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Minimum Sample Weights According to Various Pharmacopoeias, OIML R76, and EURAMET cg-18

What should a sample weigh at least to obtain a reliable weighing result?

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Abstract

The smaller the weight of the sample, the larger the relative measurement uncertainty that the weighing is subject to. There are various concepts for specifying corresponding minimum sample weights so as not to exceed a specified relative measurement uncertainty.

The most well-known concepts are those of various pharmacopoeias (particularly the United States Pharmacopeia, as well as the European, Japanese, and Chinese Pharmacopoeias), OIML R 76, and the EURAMET Calibration Guide No. 18. These are explained and compared below. Additionally, typical minimum weighing values for various Sartorius balance models are listed.

The Concept of Minimum Sample Weight and Specific Implementations According to Different Pharmacopoeias, OIML R76, and EURAMET cg-18.

Every balance has (at least) one weighing range from 0 to its maximum load (Max). The resolution within the weighing range is classified by the scale interval *d*, which describes the smallest mass difference that can be displayed on the balance's screen. For example, a typical analytical balance (QTX224IMU-1S) has Max = 220 g and *d* = 0.1 mg.

Each measured value is subject to a measurement uncertainty, regardless of where it is taken in the weighing range. Measurement uncertainty describes the range within which the true value of the measured quantity lies, with a certain probability. It encompasses all potential sources of error that can affect the measurement's accuracy and typically consists of two parts: a constant part, independent of the measurement value, and a variable part that increases with the size of the measurement value.

In absolute terms, measurement uncertainty increases with the weighed load. However, when considering the uncertainty contribution in relation to the size of the sample weight, smaller loads exhibit a larger relative uncertainty value than larger loads. For example, with an assumed uncertainty of 0.1 mg for a sample weight of 100 g, results in a relative measurement uncertainty of 0.0001 % for the aforementioned analytical balance QTX224IMU-1S. The same (absolute) uncertainty contribution of 0.1 mg for a small sample weight of 1 mg corresponds to a relative uncertainty of 10 %.

Since smaller weighing loads are associated with larger relative uncertainties, it makes sense to establish a so-called minimum sample weigth, which ensures that no sample weights are taken for which a certain relative measurement uncertainty is exceeded.

What is considered an acceptable relative measurement uncertainty and how the minimum sample weight is subsequently determined varies across different regulations for various fields and applications. The most well-known concepts are those of various pharmacopoeias—particularly the **United States Pharmacopeia (USP)** (1), the European Pharmacopoeia (Ph.Eur.) (2), the Japanese Pharmacopoeia (JP) (3), and the Chinese Pharmacopoeia (ChP) (4)—which are applied in the pharmaceutical industry; OIML R 76 (5) for balances subject to legal metrology; and the **EURAMET Calibration Guide No. 18** (6). These three concepts and the resulting (typical) values for minimum weighing loads will be further explained below.

However, minimum sample weights are always defined for net values in all three concepts. It is therefore not permitted to fall below these values due to differential weighing with a larger tare load.

Specific example: For a balance with a minimum sample weight of 1 g, it is not permitted to weigh an amount of 0.5 g substance in a vessel with a mass of 50 g in order to consider the difference between the weight of the empty vessel and the vessel including the substance (50.5 g – 50.0 g = 0.5 g) as a valid weighing value.

Figure 1: Weighing smallest amount of substance on a microbalance

Minimum Sample Weight According to OIML R 76 for Legal Metrology

The document "OIML R 76-1:2006" (5) is formally only a recommendation, but was adopted by many states and regions unchanged to determine requirements for balances which are subject to legal metrology. In Europe, for example, due to directive 2014/31/EU (4) (implemented in the member states in the form of the harmonised standard EN 45501 (5)), in the US in "Handbook 44" (6) and in China by "GB/T 23111" (7).

In all of these requirements, non-automatic weighing instruments are divided into accuracy classes, from which (taking the scale interval d of the balance and the number of verification scale intervals n into consideration) the minimum sample weight is calculated according to table 1.

The minimum sample weight is therefore determined according to OIML R 76 based on the accuracy class and the scale interval – it therefore does not have to be individually determined at the balance's installation location by means of a measurement. The minimum load is shown for balances that have an approval according to OIML R 76 on | in the display and on the identification plate. For an example, see fig. 2.

