ISSN: 2664-9640

Study on quality detection of paracetamol tablets

Jiaxin Chen*

College of Applied Technology, Xihua University, Chengdu 611700, PR China

Abstract

Tablet refers to the solid preparation of medicine mixed evenly with suitable excipients and pressed into flake by preparation technology. There are high requirements for the quality detection and evaluation of tablets, mainly because the manufactured products are pharmaceutical products that directly enter the human body to play all or part of the role, and their quality is directly related to human life. After the quality inspection of paracetamol tablets, the appearance inspection is qualified. According to the provisions of pharmacopoeia, the weight difference limit of 0.3g tablets is ±7.5%, 0.3g or 0.3g above is ±5%, all the limits are less than 5% after calculation test; Hardness is 100.5g; According to the regulations, the weight loss rate should not exceed 0.8%, and two agents failed

Keywords

Acetaminophen tablet; Hardness;Friability; Difference limit.

1. Introduction

Tablet refers to the solid preparation of medicine mixed evenly with suitable excipients and pressed into flake by preparation technology. It is one of the most widely used dosage forms in clinical practice[1-2]. It has the advantages of accurate dosage, stable quality, convenient administration and low cost. Tablets are composed of two parts: medicine and excipients. Excipients refer to all substances in tablets except the main drug, also known as excipients, for non-therapeutic substances. The purpose of adding excipients is to make the drug have good fluidity and compressibility in the preparation process. There is a certain adhesion; Meet body fluid can disintegrate quickly, dissolve, absorb and produce curative effect. Excipients should be "inert substances" with stable properties, no reaction with the main drug, no physiological activity, no influence on the content determination of the main drug, and no adverse impact on the dissolution and absorption of the drug[3-5]. However, in fact, completely inert excipients are very few, excipients can have a great impact on the properties of tablets and even drug effect sometimes, therefore, we should pay attention to the selection of excipients. Excipients commonly used in tablets include fillers, wetting agents, adhesives, disintegrating agents and lubricants[6].

The prepared tablets shall be inspected in accordance with the tablet quality standards stipulated in the Chinese Pharmacopoeia. The appearance of tablets should be complete and smooth, with uniform color and appropriate hardness, so as to avoid fragmentation in the process of packaging, storage and transportation. The weight difference and disintegration time limit of tablets must also be checked[7]. For some tablets, it is also stipulated in the pharmacopoeia to check the uniformity of content and dissolution rate, and it is clearly stipulated that the weight difference of the tablets inspected for uniformity of content is no longer checked, and the disintegration time limit of the tablets inspected for dissolution rate is no longer checked.

ISSN: 2664-9640

2. Materials and production methods

Main drugs, reagents and equipment, analytical balance, ordinary balance, hardness tester, friability meter (Tianjin New Electronics), disintegration time limit detector (Shanghai Yellow Sea drug testing instrument sales), acetaminophen tablet (drugstore purchase).

2.1. A visual inspection

10 tablets were randomly selected, laid flat on a white porcelain plate, placed 60cm under a 75W incandescent lamp, 30cm away from the center of the tablet, and observed with naked eyes for 30 seconds. The color should be consistent, the speckled spots of 80-100 mesh size should not exceed 5%, the freckled surface should be less than 5%, and there should not be serious spots and foreign bodies.

2.2. Weight difference inspection

10 tablets were randomly selected, the total weight was accurately weighed, the average tablet weight was obtained, and then the weight of each tablet was accurately weighed. According to the pharmacopoeia, the weight difference limit of 0.3g tablets is ±7.5%, 0.3g or 0.3g tablets is ±5%, exceeding the weight difference limit of not more than 2 tablets, and not more than 1 tablet is twice the limit.

2.3. Hardness test

It was determined by tablet hardness tester. A total of 2 tablets were determined and their average value was taken.

2.4. Check for fragility

Take 4 tablets, weigh them accurately, put them into the tablet fragility tester, and vibrate for 4min to remove the fine powder and broken particles. After weighing, the weight loss rate should not exceed 0.8% compared with the weight of the original tablets. The friability can be calculated as follows:

$$Brittle\ broken\ degrees = \frac{Weight\ of\ fine\ powder\ and\ crushed\ grain}{Total\ weight\ of\ original\ tablets} \times 100\% \quad (1)$$

2.5. Disintegration time limit inspection

Take 2 tablets and place one tablet in each glass tube of the hanging basket. The hanging basket is immersed in a 1000ml beaker filled with water (37±1℃). Adjust the height of water level so that the screen is 15mm below the water surface when the hanging basket is rising and 25mm above the bottom of the beaker when it is falling. All tablets should be dissolved or disintegrated into fragments within 15 minutes and passed through the screen. If the remaining small particles can not pass through the screen, another 2 tablets should be taken for retest, and 1 baffle plate should be added to each tube after adding tablets, and all the particles should pass through the screen within 15 minutes according to the above method.

