	Position [°2θ]	Relative Intensity [%]
9	16.37	31
10	16.90	100
11	17.08	22
12	17.54	15
13	23.67	12

The corresponding XRPD pattern is in Figure 7.

EXAMPLE 8: Comparative experiment: trimetazidine nitrosamine formation

In order to model the formation of trimetazidine nitrosamine during the formulation process, an aqueous solution of sodium nitrite was added to the trimetazidine salt. The sodium nitrite mimics the presence of nitrites in water and/or excipients during a drug product manufacturing process.

The trimetazidine salt, in an amount corresponding to 600 mg trimetazidine, was placed in 2 mL volumetric flask. 150 µL of sodium nitrite aqueous solution at 0.12mg/mL was placed in the 2mL volumetric flask and the volume was adjusted to 2mL with water to obtain a solution at 300 mg/mL in trimetazidine equivalent.

The solution was stirred at 40°C for 22 hours. The trimetazidine nitrosamine dosage was performed by LC/MS.

Due to the low solubilities of the dioxalate and oxalate trimetazidine salts, the experiments with these two salts were respectively performed at 6 mg/mL and 30 mg/mL instead of 300 mg/mL in trimetazidine equivalent.

Results:

Compound	Trimetazidine salt	Trimetazidine nitrosamine content (ppm)
Example 1	Hemiadipate	0.7
Example 2	Hemisuccinate	0.5
Example 3	Hemimalate	0.7
Example 4	Hemisulfate	0.6