The minimum sample weight according to OIML R 76 is only defined for models that are approved for measurements in the context of legal metrology. However, it is not defined for devices without a type approval.

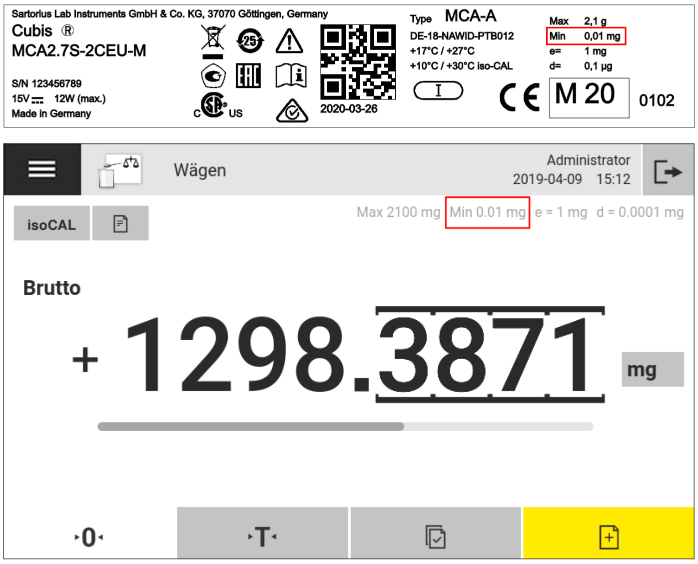

Figure 2: Specification of the minimum sample weight according to OIML R 76 on the identification plate (top) and in the display (bottom) of an MCA2.7S-2CEU-M. The minimum sample weight for this model is 0.01 mg (marked in red).

Since the minimum sample weight according to OIML R 76 is not dependent on current measured values, sample weights above this value may be taken for legally regulated applications if the balance complies with legally prescribed error limits.

Accuracy class	Verification scale interval e	Number of verification steps $n = Max/e$	Minimum load Min
I Special accuracy	$0.001\text{ g} \le e$	$50\,000 \le n$[1]	$100 \cdot d$
II High accuracy	$0.001\text{ g} \le e \le 0.05\text{ g}$ $0.1\text{ g} \le e$	$100 \le n \le 100\,000$ $5\,000 \le n \le 100\,000$	$20 \cdot d$ $50 \cdot d$
III Medium accuracy	$0.1\text{ g} \le e \le 2\text{ g}$ $5\text{ g} \le e$	$100 \le n \le 10\,000$ $500 \le n \le 10\,000$	$20 \cdot d$ $50 \cdot d$
IIII Ordinary accuracy	$5\text{ g} \le e$	$100 \le n \le 1\,000$	$10 \cdot d$

Table 1: Minimum load depending on the accuracy class and the actual scale interval according to OIML R 76-1:2006.

[1] For balances with d < 0.1 mg, n may be < 50,000.

Minimum Sample Weight According to Different Pharmacopoeias

The requirements for laboratory balances in the pharmaceutical industry have significantly evolved in recent years. Driven by a general need for clarification and the goal of international harmonization, the major pharmacopoeias—United States Pharmacopeia (USP), European Pharmacopoeia (Ph.Eur.), Japanese Pharmacopoeia (JP), and Chinese Pharmacopoeia (ChP)—have fundamentally revised and closely aligned their chapters on balances.

To reduce erroneous analyses in pharmaceutical processes to an acceptable or negligible level, the various pharmacopoeias set nearly identical requirements for determining the minimum sample weight based on a repeatability measurement with at least 10 repetitions. The repeatability measurement is satisfactory if the ratio of twice the standard deviation s (obtained from the repeatability measurement) to the "smallest (desired) net weight" (m_{SNW}) meets the acceptance criterion of ≤ 0.10%.

$$\frac{2 \cdot s}{m_{SNW}} < 0.10\%$$

It is therefore necessary for the user to establish the smallest sample amount to be weighed on the balance as the "smallest (desired) net weight."

