



PANalytical  
get insight



# EPSILON 1

Pharmaceutical catalyst residues analysis at the push of a button



46 <b>Pd</b> 106.4	45 <b>Rh</b> 102.9	77 <b>Ir</b> 192.2	78 <b>Pt</b> 195.09	44 <b>Ru</b> 101.1
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USP <232>, <233>, <735> and ICH Q3D



**Z** Factory pre-calibrated

**O** Possible to analyze with Epsilon 1

**Z** Not possible to analyze with Epsilon 1

1 H 1.008																	2 He 4.003	
3 Li 6.941	4 Be 9.012																	10 Ne 20.180
11 Na 22.990	12 Mg 24.31																	18 Ar 39.948
19 K 39.098	20 Ca 40.08	21 Sc 44.96	22 Ti 47.88	23 V 50.94	24 Cr 52.00	25 Mn 54.94	26 Fe 55.85	27 Co 58.93	28 Ni 58.69	29 Cu 63.55	30 Zn 65.39	31 Ga 69.72	32 Ge 72.61	33 As 74.92	34 Se 78.96	35 Br 79.904	36 Kr 83.80	
37 Rb 85.47	38 Sr 87.62	39 Y 88.906	40 Zr 91.22	41 Nb 92.91	42 Mo 95.94	43 Tc (98)	44 Ru 98.91	45 Rh 101.07	46 Pd 106.42	47 Ag 107.87	48 Cd 112.41	49 In 114.82	50 Sn 118.71	51 Sb 121.75	52 Te 127.60	53 I 126.90	54 Xe 131.29	
55 Cs 132.905	56 Ba 137.33	L	72 Hf 178.49	73 Ta 180.95	74 W 183.85	75 Re 186.2	76 Os 190.2	77 Ir 192.22	78 Pt 195.08	79 Au 196.97	80 Hg 200.59	81 Tl 204.38	82 Pb 207.21	83 Bi 208.98	84 Po (209)	85 At (210)	86 Rn (222)	
87 Fr (223)	88 Ra 226.02	A																
		L	57 La 138.91	58 Ce 140.12	59 Pr 140.91	60 Nd 144.24	61 Pm (145)	62 Sm 150.36	63 Eu 151.97	64 Gd 157.25	65 Tb 158.93	66 Dy 162.50	67 Ho 164.93	68 Er 167.26	69 Tm 168.93	70 Yb 173.04	71 Lu 174.97	
		A	89 Ac (227)	90 Th 232.04	91 Pa 231.04	92 U 238.03	93 Np 237.05	94 Pu (244)	95 Am (243)	96 Cm (247)	97 Bk (247)	98 Cf (251)	99 Es (252)	100 Fm (257)	101 Md (258)	102 No (259)	103 Lr (260)	

# Pharmaceutical catalysts

## Accurate, easy and fast quantification

The Epsilon 1 X-ray fluorescence (XRF) spectrometer is the ideal analytical solution for quantification of palladium, platinum, rhodium, ruthenium and iridium in pharmaceutical materials. Considerable savings in time and cost are two of the many benefits XRF can bring to the pharmaceutical industry.

Epsilon 1 is pre-calibrated with an out-of-the-box solution for easy quantification of residual metal catalysts Ru, Rh, Pd, Ir and Pt in pharmaceutical materials. Epsilon 1 uses XRF (USP <735> and EP 5.2.2.37.) to produce fast, cost-effective, precise and accurate data in line with USP chapters <232>, <233> and ICH Q3D without the need for additional chemicals or operating gasses.

The measurements are carried out directly on the solid powder with little or no sample preparation. Since XRF is a non-destructive technique, the sample can also be measured subsequently by other analytical techniques, if required.

Epsilon 1's software has the flexibility to perform basic as well as more sophisticated analyses. The Enhanced Data Security module facilitates compliance with FDA 21 CFR Part 11 regulations.

PANalytical has a strong reputation for safe and high-end X-ray instrumentation. Epsilon 1 is built using PANalytical market-leading technology with superior quality, worldwide service and application support. Also application training, courses and expertise are available upon request.

## The total solution consists of:

- Epsilon 1 instrument with user software
- Factory pre-calibration for Pd, Pt, Rh, Ru, and Ir in pharmaceutical materials
- A set of calibration standards
- IQ/OQ documents
- 500 small-mass holders and foils for loose powders

46	45	77	78	44
<b>Pd</b>	<b>Rh</b>	<b>Ir</b>	<b>Pt</b>	<b>Ru</b>
106.4	102.9	192.2	195.09	101.1



Epsilon 1 spectrometer



500 sample preparation foils

500 small-mass holders

Calibration standards

IQ/OQ documents

# Results in just 4 steps

## Easy sample preparation



1 Prepare small-mass holder for small amounts of sample.



2 Fill small-mass holder with typically 100 – 200 mg sample.

## Easy analysis



3 Place your sample for measurement.



4 Enter sample name and touch the 'measure' icon.

## Compliant results (Supports USP and ICH)





**Measure in your own language**

Ten most common languages are available for the operator:

測量  
Measure  
測定  
Mesurer  
Messung  
Mesure  
Zmierzyć  
Medida  
Измерить  
Médír

# Built for pharmaceuticals

The Epsilon 1 is a fully integrated energy dispersive XRF analyzer consisting of a spectrometer, built-in computer and analysis software. Powered by the latest advances in excitation and detection technology the Epsilon 1 is a star performer in the low-cost benchtop instrument class. A well-designed optical path, a wide range of excitation capabilities ranging from 10 to 50 kV for light and heavier elements and a highly sensitive SDD detector system contribute to the Epsilon 1's uniqueness.

- 1 Self-contained system**  
Built-in computer running Microsoft Windows 7 with a powerful CPU and 120 GB hard drive ensures flexibility to store and handle thousands of results.
- 2 Repeatability for years**  
A low-drift X-ray tube and a handy drift correction routine give compliant results for years without the need for time-consuming re-calibration.
- 3 Maximum sensitivity**  
The thin-window Ag anode X-ray tube, designed and manufactured by PANalytical, ensures high quality and sensitivity. The 50 kV X-ray tube and generator are ideal for exciting higher energy elements like Pd, Rh and Ru, resulting in faster analysis times.
- 4 Dust protection**  
In order to shield the delicate heart of the system from powder dust, a protection foil is in place. In case of spillage, the foil can be replaced easily by the operator.
- 5 Economical footprint**  
Compact design with a built-in computer and touch screen reduces the requirement of valuable lab space to less than 0.15 m<sup>2</sup>.
- 6 Easy operation**  
High-resolution (1024 x 768), 10.4" LCD touch screen for easy walk-up and operation



## Advantages of XRF for pharmaceutical material analysis

- Non-destructive analysis
- No chemical waste
- Low running costs
- Quick screening method
- Simple, fast and safe sample preparation
- Wide analytical concentration range (ppm – %) reducing the necessity for dilution and associated errors



**7 Easy communication**

USB and network connections for use of standard computer peripherals enable extended use, application development and seated operator.

**8 Best accuracy**

Epsilon 1 uses the latest high-resolution silicon drift detector technology to separate analytical lines in the XRF spectrum. Characteristic lines of metallic catalysts are sufficiently separated to ensure best accuracy.

**9 Atmospheric variations**

Built-in temperature and air-pressure sensors compensate for atmospheric variations, ensuring excellent results whatever the weather.

**10 Sample positioning**

Highly repeatable sample positioning reduces sample-to-sample variations.

**Safety guaranteed**

Epsilon 1 complies with the latest Machinery Directive, CSA, IEC, EMC, Vollschutz norms and standards for protection and radiation safety to guarantee a safe instrument for the operator.





# Easy, robust and accurate pharmaceutical catalyst re

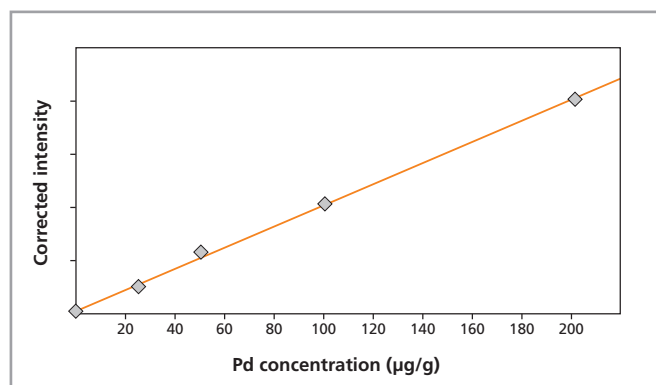
## Calibration

Six calibration standards were used to calibrate Epsilon 1 for ruthenium, rhodium, palladium, iridium and platinum in cellulose powder. Samples (200 mg) were weighed and measured for a total of 20 minutes per sample.

Element	Concentration range (µg/g)	RMS (µg/g)	Correlation
Ru	0 - 200	0.3	0.99996
Rh	0 - 200	1.9	0.99976
Pd	0 - 200	2.9	0.99946
Ir	0 - 200	0.8	0.99997
Pt	0 - 200	0.7	0.99997

\* The RMS value is a measure of the difference between the calculated concentration and the certified chemical concentration and is therefore a measure of the accuracy of the method (standard deviation).

The calibration curves show good correlation coefficients together with small root mean square (RMS) values as presented in the table. These values demonstrate a high degree of accuracy for the method.



Calibration graph for palladium in 200 mg cellulose powder





# quantification of sidues

## Accuracy comparison and repeatability

The accuracy and repeatability of the method is demonstrated by measuring a validation standard 20 times as an unknown sample and comparing the measured average concentrations against an ICP-MS value. The data in the table compares favorably with ICP-MS data.