3. Results and Analysis

3.1. A visual inspection

Requirements: 80-100 mesh size mottle spot 3%, pockmarked surface 2%, no serious spots and foreign bodies.

3.2. Weight difference inspection

ISSN: 2664-9640

Table 1 Weight difference check

Tablet number	1	2	3	4	5	6	7	8	9	10
Tablet weight（g）	0.588	0.598	0.588	0.619	0.598	0.593	0.599	0.592	0.597	0.594

It can be obtained from the formula:

$$The\ average\ piece\ of\ \ heavy = \frac{Total\ \ piece\ of\ \ heavy}{10} = 0.5979g \tag{2}$$

3.3. Weight difference limit

$$Weight\ \ difference\ \ \lim it(\%) = \frac{Every\ \ piece\ of\ \ heavy - The\ \ average\ \ piece\ of\ \ heavy}{The\ \ average\ \ piece\ of\ \ heavy} \tag{3}$$

It can be obtained from Formula (3) :

Table 2 Weight difference limit

Tablet number	1	2	3	4	5	6	7	8	9	10
Weight difference limit（%）	1.511	0.168	1.511	3.518	0.168	0.670	0.335	0.838	0	0.503

The above limits are all less than 5%.

3.4. Hardness test

Hardness of 1:0.588g: 118.0

2.599g hardness: 83.0

Average value: 100.5g

3.5. Check for fragility

Tablet 1:0.589g weight loss: 0.007g

Tablet 2:0.619g Weight loss: 0.005g

Tablet 3:0.579g Weight loss: 0.007g

Tablet 4:0.589g Weight loss: 0.004g

$$Brittle\ \ broken\ \ \deg rees = \frac{0.007}{0.589} \times 100\% = 1.18\% \tag{4}$$

Table 3 Brittle broken degrees

Tablet number	1	2	3	4
Brittle broken degrees（%）	1.18	0.8	1.21	0.68

According to the regulations, the weight loss rate should not exceed 0.8 percent.Therefore, we can get that 1 piece 3 is not qualified, and 2 pieces 4 are qualified.

4. Conclusion

There are high requirements for quality testing and evaluation of tablets, mainly because the manufactured products are pharmaceutical products that directly enter the human body to play a full or partial role, and their quality is directly related to human life. Therefore, each country has its own set of pharmacopoeia, which is in line with the minimum quality standards of

ISSN: 2664-9640

human safety. And according to the "Chinese Pharmacopoeia" for strict quality testing and evaluation.

After the quality inspection of paracetamol tablets, the appearance inspection is qualified. According to the provisions of pharmacopoeia, the weight difference limit of 0.3g tablets is ±7.5%, 0.3g or 0.3g above is ±5%, all the limits are less than 5% after calculation test; Hardness is 100.5g; According to the regulations, the weight loss rate should not exceed 0.8%, and two agents failed.

References

[1] Abebe A, Akseli I, Sprockel O, et al.Review of bilayer tablet technology[J].International journal of pharmaceutics, 2014, 461(1): 549-558.

[2] Allen LV， Popovich NG， Ansel HC. Ansel′s pharmaceutical dosage forms and drug delivery systems [M]. 9th edition. Philadelphia: Lippincott Willians & Wilkins，2010：231-242.

[3] Jackson 2nd KC. Pharmacotherapy in lower back pain[J].Drugs of today (Barcelona, Spain: 1998), 2004, 40(9): 765-772.

[4] Borenstein DG. Cyclobenzaprine and naproxen versus naproxen alone in the treatment of acute low back pain and muscle spasm [J]. Cl in Ther, 1990, 12: 125-131.

[5] Chou R. Pharmacological management of low back pain [J]. Drugs, 2010, 70(4): 387-402.

[6] Deyo RA, Rainville J, Kent DL . What can the history and physical examination tell US about low back pain [J]. Jama, 1992, 268(6): 760-765.

[7] Hamza YES, Aburahma MH. Design and in vitro evaluation of novel sustained-release double-layer tablets of lornoxicam:utility of cyclodextrin and xanthan gum combination[J].Aaps Pharmscitech, 2009,10(4): 1357-1367.