The theoretically smallest possible minimum sample weight (m_{min}) can be calculated from the standard deviation s of the repeatability measurement:

$$m_{min} = \begin{cases} 2\,000 \cdot s & \text{if } s \geq 0.41 \cdot d \\ 2\,000 \cdot 0.41 \cdot d & \text{otherwise} \end{cases}$$

The minimum sample weight (m_{min}) is therefore determined pragmatically so that any sample weights are larger than random deviations by a factor of 2000 (or than its standard deviation, to be mathematically correct). The second line in the formula above only limits this to a minimum value of $2000 \cdot 0.41 \cdot d = 820 \cdot d$, as otherwise a measured standard deviation of $s = 0$ g would result in a minimum sample weight of $m_{min} = 0$ g.

Remark: The minimum weighing load (m_{min}) represents the (temporary) result of a performance check from a repeatability measurement and can change with each test. It is therefore strongly advised against adopting the calculated minimum weighing load (m_{min}) as the "smallest (desired) net weight" as it would otherwise change with each test. If users obtain a standard deviation of, for example, $s = 5$ µg from a repeatability measurement, set the minimum sample weight for their balance accordingly to $2000 \cdot s = 10$ mg, and then weigh samples down to this value, they risk that at the next repeatability measurement $s = 8$ µg is obtained, and therefore a minimum sample weight of $2000 \cdot s = 16$ mg results.

In this case, it would then be questionable whether the previous weighings between 10 mg and 16 mg met the requirements of the pharmacopoeias. We therefore recommend setting the "smallest (desired) net weight" (m_{SNW}) based on the actual requirements. Here, the concept of a "Safety Factor" (SF) also comes into play, representing the ratio between the "smallest (desired) net weight" (m_{SNW}) and the minimum weighing load (m_{min}). Such a safety factor is described in the current version of USP<1251> (11) and can provide additional security for small weighings. On balances used under a pharmacopoeia, the "smallest (desired) net weight (m_{SNW}) should be clearly marked.

Some Sartorius balances allow this to be entered in the service menu, net weighings below the "smallest (desired) net weight" (m_{SNW}) must not be performed (see section on the SQmin function).

Minimum Sample Weight According to EURAMET Calibration Guide No. 18

The "Calibration Guide No. 18" (in the following "cg-18" for short) is a calibration guideline for non-automatic weighing instruments published by EURAMET (the European Association of National Metrology Institutes). Unlike the two preceding sections, the cg-18 is not obligatory. However, it is a very comprehensive consideration of the topic of "Calibrating balances" and, above all, the associated uncertainty calculation. Its worldwide acceptance among accreditation bodies, experts, and users is steadily increasing.

The biggest difference from the concepts of both preceding sections is that cg-18 takes the user's process requirements into consideration. In many countries, Sartorius issues accredited or non-accredited calibration certificates according to cg-18, which also specify the "Uncertainty in use", i.e. the measurement uncertainty for the user, in the form of a linear equation.

A typical "uncertainty in use" for a typical laboratory balance (MCA224S) on a calibration certificate might look as follows:

Uncertainty of the weighing result $U_{gl}(W)$:
$U_{gl}(W) = 0.00024\ \text{g} + 3.88 \cdot 10^{-6} \cdot R$

This equation allows the calculation of the expanded measurement uncertainty $U_{gl}(W)$ for each weighed value R within the weighing range.

Expressed in absolute terms, this results in uncertainties between

$U_{gl}(0) = 0.00024\ \text{g} + 3.88 \cdot 10^{-6} \cdot 0\ \text{g} = 0.00024\ \text{g}$

and

$U_{gl}(\text{Max}) = 0.00024\ \text{g} + 3.88 \cdot 10^{-6} \cdot 220\ \text{g} = 0.0011\ \text{g}$.

Expressed in relative terms, this uncertainty is negligible again at high loads (at Max: 0.0011 g / 220 g = 0.0005 %), but increases at small loads (at the minimal load d = 0.0001 g: 0.00024 g / 0.0001 g = 240%).

The concept of the minimum sample weight as per EURAMET cg-18 now provides that the user sets the maximum relative measurement uncertainty – for example, 1 %. With a relatively simple calculation it can then be seen that the sample weight must always be at least 0.0242 g (also see the dotted lines in fig. 3) – at this load, the relative measurement uncertainty is exactly the required 1 %; at higher loads, the relative measurement uncertainty is lower, and at smaller loads it is higher.

In many application areas, it is further common practice to include an additional safety factor (SF) that is used to multiply the measurement uncertainty. If the user selects, for example, a safety factor of SF = 2, this corresponds to a multiplication of the above equation for $U_{gl}(W)$ by 2.

