

# Lactose Analysis for Pharmaceuticals

prepASH 340 Series



Burning



High Temperature



Improved Safety



Weighing Samples



Lactose is a common substance widely used as a filler or filler-binder in the manufacture of pharmaceutical tablets and capsules. The analysis of moisture and sulphated ash within pharmaceuticals is essential to ensure that the quality of drugs meets the guidelines set out by the European Pharmacopoeia.

## Sulfated Ash Test European Pharmacopoeia

“The test ensures that the substance to be examined has a content of inorganic cations capable of forming non-volatile sulfate salts, which is below the limit defined in the individual monograph. These unintended cations could either be present as a consequence of contamination, but most often they will be residues of inorganic reagents and chemicals used in the synthesis of the substance to be examined. So the typical residue contained in the sulfate salt is the most widely used alkali metals, sodium and potassium. Since these cations are in most cases easily eliminated in the purification steps, the test gives a very important insight into the general quality in the production process of the substance to be examined, and it is therefore referenced in several hundred monographs. The test is predominantly used in testing chemically pure substances, whereas the limit test

6.14. Total ash is used for vegetable drugs. The sulfated ash is preferred to the total ash and other ashing procedures (see 6.14. Total ash) since it gives a more well-defined ash and thereby a more reproducible result. In a few monographs the test is used as a way to determine, for example, sodium deliberately present in the substance to be examined as a counter-ion.”

In this application note Precisa’s prepASH 340 Series sulphated ashing system is used to determine the ash content of lactose for use within pharmaceuticals.

## Materials and Methods

Tests were carried out using the pepASH 340 Series.



# Lactose Analysis for Pharmaceuticals

## prepASH 340 Series

The Series 340 EM prepASH thermogravimetric analyzer (TGA) automatically measures moisture, ash, and loss of ignition at reduced workload and costs. The entire process is monitored and recorded from start to finish in a closed system. The prepASH is designed as an autonomous device and does not require any additional PC.

### Thermal Analysis of Pharmaceuticals

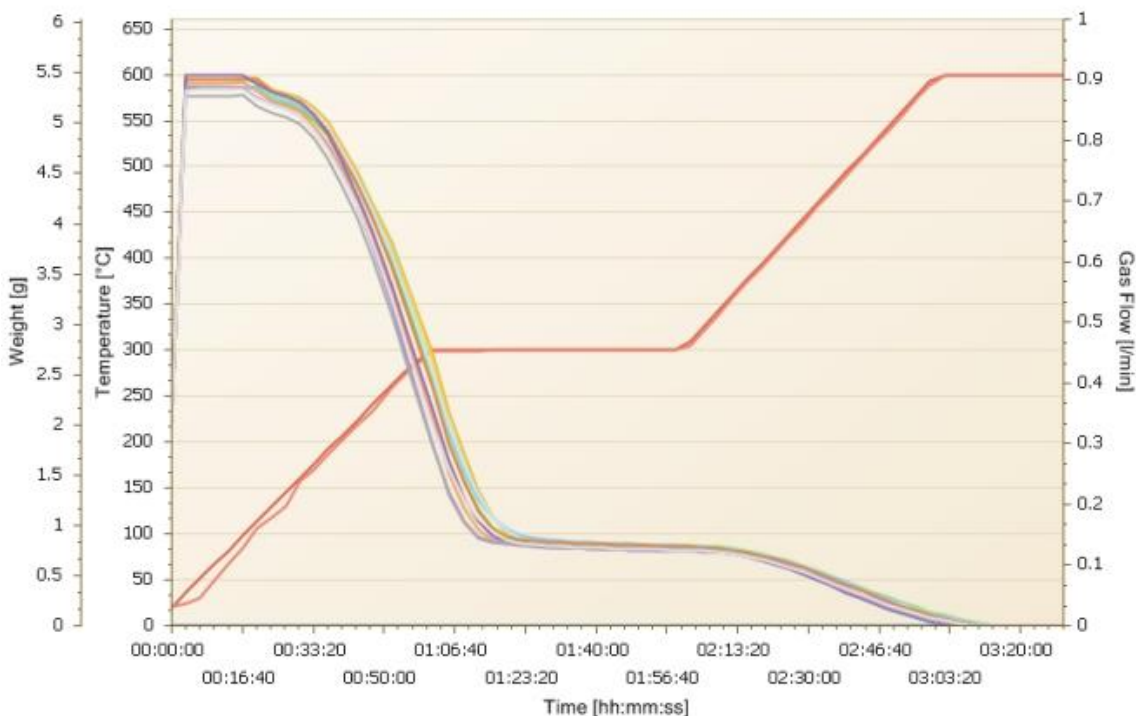
Representing the highest level of thermos-gravimetric analysis, Precisa’s prepASH Series 340 offers revolutionary improvement of sample preparation, analysis and documentation. It is the optimal solution to determine sulphated ash. With improved safety and efficiency there is no longer the need for dangerous ash analysis with open flames.

### Lactose Analysis

Automatic fuming of sulfuric acid under controlled conditions within closed prepASH.

Moisture and sulphated ash within 3.5 hours.

Step	Temp 1 [°C]	Temp 2 [°C]	Gas	Gas Flow [l/min]	Time [min]	Auto Stop [1/min]	Manual Stop	Result
1	20	300			60			
2	300	300			60			
3	300	600			60			
4	600	600			370	0.5 mg/10		Reside [%]/Start (A)



# Lactose Analysis for Pharmaceuticals

prepASH 340 Series

## Result:

Group	Pos.	Sample	ID	Tare [g]	Weight [g]	Result	Weight [g]	Calc.	Time
1	1	501982aus678088	-	40.0333	2.049	A	(AS) 0.0003	0.015	03:22
1	2	501982aus678088	-	38.7963	2.0519	A	(AS) 0.0002	0.010	03:26
1	3	501982aus678088	-	41.1973	2.0528	A	(AS) 0.0004	0.019	03:26
1	4	501982aus678088	-	40.8934	2.0919	A	(AS) 0.0006	0.029	03:29
1	5	501982aus678088	-	39.4966	2.0919	A	(AS) 0.0003	0.014	03:30
1	6	501982aus678088	-	41.1511	2.0248	A	(AS) 0.0004	0.020	03:26
1	7	501982aus678088	-	38.8552	2.1027	A	(AS) 0.0005	0.024	03:27
1	8	501982aus678088	-	37.8869	2.0124	A	(AS) 0.0003	0.015	03:24
1	9	501982aus678088	-	38.9983	2.0493	A	(AS) 0.0003	0.015	03:21
1	10	501982aus678088	-	38.577	2.0228	A	(AS) 0.0004	0.020	03:24
1	11	501982aus678088	-	38.3618	2.0538	A	(AS) 0.0004	0.019	03:21
1	12	501982aus678088	-	39.0446	2.0151	A	(AS) 0.0002	0.010	03:25

## Statistic:

Group: 1	A-Result	A-Calc: Res[%]/Start
mean	0.00036	0.01743
std	0.00012	0.00553
rstd	32.49768	31.72056
n	12	12

## Info:

ID#1:

ID#2: Precisa 1

ID#3:

### prepASH Info

Type: 229

S/N: 3400020

Software Version: A1-1-2-04

### Balance Info

Software Version: E01-0090 P16

S/N: 5001576

### Temperature Calibration

Date: 11/1/2016 11:01AM

Operator: PRECISA

### Balance Calibration

Date: 11/30/2016 10:16AM

Operator: PRECISA