



COMPOUNDER'S INTERNATIONAL
ANALYTICAL LABORATORY
Better Quality Through Quality Testing

Methylcobalamin and Light (10/2018 Update)

Vitamin B12 is a common nutritional supplement in many formulations. The three most often used forms are Cyanocobalamin (B₁₂), Methylcobalamin (Me-B₁₂) and Hydroxocobalamin (B_{12a}).

When formulating methylcobalamin, many are aware of its sensitivity to light but may not know just how sensitive it is. In our lab we carried out an experiment to see just how sensitive a typical formulation might be to typical interior lab lighting. The formulation we selected as our test sample was one containing methylcobalamin 1000 mcg/mL in normal saline plus benzyl alcohol 2%. We assayed the sample to check its potency and found it to be 985mcg/mL so it was 98.5% potent, thus meeting requirements. We then exposed the solution in a clear glass vial for 5 minutes under our lab's typical florescent lighting, then once again tested it for potency. The potency was now at 54.4%, a 44.1% decline! Much of the active had converted to hydroxocobalamin (B_{12a}). After another 5 minutes exposure, now a total of 10 minutes, the potency was now down to 30.8% a 67.7% decline from the initial potency. After a total of 15 minutes, the potency stood at 15.2%, a total decline of 83.3% from the starting point! Clearly, methylcobalamin is **VERY** light sensitive and easily converts to hydroxocobalamin.

Another series of tests was performed to determine the length of time methylcobalamin solutions could be left in amber glassware in ambient light. We found, to our surprise, even in amber glassware we have found some breakdown. Also, to our surprise, it isn't very sensitive to heat. We were able to hold it in the dark at 80°C for several hours with minimal breakdown. It is, however, **VERY** sensitive to mechanical shock. It cannot be shaken, sonicated, or even rapidly mixed on a magnetic stirring apparatus. It can however, be swirled, slowly stirred, or rocked to help dissolve and mix.

To maintain potency all precautions possible to protect it from light should be taken. A possibility is to wrap all glassware with aluminum foil. This works but is awkward because the sample cannot be inspected to make sure all of the active has dissolved nor can volumetric graduations be seen to verify proper dilution has been accomplished. (Please note: when weighing out the dry API powder, methylcobalamin is fairly light stable so this step can be completed in normal room light. Once it has been put into solution however, it becomes very light sensitive.)

Compounding Suggestions

We found we could prepare and test a methylcobalamin formulation successfully by turning off the lab lights and operate by the small amount of light coming into the lab from a distant window. The work area was quite dark, glassware graduations could just barely be read, but the technique does work, methylcobalamin did not break down to any measurable degree. Unfortunately, others in our lab didn't appreciate the idea so much!

More recently, we found we could use a red light bulb in an enclosed area of our lab and the potency did not decline at all, even after 15 minutes exposure time. The bulb we used was a Philips LED 8 Watt bulb which was purchased at our local Home Depot for a very nominal cost. We repeated our aforementioned 5, 10 and 15 minute test with this bulb as the only light source and found it worked very well, no breakdown occurred. Our analyst had plenty of light to carry out all our normal testing procedures, could easily read glassware graduations, and best of all, didn't upset the others!