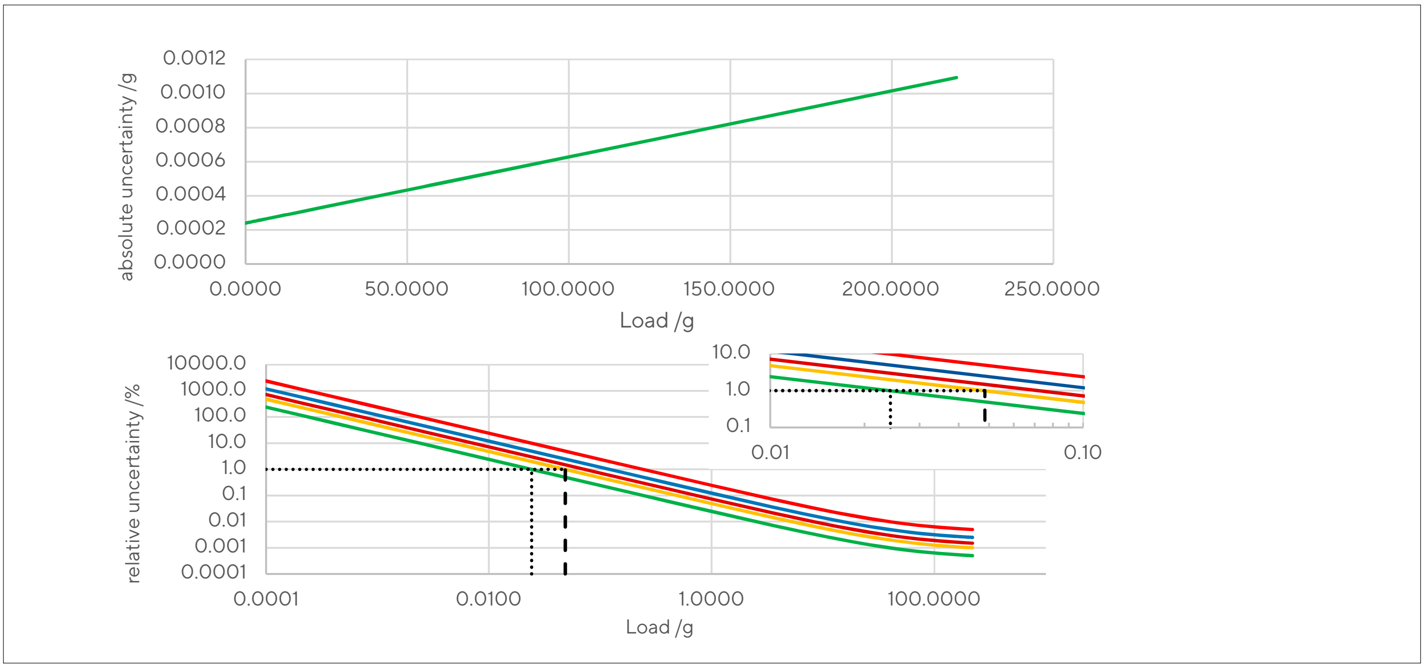

Figure 3: Example of absolute (top) and corresponding relative (bottom, green line) uncertainty according to EURAMET cg-18 for a laboratory balance Secura224-1S. In the diagram below, additional lines are entered, which result from multiplication with a safety factor of 2 (orange), 3 (dark red), 5 (blue) or 10 (light red). The determination of a minimum sample weight described in the text is represented by black lines. The additional small diagram is an enlarged section.

The relative measurement uncertainty multiplied by such a safety factor is then generally referred to as the process accuracy. According to the safety factor, more must be weighed to always remain above the required accuracy.In the example of a required process accuracy of 1% with a safety factor of 2, this is 0.0485 g (dashed line in Fig. 3). Note: Even if in this example, the safety factor of 2 almost exactly doubles the value for the minimum sample weight, it is not always the case that the safety factor is directly proportional.

Remark: As with the minimum sample weight as per USP, chapter <41> for the minimum sample weight according to EURAMET cg-18, we also recommend setting the actual minimum sample weight for your processes somewhat higher. If, in the above example (1 %, SF = 1, Min_{cg18} = 0.0242 g = 24.2 mg) it were set to 25 mg, there would be a risk that during the next determination of the minimum weighing load according to EURAMET cg-18, it might be higher due to somewhat poorer measurement results.

