

Storage : Store in tightly closed container.

Date of Expiry : 18 months from the date of manufacture.

Production Yield :

In-process Quality Control :

1. Diameter
2. Thickness
3. Weight variation
4. Hardness
5. Friability
6. Disintegration time: (Calcium lactate tablets hardens on storage and therefore maximum time allowed for disintegration is 30 min).

Report :

QUESTION BANK

1. Wet granulation (water based) is not suitable to manufacture of calcium lactate tablets. Why?
2. Draw flow-chart for the production of calcium lactate tablets.
3. List the reasons for producing calcium lactate tablets by dry granulation method only, not by other methods.
4. What are the problems involved in the compression of calcium lactate tablets, when fines are more or less in the granules. Give the reasons for the problems and remedial measures.
5. Describe the slugging process and list its advantages and disadvantages.

Aspirin Tablets IP

Experiment No. 5

Date:

Aim : To prepare and submit 50 aspirin tablets IP, each containing 300 mg of aspirin.

Synonym : Acetyl salicylic acid tablets.

Formula : As per IP

Ingredients	Official formula	Working formula
Aspirin	0.300 g	
Starch powder, 5%	0.015 g	
Talc, 2%	0.006 g	

Note : The working formula is calculated for 60 tablets. Extra 10 tablets are required to account for the production losses.

Manufacturer's Definition : Aspirin tablets are white or off white, flat faced, round tablets having a diameter of _____ mm and thickness of _____ mm.

However, different manufacturers produce aspirin tablets of different shapes and colours.

Standards (IP) : Aspirin tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of aspirin, $C_9H_8O_4$.

Usual Strengths (IP) : 75, 150, 300, 450, 500, and 600 mg.

Type : Heterogeneous powders—solid.

Theory

Aspirin tablets are used for analgesic, antipyretic, antirheumatic, and antithrombotic actions.

Acetyl salicylic acid is highly unstable and readily undergoes hydrolysis reaction. Hence, wet granulation method (containing water) cannot be used. When aspirin is available as granular material, direct compression method is normally used. If powdered aspirin is available, dry granulation method (slugging) is preferred. Direct compression

method is economical and quick method of production, because the number of steps involved are less compared to wet or dry granulation methods.

Since the dose of aspirin is high i.e., 300 mg, only small amount of additives are required. For direct compression of tablets, normally directly compressible vehicles such as microcrystalline cellulose (MCC), spray dried lactose, dicalcium phosphate dihydrate are used. An agent such as starch is used for better disintegration process. Talc is used as lubricant.

Apparatus and Chemicals

Mortar and pestle	1	Aspirin
Compression machine	1	Starch powder
Sieves # 22, 44	1 Set	Talc
Balance	1	

Procedure

Depending on the number of tablets to be submitted, the working formula is calculated. A flow sheet for the manufacture of aspirin tablets is given in Figure 3. The detailed procedure is as follows.

Weighing : Granular acetyl salicylic acid is weighed approximately (more than required quantity).

Screening : Weighed aspirin is passed through 22/44-mesh sieves. The material retained on 44-mesh sieve is collected (H g) and is called as coarse granules. The material passed through 44-mesh sieve is collected (I g) and is called as fines.

Fifteen per cent of fines required are weighed (J or I g). Five per cent of starch powder and 2% of talc powder are weighed.

Blending : Coarse granules, fines, starch powder, and talc powder are blended thoroughly in mortar with pestle in order to get a uniform distribution of ingredients. Now the granules are ready for compression.

Compression : Three packets of granules, each containing the practical weight of one tablet, are prepared. These are used to adjust the pressure of the punches in order to get tablets of sufficient hardness. The remaining granules are compressed to obtain tablets.

The production yield is calculated using the formula.

Packing : Compressed tablets are placed in wide-mouthed, tightly-closed container in a cool, dry place. The container is capped and cleaned.

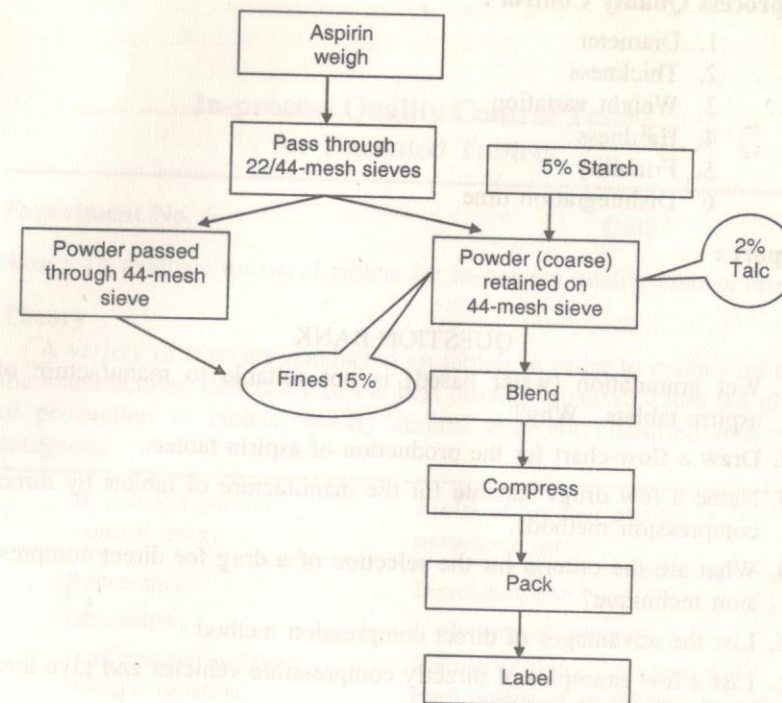


Figure 3. Flow chart for the manufacture of aspirin tablets by direct compression method.

Composition : Each tablet contains 300 mg of aspirin.

Category : Analgesic, antipyretic, antirheumatic, and antithrombotic.

Dose :

As analgesic and antipyretic, 300 to 600 mg, four to six times a day.

As antirheumatic, 1 to 2 g, four to six times a day, up to 10 g daily.

As antithrombotic, 75 mg daily.

Storage : Store in tightly closed container in a cool and dry place.

Auxiliary Label : Not to be used in children below 12 years of age except under medical advice.

Date of Expiry : 15 months from the date of manufacture.

Production Yield :