STABILITY LAB

Bosch Pharmaceuticals PVT. LTD.

ABSTRACT

Past Experience of mine in Bosch Pharmaceuticals PVT. LTD. at Stability Lab for sixth months report worked on Management Trainee Officer post.

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After attending orientation from every department of Bosch Pharmaceuticals PVT. LTD. I was appointed as lab analyst in stability lab for 6 months of Management Trainee Officer after which I was aimed for senior post.

Stability lab:

This lab stores medicinal products at specific temperature and relative humidity. For one batch of product six samples must be collected among which one sample is used to take initial tests of sample for tablets and capsules we conduct UV/Vis Test, HPLC test for Assay, Dissolution and Disintegration test while Friability and Hardness tests results assumed from the CA provided by QC department.

In six samples three or four are kept in stability chamber room where they are working on specific and controlled temperature and humidity level such as:

1. 5°C ± 3°C (No humidity)
2. 25°C ± 2°C, 60% humidity
3. 30°C ± 2°C, 65% humidity
4. 40°C ± 2°C, 75% humidity

The sample storage in desired chamber depends upon the below range of product i.e. If the mentioned below range is 30°C, then product is stored in 30°C and 40°C chamber only. The storage time period must be in such sequence 3,6,9,12,18,24,36,48 months. In these months samples are taken out from chamber room and they are subjected to both physical and chemical tests. Stability of samples kept at 5°C tests after 12 months while stability of samples kept at 40°C ends after 6 months.

Stability lab performs stability on short term and long term.

The stability also keeps the assay results in a trend accordingly previous readings of assay for example if the previous results are 101% for initial testing then after 3 months it should be 100% but not less than 99%. In case if the results are still 101% then it is still not eligible somehow you have to set a trend for gradual decrease in API (active pharmaceutical ingredient) after short time period for these we have some manipulative ways to get our desired results.

HPLC Test:

For this we required a chromatogram and the area of it. The recorded area of standard and samples defines the upcoming results. Which means that in case of unclassified trends such as 100% in initial but still 100% we need to change area, changing the area meant we need some hacks which are given below:

- If we required to decrease peak area, then we can increase diluent amount in sample (if concentration of sample and standard is same).
- If we required to increase the peak area, then we can increase standard amount or sample amount at 5°C in that vial (if concentration of sample and standard is same).

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The taken amount is 0.1 ml which is added through spike syringes into sample vials.

- If the concentration is not same then switching off and on the pump for a second would work and increase the peak area and for decreasing diluent (mobile phase) is added.

HPLC batch file contains One diluent, five standards and 2 samples chromatogram.

UV/Vis Tests:

For this we required spectra and the absorbance on it. The recorded absorbance of standard and samples defines the upcoming results. Which means that in case of unclassified trends such as 100% in initial but still 100% we need to change absorbance, changing the area meant we need some hacks which are given below:

- To obtain the required absorbance we first inserted empty cuvette in jet and its rough side is subjected to the UV/Vis rays, we can see absorbance of 0.88 to 1.00 on screen, to decrease this to any desired absorbance we simply lift up the tray which decreases the value and when the value is reached record the absorbance.
- This might take up long so to achieve accurate time reading set the clock on your system for example at 4:20:00 pm for blank (cuvette is placed on clean side or filled with water then auto zero it) the standard reading is required which is taken by moving rough side cuvette subjected to rays.
- Lift the tray down and start the clock again from 4:20:00 pm and after 30 seconds record the absorbance by lifting up the tray of spectrophotometer.
- It means that the time record between each absorbance should be 30 to 40 seconds.
- For this we required 1 blank reading, 1 standard and 6 absorbance of samples.

If the peak is abnormal then column is inverted otherwise detector cell is checked. They were using DAD detector and C8 and C18 columns for testing.

But why do we need such hacks? Because of ICH guidelines, its required for every pharmaceutical industry to keep data analysis in a trend but they never tell you how? So we use such hacks only we get same results or assay results less than 3% drop w.r.t to past reading. For this Stability lab prepared an actual report and corrected report termed as Ok- report.

Actual report meant to store the actual results of drugs while corrected report is sent forward to ICH for review. For particular drugs such as Zerica the dissolution collected samples are taken for HPLC tests and UV/Vis tests both. Then a separate HPLC tests is also performed with mobile phase of Methanol as diluent. Orthofenac SR 100 mg is only product on which Dissolution is performed for 16 hours. First reading is taken after two hours, second after four, third after eight and then last after 16 hours. For all samples absorbance is checked but what I learned through this is absorbance of standard is changed every time so you have to keep it in fridge to avoid degradation.

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For Calamox suspension dissolution is also carried and absorbance is taken, sometimes spectra is also recorded instead of absorbance according to specification.

Karl Fisher Test:

- Here the Ok- report is finalized by taking less weight and entering the higher weight value which gives less results.

Stability report consists of:

1. CA at front page
2. Combined stability report for different temperature and humidity reading on different sheets.
3. Summary report showing different temperature and humidity testing results in a single sheet.

That's All