Determination of the process accuracy and the safety factor under Euramet cg-18

The freedom to independently set process accuracy and the safety factor for determining the minimum sample weight can lead to uncertainty for some users, raising the question of which values are suitable. In general, the user must decide this in accordance with the requirements of their processes. A helpful method for how test intervals and tolerances can be established based on risk is described in our white paper "Test Intervals and Tolerances".

For the **safety factor** in particular, additional considerations can be made as to what exactly should be achieved with this additional safety:

For very special applications, uncertainty contributions may be relevant, which (cannot be) are not taken into consideration in the uncertainty in use determined as part of calibration as per cg-18 – for example creep and hysteresis effects can occur during very long weighing processes. If determining these contributions is very complex or is not possible, they can pragmatically be "covered" by a safety factor.

Another way to sensibly determine the safety factor comes from the "confidence level": By convention, uncertainties are specified with a confidence level of 95.45 % – which means that the true value lies in the interval [measured value – uncertainty ... measured value + uncertainty] with a probability of 95.45 %. With a safety factor of 1.5, this confidence level can be increased to 99.73 % and even to 99.99 % with a safety factor of 2. Fig. 4 illustrates this.

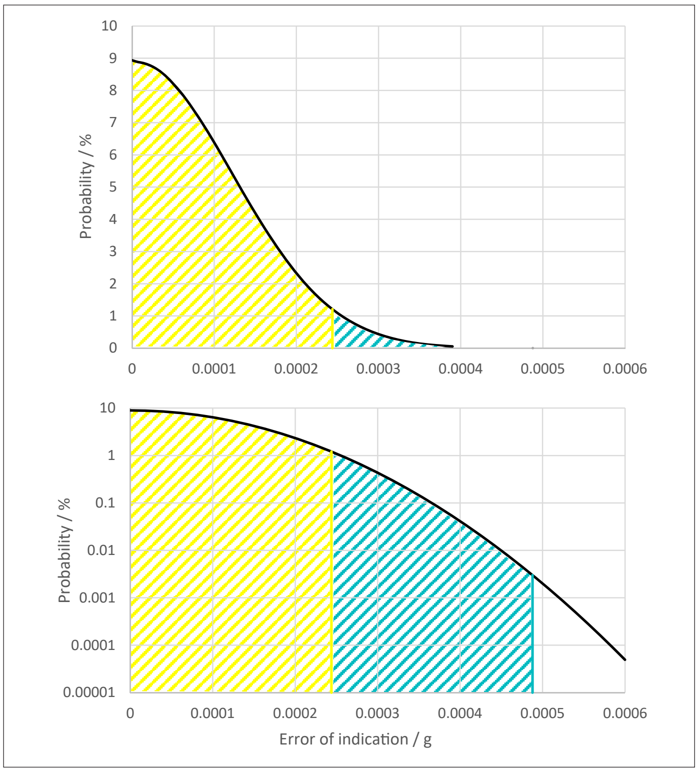

Figure 4: Probability for a determined error of indication, calculated for an example. If the specified expanded uncertainty is taken, "only" 95.45 % of all cases are covered (area shaded in yellow). If the specified uncertainty is multiplied by a safety factor of 2, 99.99 % of all cases are covered (area shaded in yellow + area shaded in cyan).

What Does Sartorius Offer Regarding Minimum Sample Weight?

Minimum sample weight according to OIML R 76 for legal metrology
The minimum sample weight according to OIML R 76 is determined for each balance model; in other words, it is not dependent on ambient conditions or measurement results, and therefore is permanently printed on the identification plate or is permanently visible in or on the display. However, users must ensure that the balance complies with the permissible error limits at any time, i.e. also between any legally prescribed (re)verifications. For this purpose, Sartorius Service offers corresponding reports in many countries, which document that the balance complies with the legally permissible error limits and that weighing down to the specified minimum load is also permitted. For this purpose, also see the corresponding white paper of this series(12).

Minimum sample weight according to USP, chapter <41>
In many countries, Sartorius Service offers the determination of the minimum sample weight according to various pharmacopoeias as a service, along with corresponding professional documentation for the user's quality management records.

