

Paracetamol Tablet
Compressi Paracetamololum

Paracetamol	0.250 g
Starch	0.100 g
Lactose	0.050 g
Gelatin solution (8% w / w)	q.s.
Glidant-lubricant	q.s.

Formula is for 1 tablet

Glidant-Lubricant Mixture:

	%
Talc	50
Starch	40
Magnesium stearate	8
Colloidal Silicon Dioxide (Aerosil 200)	2

Preparation:

Paracetamol, starch and lactose are mixed in the cube mixer for 15 minutes. The powder mixture is fed into the planetary mixer by means of a shovel. Weigh the gelatin solution. Mix the powder in the planetary mixer for 5 minutes. With a 10 ml pipette, add a little bit of gelatin solution. Stirring is continued to homogenously distribute the solution. When the mixture comes to the consistency of the paste (it should not be dispersed when compacted between fingers and become compact), the addition of gelatin solution is terminated. The gelatin solution is weighed again and the amount of binder solution used is recorded. The resulting mass is taken into a plastic container with the help of plastic spatulas. The mass is discharged into the oscillating granulator with a 1.25 mm mesh diameter and the granulator is operated at medium speed. The resulting granulate is dried in a thin layer on paper-coated trays and dried at 50 ° C. The dried granule is passed through a granulator with a 1.00 mm pore size. Add 3% of the weight from the glidant-lubricant mixture. This mixture is mixed in the cube mixer for 20 minutes at 20 rpm and then shoveled into a plastic container. The weight of 1 tablet is calculated as per 250 mg paracetamol. The final mass is put into the feed hopper with shovel and the lower punch position for the calculated weight and the upper punch position for the desired hardness are adjusted for compaction. Prepared tablets are appropriately labeled. Results shown on an table.

Questions

1. Which method is used in this production?
2. How many grams of gelatin solution did you use? How many grams of gelatine corresponds to?
3. How many grams is the theoretical mass? How many grams is your mass (practical mass)?
4. How many grams of glidant-lubricant have you added?
5. What is the weight of a tablet containing 250 mg of paracetamol?
6. How many tablets that contain as per 250 mg Paracetamol you can produce with final mass? Calculate.
7. Evaluate the result by determining the moisture content of the granule you prepared.

Sodium Novamin Sulfonate (Novalgin) Tablet
Compressi Natrii Novamin Sulfonas

Sodium novamine sulfonate	0,500g
Lactose	0,040g
Potato starch	0,060g
Gelatin solution (10% w / w)	q.s.
Magnesium stearate	% 1
Aerosil 200: Starch (0.5: 9.5)	% 2

Formula is for 1 tablet

Preparation:

The potato starch, lactose and sodium novamine sulfonate are mixed in the cube mixer for 15 minutes. The powder mixture is transferred to the sigma mixer. The weight of the gelatin solution is determined. After stirring for 5 minutes with Sigma mixer, add small amount of gelatin solution. Stirring is continued to homogenously distribute the solution. When the mixture forms like a paste, addition of gelatin solution is terminated. The weight of the gelatin solution was determined again and the amount of binder solution used was recorded. The resulting mass is taken into a plastic container with the help of plastic spatulas. The mass is discharged into the oscillating granulator with a 1.25 mm mesh diameter and the granulator is operated at medium speed. The resulting granulate is dried in a thin layer on paper-coated trays and dried at 50 ° C. 10 g is taken and the humidity is determined. It is dried again at 50 ° C. 10 g is taken up and the humidity is again determined. Granule are weighted and placed in cube mixer. 2% Aerosil-starch mixture is added to the mass. For 5 minutes at medium speed bulk is mixed in the cube mixer. Add magnesium stearate and stir for further 3 minutes. This mixture is taken to a plastic container with the help of shovel. The weight of 1 tablet is calculated as 500 mg sodium novamine sulfonate. The final mass is placed in the feed hopper with shovel and the lower punch position for the calculated weight and the upper punch position for the desired hardness are adjusted. Weight and hardness are determined as 5 tablets each time during production. Prepared tablets are placed in the container and appropriately labeled. The controls mentioned above are performed on the tablets and the results are shown in table.

Questions:

1. Which method did you use to prepare this tablet formulation?
2. How many grams of gelatin solution did you use? How many grams of gelatin does this amount correspond to?
3. How many grams is the theoretical mass? How many grams is your mass (practical mass)?
4. How many grams of glidant-lubricant have you added?
5. What is the weight of a tablet containing 500 mg Novalgin?
6. How many tablets can you print with 500 mg of Novalgin each of the final mass you have? Calculate.
7. Evaluate the result by determining the moisture content of the granule you prepared.

Paracetamol Capsule

Paracetamol 200 mg
Prepare 30 capsules.

Preparation:

The total volume of the mass required to be filled according to the size of the capsule given to you is calculated. The filler to be used is selected. With the aid of a 10-ml scale, bulk densities of active substance and filler are calculated. The amounts of active substance and filler required for a capsule and the desired capsule are determined both by weight and volume. The calculated amount of active substance and filler are suitably filled into capsules in a capsule filling machine. The mass uniformity tests on full capsules are examined according to European Pharmacopoeias and the results are recorded.

Questions:

1. What size capsule should be used if the theoretical fill weight of an active ingredient in hard gelatin capsules is 350 mg and the cluster density is 0.75 g / mL?
2. The filling weight for a capsule of a material with a bulk density of 0.80 g / ml is given as 500 mg. If you have capsule 0 in your hand and you need to use a filler to make this fill, calculate the amount of filler needed for a capsule.
3. How should the ambient temperature and humidity be during the filling of hard gelatin capsules?
4. What are the points to keep in mind when storing hard gelatin capsules? Write.
5. What are the ingredients that can not be put into hard gelatin capsules? Write by explaining.

Practice

Ramipril 5 mg
Prejelatinized starch q.s.
Capsule no:4

Practice

Methyltestosterone 10 mg
Corn starch q.s.