What was done?
A computer method of gravimetric quality control of the tablet splitting process was designed.

Why was it done?
It was necessary to establish a quality control of this pharmaceutical process.

How was it done?
The procedure consists on a precision scale connected to a computer in which, according to the uniformity of mass assay of the Spanish Pharmacopoeia, the weights of 20 units of a batch of whole tablets destined to be split are automatically recorded in a spreadsheet, carrying out the following formulas:

- **=AVERAGE**
  Provides the average weight of the sample of whole tablets.

- **=MAX and =MIN**
  Select respectively the largest and the smallest of the weights.

- **=STDEV**
  Calculates the standard deviation of the sample weights.

With the average weight of the whole tablets, the theoretical weight of the half-tablets is calculated, establishing a maximum and a minimum admissible limits of weight with the following formulas:

- **=(AVERAGE/2)**
  Determines the theoretical average weight of each half-tablet.

- **=(AVERAGE/2)+(1.075)** and **=(AVERAGE/2)+(0.925)**
  Establish upper and lower gravimetric limits:
  - Only 10% of half-tablets can exceed the first limit of ±7.5%.
  - No half-tablet can exceed the second limit of ±15%.

All the half-tablets need to be weighted, as the tablet splitting process is carried out tablet-by-tablet and this modus operandi is not reproducible enough. In case of non-compliance with maximum and minimum weight criteria, the half-tablet must be discarded.

Conditional functions were established such that the spreadsheet itself reflects the half-tablet acceptance/rejection decision. Basic technical computer skills, training in the technique of tablet splitting, appropriate clothing and environmental measures to avoid risks to the operator and the medications are required.

What has been achieved?
Since 2015, two different medicinal products were subjected to the tablet splitting technique. A total of 10,536 halves of suitable tablets were obtained, which permitted safe dosing at lower doses than commercialized, and also generated a financial asset of 101,724 Euros. 566 halves were discarded.

What next?
This quality control procedure is applicable to all divisible solid oral dosage forms. The standardization of the technique and the quality controls will allow to extend it to other medicinal products with dosing and economic purposes.