Practice 12.12. Industrial Production of Suppositories

Sodium salicylate	0.200 g
Witepsol H15	q.s.

The following controls will be carried out on the suppositories prepared according to this formula.

1- Appearance: When the suppositories are longitudinally cut and examined, their inner and outer surfaces must be uniform.
2- Melting-Disintegration (EP 4): Determined at 37 ° C water bath with various instruments. It is measured when the entire suppository is melted or dispersed and the tool is tacked under or over the basket. It usually melts and disperses within half an hour.
3- Determination of the amount of active substance: As an example, how to make the determination of active substance for sodium salicylate will be explained. For other active substances, their monograph analysis methods given in the reference books should be used.

Five of the prepared suppositories are dissolved in a water bath in a beaker. It is completely dissolved and then mixed with 50 ml of purified water. The upper oily layer is left in the fridge until freezing. The two phases are separated by filtration. The remaining base is melted again. It is again mixed with 50 ml of purified water. When the base part is frozen, the lower aqueous layer is filtered over the first filtrate. 2 ml of this filtrate is taken and 100 ml of purified water is added. 9 ml of this solution is taken, 1 ml of 10% $FeCl_3$ solution is added, and the absorbance value of the solution is read at 510 nm in the calorimeter. The amount of sodium salicylate is calculated by means of the calibration line available. The concentration value (x) found is in mg / l or μg/ml. The amount of active substance found should not deviate by more than ± 10% from the desired amount.

4. Fracture and mechanical durability control: The suppositorial shaped BASE is measured on the basis of the weights placed on the specific temperature. Rectum is important in terms of understanding whether it is resistant to pressurization and loss in packaging line.

For this purpose, a tool which determines the suppository's fracture point shall be used. The device consists of a compartment into which a suppository is placed and a thermostated water tank which circulates the water in this compartment. The temperature at which the experiment is made is 25 ° C. The suppositories should be kept at the test temperature for at least 24 hours. The tool is set to the desired test temperature. The suppositories that were previously held are placed on the test section with the pointed side up. The partition is closed. The discs weighing 200 g are added every minute. This process is continued until the suppositories are broken (the empty weight of the instrument is 600 g).

NOTE: If the suppository is broken with the first 600 g empty weight, it is too soft to be used. If the suppository is broken with added discs, all weights are summed. If the last inserted disc is broken after the first 20 seconds, it is not added to the total weight. If the break is between 20-40 s, the final diskin half-weight is added (100 g). If rupture occurs after 40 s, the total weight of diskin will be added to the total weight.