XRD Technique, Reporting, and Sample Policies for Pharmaceutical samples

The submission of samples for testing constitutes acknowledgment of the information, sample requirements, and financial responsibility of the submitter which are provided in this document.

Testing for Polymorphism:

- Unless explicitly stated that a pharmaceutical sample is for R&D only and can be performed under non-GMP testing, all samples will be processed under cGMP regulations and billed for accordingly.
- Please submit any references or requirements with the sample and clearly state an objective. Requests made to alter or reanalyze the samples/report after a report has been issued are subject to revision fees.
- Analysis reports will include an objective (if supplied), any stated requirements of the objective, a description of the sample and testing conditions, a summary of the report figures and tables and discussing of any results, and a conclusion (if an objective is supplied) addressing any supplied pass/fail criteria. Supplied data will include images of the diffraction patterns, a peak listing table for each sample, and any comparative information, such as a peak listing comparison table or diffraction pattern overlay that is utilized in the analysis to accomplish the objective of the test.
- Unless an established quality agreement states otherwise, if a validated/verified specification is not met, all failing values will be reported as Out of Spec (OOS). We do not perform retesting without explicit request unless an internal error is identified in the initial investigation that warrants the retest, such as an identified machine or clerical error. If additional investigation, testing or re-analysis is required due to issues unrelated to obvious analyst, clerical, or instrument error, the client will be charged for the cost of additional investigation, testing, or analysis time as appropriate to the situation. We do not assume responsibility for failure of method requirements that have not been verified or validated by our laboratory. Validation/verification of a method is highly recommended and may be required prior to testing for non-standard requests such as spiking or detection limit work.

General Sample requirements:

- Preferred sample quantity is 250mg or more, but XRD can be performed on as little as ~20mg if needed.
- Samples must be a fine powder or easily ground to a fine powder in a mortar and pestle.
- Samples received as pills will have any coating removed via razor blade and the pills will be ground in a mortar and pestle prior to analysis.
- Capsule samples will be broken open and the contents removed for analysis.

Technique Limitations:

- The sample must be crystalline in order to identify by XRD. Non-crystalline substances present in a sample cannot be identified, but the absence/presence of crystalline forms can be verified if a known amorphous substance is submitted.
- The lower detection limit of XRD is on the order of 1% for standard scans, but longer scans can be run in limited ranges to increase the sensitivity of the scan if a specific, low-level substance, such as a small quantity of API in a placebo, is required and there is no interference with the placebo peaks.
- The identification of a substance is dependent upon the pattern it produces matching a database entry, peak listing table, or reference diffraction pattern. Crystalline substances that do not have a database entry or a provided reference will be reported as “unidentified” and we will provide you with the diffraction pattern, peak listings, and any other pertinent observations if we are unable to identify the pattern.

Please submit your samples with the required documents to the following address:

H&M Analytical Services
1301 Whitehorse Mercerville Road
Suite 101
Hamilton, NJ 08619

https://h-and-m-analytical.com
Tel: +1 609 758 5700
admin@h-and-m-analytical.com