



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

Title: Determination of Loss on Drying

SOP No.:		Department:	QC
Effective Date:		Review Date:	
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Supersede SOP No.:	Nil		

1.0 OBJECTIVE:

1.1 To lay down a procedure for Sulphated Ash.

2.0 SCOPE:

2.1 It is applicable for the estimation of Raw material.

3.0 RESPONSIBILITY:

3.1 Analyst / Officer / Executive follow the procedure.

3.2 Head-QC are responsible for effective implementation of this SOP.

4.0 REFERENCE:

4.1 BP (Ph. Eur. Method)

5.0 DEFINITION:

5.1 Loss on drying is the loss of mass after drying under specified conditions, calculated as a percentage (m/m). Drying to constant mass means. that 2 consecutive weighings do not differ by more than 0.5mg, the 2nd weighing following an additional period of at least 30min of drying. under the conditions prescribed for the substance to be examined.

5.2 **Equipment:** The equipment typically consists of:

- weighing bottles that are made of suitable inert material and can easily be dried to constant mass; their diameter is large enough so that the layer of the substance to be examined does not exceed about 5 mm.
- An analytical balance by which it is possible to determine a change in mass of 0.1 mg.
- Depending on the procedure to be applied. a desiccator, a vacuum cabinet, a vacuum oven or an ordinary laboratory oven; in any case, the temperature of ovens is adjustable to the specified temperature $\pm 2^{\circ}\text{C}$, vacuum ovens in which the pressure can at least be reduced to about 2 kPa are suitable; ovens are qualified according to established quality system



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procedures, for example by using a suitable certified reference material (sodium amino salicylate dehydrate for equipment qualification CRS may be used).

Equipment using other means of drying such as microwaves, halogen lamps, infrared lamps or mixed technologies may be used provided they are demonstrated to be fit for purpose.

6.0 PROCEDURE:

6.1 It is recommended to perform the test in an environment that has minimal impact on sample measurement (e.g. humidity).

Weigh an empty weighing bottle that has been previously dried under the conditions prescribed for the substance to be examined for at least 30 min, then weigh the weighing bottle filled with the prescribed quantity of substance to be examined. Dry to constant mass or for the prescribed time. Where the drying temperature is indicated by a single value rather than a range, drying is carried out at the prescribed temperature $\pm 2^{\circ}\text{C}$. Use one of the following procedures, unless otherwise prescribed in the monograph.

- In a desiccator: the drying is carried out over about 100 g of molecular sieve at atmospheric pressure and at room temperature.
- In vacuo: the drying is carried out over about 100 g of molecular sieve at a pressure not exceeding 2.5 kPa, at room temperature or at the temperature prescribed in the monograph.
- In an oven at a specified temperature: the drying is carried out at atmospheric pressure in an oven at the temperature prescribed in the monograph.

After drying in an oven, allow the weighing bottle and the sample to cool to room temperature in a desiccator and weigh the weighing bottle containing the dried sample.

The mass of the sample is the difference between the mass of the filled weighing bottle and the mass of the dried empty weighing bottle.

The loss on drying is the difference in the "mass of the sample before and after drying, expressed as a percentage, m/m being implicit.

7.0 Annexures: NA



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8.0 Distribution:

8.1 Display copy 1 : Quality Control Lab

9.0 Abbreviation:

GTP : General Test Procedure

QC : Quality Control laboratories

10.0 Revision History:

10.1 Revision history table:

Document Number	CC Number/Date	Brief Description of Change