Element	Ru	Rh	Pd	Ir	Pt
Average conc. (µg/g)	52.4	51.1	49.9	50.9	50.6
RMS (µg/g)	0.9	0.8	1.5	0.6	0.4
ICP-MS (µg/g)	50.0	49.9	50.4	49.9	50.5

## Lower limit of detection

Lower limit of detections (LLD) vary depending upon the sample matrix (composition), measurement time and the amount of sample being analyzed. When more than 200 mg of material is available for analysis, the LLD can be improved even further. LLD values for 20 minutes and 35 minutes are shown in the table.

Element	Ru	Rh	Pd	Ir	Pt
LLD using 20 min (µg/g)	0.8	2.7	5.2	0.3	0.4
LLD using 35 min (µg/g)	0.5	1.5	3.3	0.3	0.2



# GMP, GLP and FDA 21 CFR Part 11 Enhanced Data Security

The Enhanced Data Security (EDS) software module option is designed for GMP and GLP environments, and enables the user to comply with FDA 21 CFR Part 11.

The software includes every feature required to satisfy the strict environmental protocols:

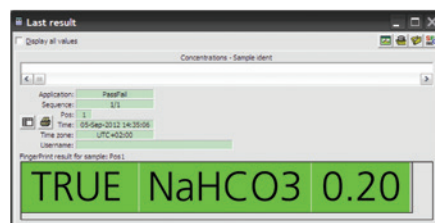
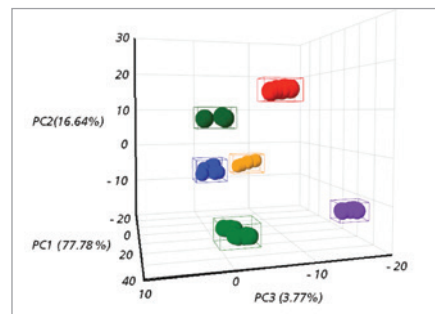
- Multiple security levels
- Log in with user identification to prevent improper use of the system
- Reporting of date and time in Universal Time Coordinate (UTC)
- Results are stored in the 'history' setting
- Inclusion of user names in reports
- Extensive audit trail of results
- LIMS integration



The FingerPrint option is available for material characterization and PASS/FAIL analysis. It is ideal for material testing when identification or speed is important but the actual composition is not of interest.

FingerPrint generally involves little or no sample preparation and the unknown sample is compared against a library of standards or other in-house samples. Then the closest match is reported with a level of uncertainty.

Principal components analysis (PCA) in combination with cluster analysis are powerful tools to investigate materials by setting up automated fingerprinting applications. With this tool a 3D graphical visualization of the data set is also possible.



## About PANalytical

PANalytical's mission is to enable people to get valuable insight into their materials and processes. Our customers can be found in virtually every industry segment, from building materials to pharmaceuticals and from metals and mining to nanomaterials. The combination of our software and instrumentation, based on X-ray diffraction (XRD), X-ray fluorescence (XRF) and near-infrared (NIR) spectroscopy as well as pulsed fast thermal neutron activation (PFTNA), provides our customers with highly reliable and robust elemental and structural information on their materials and is applied in scientific research and industrial process and quality control.

PANalytical employs over 1,000 people worldwide. The company's headquarters are in Almelo, the Netherlands. Fully equipped application laboratories are established in Japan, China, the US, Brazil, and the Netherlands. PANalytical's research activities are based in Almelo (NL) and on the campus of the University of Sussex in Brighton (UK). Supply and competence centers are located on two sites in the Netherlands: Almelo (X-ray instruments) and Eindhoven (X-ray tubes), in Nottingham, UK (XRF applications and standards), in Quebec, Canada (fusion sample preparation) and in Boulder CO, US (near-infrared instruments).

PANalytical is active in all but a few countries of the world. This worldwide sales and service network ensures unrivalled levels of customer support.

The company is certified in accordance with ISO 9001 and ISO 14001.

Visit [www.panalytical.com](http://www.panalytical.com) for more information about our activities.

PANalytical is part of Spectris plc, the productivity-enhancing instrumentation and controls company.

## Access to expertise

With the largest service network we are able to offer the most comprehensive support package possible.

### Expertise:

- On-site training available
- XRF training courses
- Performance optimization
- Customizable expertise programs
- Assistance with multi-laboratory standardization

## Care Agreements

Our customer support solutions have been developed with your business in mind. They are formulated as a family of four Care Agreements which can be tailored to your specific needs and provide fast, secure and reliable support.

- **ECONOMY:** indispensable coverage for self-sufficient operations
- **ADVANCED:** cost-effective support for routine usage
- **PREMIUM:** flexible package for high equipment usage
- **ELITE:** most comprehensive package for demanding environments

## Global and near



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