For Sartorius Cubis® balances, there is still the "USP Advanced" Q-app, available via the corresponding app center, which allows the users themselves to determine the working range according to USP, chapter <41>. The optimal working range is automatically evaluated here. The documentation of the check can occur on a connected Sartorius printer and|or via the network based on Q-Web via HTML visualisation. For this purpose, also see the corresponding white paper of this series (9).

Minimum sample weight according to EURAMET Calibration Guide No. 18
Through Sartorius Service, a minimum weighing load certificate is optionally offered alongside the calibration certificate during calibration according to EURAMET cg-18. In this certificate, the minimum weighing loads for different process accuracies and safety factors can be easily and clearly read from a table. See also the corresponding white paper in this bundle (10).

Minimum weight function on Sartorius premium balances
The premium balance series from Sartorius (Cubis®, Secura®, Cubis® II, ...) feature the "Minimum Weight" function to monitor compliance with a minimum sample weight during the weighing process. With this function, a Sartorius service technician can input a value for a minimum sample weight into the balance, so that when the function is activated, the user is visually alerted if the weighing value falls below this minimum sample weight. This function is primarily intended for a minimum sample weight according to chapter <41> of the USP – but, of course, at the request of the user, the service technician can also save a value for a minimum sample weight that has been otherwise determined.

Figure 5: Display of a Secura524-1S with switched on SQmin function. If the value that has been determined based on the USP and stored by Sartorius Service of, in this case, 0.1 g is not reached, the indication of the minimum sample weight lights up in red. With a correspondingly set higher security level, the weighing result is also identified as "not valid" by the exclamation mark and | or the result cannot be expressed or printed..

Literature

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2. OIML R 76-1 Edition 2006 (E). "Non-automatic weighing instruments. Part 1: Metrological and technical requirements – Tests."
3. EURAMET Calibration Guide No. 18, Version 4.0. "Guidelines on the Calibration of Non-Automatic Weighing Instruments" (10|2015).
4. Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.
5. DIN EN 45501:2016; Metrological Aspects of Non-Automatic Weighing Instruments.
6. NIST Handbook 44 Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, 2020.
7. GB/T 23111-2008 Non-Automatic Weighing Instrument.
8. Sartorius White Paper: Working in Legal Metrology (Use and Testing of Laboratory Balances in a Legally Regulated Environment), 2024.
9. Sartorius White Paper: Use of Laboratory Balances in the Pharmaceutical Industry (Chapters <41> and 1251 of the US Pharmacopeia as well as Chapter 2.1.7 of the EU Pharmacopeia), 2021.
10. Sartorius White Paper: EURAMET cg-18 Calibration Guideline for Electronic, Non-Automatic Weighing Instruments (Specifications, Options, and Implementation of the Guideline by Sartorius), 2020.

Sartorius Recommendations

- Check which minimum sample weight concept applies to your balance | your application.
- If you have the minimum sample weight determined according to EURAMET cg-18, check whether specifications regarding process accuracy and the safety factor apply to your applications. Otherwise select these values according to the recommendations mentioned in the text.
- Determine a minimum sample weight that is also adhered to with the following provisions and have it checked regularly.

This white paper is part of the white paper series "Best Practice Guide: Lab Weighing". To be able to dynamically add updates and corrections and at the same time giving users as clear a reference as possible, for example in their QM documentation, versions are provided.

Version history

Version	Date	Changes
1.0	July 2020	Initial version
2.0	April 2026	Complete rework

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Simplifying Progress

Smallest possible, typical and recommended values for minimum net weights according to OIML R76 | USP <41> | EURAMET cg-18

Smallest possible and typical values for minimum net weights for some models of the Cubis® II series.
The values can be used as good approximations for models of other series as well, when they comprise the same metrological characteristics (Max and d).
The following table is functional - in the pdf version, values for the process accuracy and the safety factor can be entered and the respective values in the table will change accordingly.

