Active Pharmaceutical Ingredients: Frequently Asked Questions

TECHNICAL BULLETIN

Maxxam offers highly sensitive and specific Industrial Hygiene sample analysis for air and surface samples collected for Active Pharmaceutical Ingredients (APIs), Isolated Process Intermediates (IPIs), as well as many process chemical agents and solvents. We don't just provide analysis – we will be there to provide information and support, as well as sampling media which is included in the cost of analysis. Samples may be submitted for analysis "upon demand", with a standard turnaround of 7 working days from receipt of sample submissions. Confirmation of sample receipt is provided by email, as well as the analysis report in PDF format upon completion of analysis. Expedited service is available for a surcharge, which must be coordinated with the laboratory in advance of sample.

How do I get information on available sampling and analytical methods?

Search for the API or sampling target using the Maxxam sampling guide. If an application is found, assess the details to see if it meets the requirements of your sampling plan.

If you do not find an available application, or the application doesn't fulfill your needs, inquire with us to assess if a method is pending or other sampling options exist, such as semi-specific or nonspecific methods or if process surrogates may be an option.

Where do I find exposure limits for APIs?

Because of the wide variety of APIs and dynamics of the pharmaceutical industry, there are very few defined regulatory or published health limits (such as PELs, RELs, TLVs, etc.) available. This doesn't mean you don't need to worry about them, as they are regulated indirectly. Employers are required to provide their employees with a place of employment that "is free from recognizable hazards that are causing or likely to cause death or serious harm to employees." In the pharmaceutical industry, API Occupational Exposure Limits (OELs) are typically derived by the innovator during development, subject to refinement based upon toxicology and clinical testing. While they aren't typically published, they can sometimes be found on the manufacturers SDS, or should be available from the commercial supplier of the material. If you are having difficulty finding a limit, contact us to discuss options for having one developed.

I need results urgently! How can I expedite analytical service?

- Coordinate with our laboratory by phone or email prior to laboratory sample receipt
- Specify when you need results on your submittal form, checking the box approving ASAP surcharges
- Provide our laboratory with shipping details - tracking info or airway bill
- Notify our laboratory of any schedule changes as soon as you are aware
- Surcharges will be applied, and must be agreed to prior to sample submission

How can I get sampling media?

Sampling media is provided and included in the cost of analysis. It can be ordered online or through our Lake Zurich laboratory.

How do I ship samples back to the lab for analysis?

- Short term storage and shipping conditions are specified by method
- Use adequate and appropriate packing to protect samples during shipment
- For International shipments:
    - Use a carrier with import/export authority and tracking systems (DHL or FedEx)
    - List samples as "air samples for analysis only" on all shipping documents, avoiding the use of API or chemical names
    - Limit the declared value of samples to a minimum "of no commercial value, assigned $xx USD for customs purposes"
    - Ship as "non-hazardous; not subject to TSCA, DEA, FDA or USDA control or restriction"

What happens if I submit samples on the wrong media?

- Our laboratory will review if the submitted media was evaluated during method development. If yes, and results were satisfactory, analysis will proceed and final report will indicate "non-conforming" media used in sampling. If the media was evaluated as "unsatisfactory" for your application, you will be notified that "analysis is not possible".
- If the media has not been previously evaluated, it will be at the option of the sample submitter to discard the samples, or request that the laboratory evaluate blanks and matrix spikes. If analysis is determined to be possible, analysis will proceed, and final report will indicate "non-conforming" media used in sampling.

How long should can I retain unused media, and what should I do if it expires?

- Maxxam-supplied media is barcoded and tracked
- Limit supplies to 60 days at US locations, or up to 120 days at international locations
- Return unused or expired media to our Lake Zurich laboratory for media credit, barcode retirement and recycling
- Most filter media expiration dates are assigned for media management purposes, not due to loss of efficacy for sampling. If you are considering using expired media, contact our laboratory
- Sites with a significant negative balance of unreturned media will be invoiced at media replacement cost

About Us

Maxxam is a leading North American provider of analytical services and solutions to the energy, environmental, food, Industrial Hygiene and DNA industries. We are a member of the Bureau Veritas Group of companies – a world leader in testing, inspection and certification services. We support critical decisions made by our customers through the application of rigorous science and the knowledge and expertise of over 2,500 employees.

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