Min Tong Pharmaceutical Company

To know more about the storage of Western medicine, we also conducted an interview with Min Tong Pharmaceutical Company, which manufactures Western medicine. These are the answers we~~'ve~~ got.

Q1: Among your products, is there any that is not required to be kept in freeze storage, but is still relatively vulnerable to high temperature (37degrees Celsius)? For example, Tortoise Shell & Deer Antler Combination could melt at high temperatures. If yes, can you supply us with the names of the drugs and the highest temperature they can tolerate?

A1: The preparations of Western medicine (powders, granules, lozenges, solutions) made in our company are usually stored under 25 or 30 degrees Celsius, to meet the standard of Chinese Pharmacopoeia. However, when we apply for licenses, the drugs must pass the accelerated test (40 degrees Celsius for half a year without deteriorating). So, a short exposure to 30 degrees Celsius should not do harm on our drugs.
The only drug we can think of that may not deteriorate at 37 degrees Celsius is the suppositories, for they might have appearance deformation, and thus will fail to pass quality control tests.

Q2: Is any of your products sensitive to UV light? If yes, can you supply us with the names of the drugs and the way they are stored and transported?

A2: We know that high energy lights will affect the stability of drugs, so we always use bottles that are capable of blocking UV rays. The bottle is then placed in a box for further protection against direct sunlight. We've never conducted experiments on the correlation between the amount of UV and the degree of damage to our drugs, and we've never tested whether ~~the~~ UV light~~s~~ can penetrate the containers. But basically, we will package them well and try to keep the containers away from sunlight.

Q3: Can you tell us how your company do the stability test? During the process, what is the target temperature and how long is the duration? What items do you check?

A3: Since the medicines we make are not biological agents, we ~~shall~~ do stability tests and accelerated test to assure the stability of our drugs, according to the "drug stability test benchmark," which is declared by the Ministry of Health and Welfare Food and Drug Administration. The stability tests we do are as follows: First, 25 degrees Celsius, RH 60%, one year (checkpoint: 0, 3, 6, 9, 12 months). Second, 30 degrees Celsius, RH 60% one year (checkpoint: 0, 3, 6, 9, 12 months). Third, the accelerated test, 40 degrees Celsius, RH 75%, half of a year (checkpoint: 0, 3, 6 months). If the results meet the standard of the drug stability test benchmark, then it has a shelf life of 2 years. However, to obtain an accurate expiration date, we have to conduct long-term experiments. And, if we want to claim a 3-year shelf life, then we should have at least 3 batches of drugs that pass the 3-year long-term test. The items we~~'ve~~ check~~ed~~ include appearance traits, composition identification test, unit dose uniformity, component content test, heavy metal, moisture content, microbial limit, etc. You can refer to the quality guidelines of ~~the~~ stability on the website of ICH (International Conference on Harmonisation) for more information.

Q4: How does your company determine the expiration date of the drugs? Is there any data you can provide us? (like 37 degrees for 1 month may equal 25 degrees for half a year)

A4: The answer is identical to that of question 3. However, it is worth mentioning that the real expiration date cannot be inferred only from the accelerated test. Instead, it takes more whole time experiments to find out.

Q5: Our product is a sticker that can detect UV and temperature above 37 degrees Celsius. Will your company be interested in this kind of product? If yes, how much would you spend on it?

A5: Our company has no need of your product, since we have light blocking packages, and few of our products will go bad within a short time at high temperature.