Model	Min$_{R76}$	Min$_{USP<41>}$			Min$_{CG-18}$		
		Safety factor (optional): 1.00			Process accuracy: 1.0 %		Safety factor: 3.0
		Smallest possible	Typical**	Recommended***	Smallest possible	Typical**	Recommended***
MCA2.7S	10 µg*	0.082 mg	0.30 mg	1.00 mg	24 µg	143 µg	309 µg
MCA3.6P	100 µg*	0.82 mg	1.0 mg	2.5 mg	240 µg	406 µg	1218 µg
MCA6.6S	100 µg*	0.82 mg	1.0 mg	2.5 mg	240 µg	406 µg	1218 µg
MCA10.6S	100 µg*	0.82 mg	1.0 mg	2.5 mg	240 µg	406 µg	1218 µg
MCA36S	100 µg*	0.82 mg	1.5 mg	3.5 mg	240 µg	752 µg	1218 µg
MCA36P	100 µg*	0.82 mg	1.5 mg	3.5 mg	240 µg	752 µg	1218 µg
MCA66S	100 µg*	0.82 mg	1.5 mg	3.5 mg	240 µg	752 µg	1218 µg
MCA66P	100 µg*	0.82 mg	1.5 mg	3.5 mg	240 µg	752 µg	1218 µg
MCA116S	200 µg*	1.64 mg	5.0 mg	8.0 mg	0.48 mg	1.35 mg	2.10 mg
MCA226S	500 µg*	4.10 mg	8.0 mg	12.0 mg	1.23 mg	3.00 mg	4.51 mg
MCA125S	1 mg*	8.2 mg	13.0 mg	25.0 mg	2.4 mg	5.5 mg	12.1 mg
MCA125P	1 mg*	8.2 mg	13.0 mg	25.0 mg	2.4 mg	5.5 mg	12.1 mg
MCA225S	1 mg*	8.2 mg	13.0 mg	25.0 mg	2.4 mg	5.5 mg	12.1 mg
MCA225P	1 mg*	8.2 mg	13.0 mg	25.0 mg	2.4 mg	5.5 mg	12.1 mg
MCA124S	10 mg*	82 mg	100 mg	250 mg	24 mg	39 mg	60 mg
MCA224S	10 mg*	82 mg	100 mg	250 mg	24 mg	39 mg	60 mg
MCA324S	10 mg*	82 mg	100 mg	250 mg	24 mg	39 mg	60 mg
MCA324P	10 mg*	82 mg	100 mg	250 mg	24 mg	39 mg	60 mg
MCA524S	10 mg*	82 mg	100 mg	250 mg	24 mg	39 mg	60 mg
MCA524P	10 mg*	82 mg	100 mg	250 mg	24 mg	39 mg	60 mg
MCA323S	20 mg*	0.82 g	1.00 g	2.00 g	240 mg	397 mg	604 mg
MCA623S	20 mg*	0.82 g	1.00 g	2.00 g	240 mg	397 mg	604 mg
MCA623P	20 mg*	0.82 g	1.00 g	2.00 g	240 mg	397 mg	604 mg
MCA1203S	0.1 g*	0.82 g	1.00 g	2.00 g	240 mg	397 mg	604 mg
MCA2203S	0.1 g*	0.82 g	1.00 g	2.00 g	240 mg	397 mg	604 mg
MCA3203S	0.1 g*	0.82 g	1.20 g	2.50 g	240 mg	397 mg	604 mg
MCA5203S	0.1 g*	0.82 g	1.20 g	2.50 g	240 mg	397 mg	604 mg
MCA1202S	0.5 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g

MCA2202S	0.5 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA4202S	0.5 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA5202S	1 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA6202S	0.5 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA6202P	0.5 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA8202S	0.5 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA10202S	1 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA14202S	1 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA14202P	1 g*	8.2 g	10.0 g	15.0 g	2.4 g	4.1 g	5.5 g
MCA8201S	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA11201S	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA12201S	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA20201S	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA36201S	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA36201P	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA50201S	5 g*	82 g	100 g	120 g	24 g	36 g	49 g
MCA36200S	50 g*	820 g	1000 g	1200 g	24 g	370 g	511 g
MCA70200S	50 g*	820 g	1000 g	1200 g	24 g	370 g	511 g

*Note: The minimum net weight according to OIML R76 is only defined for devices that are approved for legal applications - for all other devices, this value is neither defined nor relevant.

**The typical values do not represent a guarantee of properties. They correspond to the mean value from a sufficiently large number of measurements.

***The recommended values do not represent a guarantee of properties. They correspond to the value that is met in 90 % of a sufficiently large number of measurements.