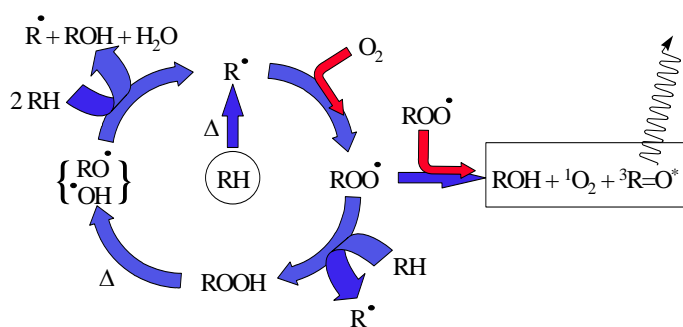


Fig. 1 illustrates in a simplified scheme the oxidation behaviour (left) and the peroxy radical recombination with the formation of excited ketones (right).

Pharmaceutical formulation

Oxidative decay is highly undesirable in pharmaceutical industry. Active ingredients lose their effect and/or cause side effects, raw materials may change taste or become inedible or may harm other ingredients.

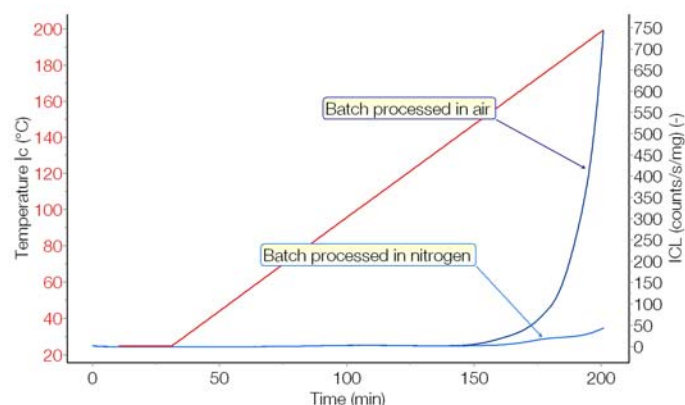


Fig. 2: Assessment of the hydroperoxide concentration of lipidic-based pharmaceutical formulation after processing in air (dark blue curve) and in nitrogen: screening in nitrogen.

In this example, we demonstrated that the processing in ambient air condition may harm the given product formulation by oxidative degradation. The result is the formation of significant high amounts of hydroperoxides. When the same formulation is processed in the absence of oxygen, almost no hydroperoxides are detectable.

Benefit for the customer: fast and easy procedure to test the quality of samples. Indication how to process the formulation to prevent oxidative damage.

Pharmaceutical raw material

The processing of pre-oxidised raw materials due to low quality and/or inaccurate storage and transportation is a severe problem for the pharmaceutical industry. Incoming materials are normally excessively tested prior to processing steps to avoid the loss of badges, money and reputation.

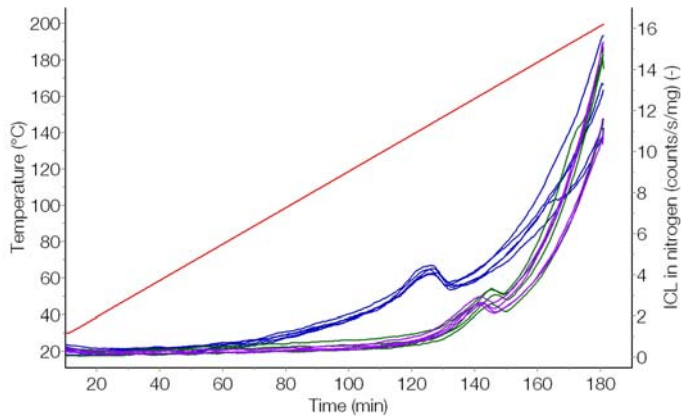


Fig. 3: Quality assessment of an unknown pharmaceutical raw material originating from 3 different suppliers: Each sample was tested 5 times by screening in nitrogen. Obviously the blue sample emits significantly higher amounts of CL due to hydroperoxide presence than the other samples (green and purple).

Benefit for the customer: fast and easy procedure to test the quality of incoming samples prior to processing.

Nutraceutical formulation

The intrinsic weakness of many pharmaceutical and nutraceutical (e.g. polyunsaturated fatty acids like EPA and DHA) substances against oxidation is a challenge to transform them into stable products.

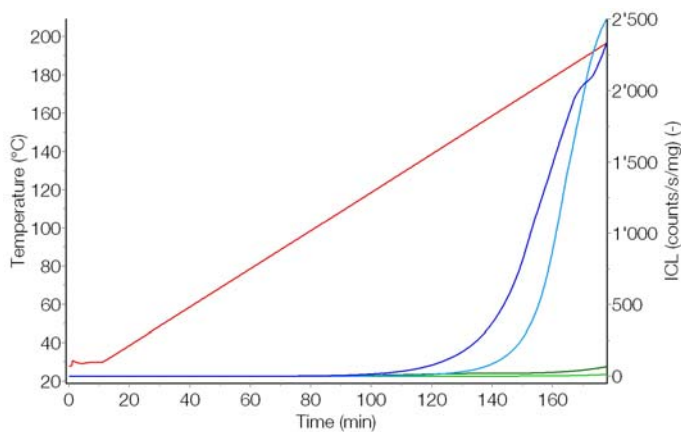


Fig. 4: Stability of two different Astaxanthin formulations against oxidation: sample (bright curves) without, sample b (dark curves) with iron content. The blue curves were assessed in oxidative (air), the green curves were assessed in inert (nitrogen) conditions.

Transition metals like iron catalyse the oxidative decay of organic substances. With the CL approach, product developers have a powerful tool to assess the impact of stabilisers and pro-oxidants to optimise the shelf life of their formulations.

Biotechnical formulation

The long term (storage) stability of many products and raw materials from biotechnical sources is of great interest for producers and consumers. In the following example we depict the ageing behaviour of a biotechnical compound as a function of different storage temperatures.

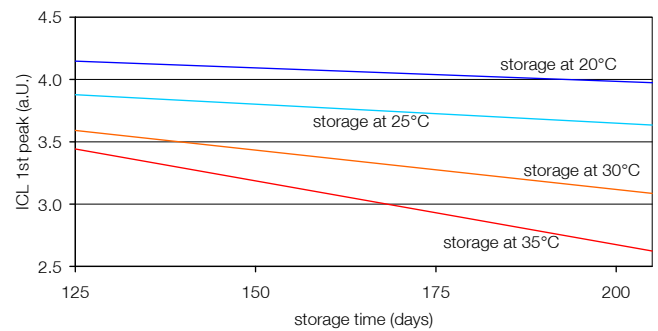


Fig. 5: Ageing behaviour of a biotechnical formulation as a function of the storage temperature: long term over ageing procedure, monitoring of oxidation every 14 days.

Benefit for the customer: monitoring of the real oxidation behaviour. The results may be kinetically analysed and extrapolated to other temperature profiles.

ACL Instruments added value offer

Unstable ingredients or materials in your products can destroy your reputation and brand in a second. To protect consumers from potential hazards resulting from oxidation reaction, our testing services provide profound information about your products stability and quality.

Do you know the ACL Instruments application service Lab? Our knowledge about the applications allows providing additional value to the customers. If you plan to out-source your testing capacities or if you need an answer to a given problem, ACL Instruments can provide you with innovative service solutions.