



## Keywords

Lincomycin,  
Dissolution,  
Disintegration,  
Spectrophotometer

Received: August 28, 2014

Revised: September 16, 2014

Accepted: September 17, 2014

# Manufacturing of new formulation of lincomycin capsule

Safila Naveed, Huma Dilshad, Shabana Naz Shah, Fatima Qamar,  
Nimra Waheed, Safeena Nazeer

Faculty of Pharmacy Jinnah University for women Karachi

## Email address

safila117@yahoo.com (S. Naveed), fatimamudassar2009@hotmail.com (F. Qamar)

## Citation

Safila Naveed, Huma Dilshad, Shabana Naz Shah, Fatima Qamar, Nimra Waheed, Safeena Nazeer. Manufacturing of New Formulation of Lincomycin Capsule. *International Journal of Clinical Medicine Research*. Vol. 1, No. 4, 2014, pp. 128-131.

## Abstract

Lincomycin is a lincosamide antibiotic in the present study new formulations of lincomycin was manufactured using Lactose, magnesium stearate. The present study is divided into two phases. In the first phase new formulation of lincomycin capsules were prepared. In the 2nd phase of study new formulation is evaluated for their average weight variation and other parameters like disintegration and dissolution. Three quality control parameters: weight variation test, disintegration test and dissolution test were carried out specified by BP/USP (British and United state Pharmacopoeia) for capsules. The results showed that all parameters of new formulations are in accordance with the BP/USP limits.

## 1. Introduction

Lincomycin is a lincosamide antibiotic derived from *Actinomyces Streptomycin*. Chemically it is a 6,8-dideoxy-6-aminooctose lincosamine. Clindamycin is one of its important derivatives obtained by replacing 7-hydroxy group with a chlorine atom using thionyl chloride [1] the spectrum of activity of lincomycin covers gram-positive bacteria. It is often used to treat infections caused by anaerobic bacteria [2]. Lincosamines are protein synthesis inhibitors; they block the peptidyltransferase site of the 23S rRNA component of the 50S subunit of the bacterial ribosome. [3] Although it is similar in antibacterial spectrum, as well as structure, and MOA mechanism of action to macrolide, lincomycin is effective against other organisms like mycoplasma, actinomycetes, and species of *Plasmodium*.

However, because of its toxicity and adverse effects lincomycin is rarely prescribed today and reserved for those patients allergic to penicillin.

Intramuscular (IM) administration of single dose of six hundred 600 mg of lincomycin produces peak serum levels of 11.6 micrograms/ml and it maintains the therapeutic levels for at least 15 to 20 hours, for susceptible G+ gram-positive organisms. Urinary excretion after this dose ranges from (1.8 to 24.8 percent) mean: 17.3 % percent.

A 2 hr two-hour (IV) intravenous infusion of 600 mg of lincomycin basically achieves average peak serum levels 15.9 micrograms per ml and the yields therapeutic levels for fourteen hours for most susceptible G<sub>-</sub> gram-positive organisms. Urinary excretion ranges lies from (4.9 to 30.3 percent ) mean: 13.8 percent.

The biological half-life after IV /IM administration is  $5.4 \pm 1.0$  hours. The serum  $\frac{1}{2}$  half-life of lincomycin prolonged in patients with severe renal function impairment if compared to patients with normal renal function. In patients with disturb hepatic function, serum half-life may be increased twofold longer than in patients with normal hepatic function. Peritoneal dialysis and hemo dialysis are not effective in removing lincomycin from the blood serum.

Tissue level monitoring indicate that bile is an important route of excretion. Significant levels of lincomycin have been demonstrated in the majority of body tissues. Although lincomycin appears to diffuse in the cerebrospinal fluid (CSF), levels of lincomycin in the cerebro spinal fluid CSF appear inadequate for the treatment of meningitis.

The manufacturing of Pharmaceutical drug, from formulation development to finished product, is very difficult process. This includes interactions of various kinds between process conditions and raw materials. These interactions are of great importance for the process ability and quality of the finished product, so these interactions should be taken into account earlier, such that to save later loss of time and money. [4]

In our present study a new formulation of lincomycin was developed and all of the following parameters were analyzed i.e. weight variation, disintegration and dissolution.

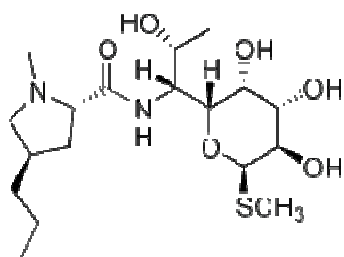


Fig. 1. Structure of Lincomycin

## 2. Methodology

### 2.1. Materials

The ingredients used in this formulation were lincomycin, lactose, magnesium stearate, aerosol 200 and starch. All of them were of analytical grade. For quantitative analysis, the standard used was gentamycin (B.P grade 93-101%).

### 2.2. Manufacturing of New Formulations

Accurately weigh all the ingredients of capsules than transferred them into suitable polyethylene bag. Ingredients were mixed by tumbling action in a large size poly bag for 5 minutes. Finally adjust the capsules shell into the capsules filling machine carefully so the body adjust in the lower hole. The head of capsules were unlocked by adjusting the lever. Fill the powder blend in the body of capsule. Place the upper plate carrying head of the capsules and locked them on the body with the help of the lever.

### 2.3. Capsules Specifications

After manufacturing of a new formulation of capsules all of the following parameters were analyzed i.e. weight variation, disintegration and dissolution.

#### 2.3.1. Weight Variation Test

Weight Variation (in process test) ensures that content of each dosage units is uniform during compression. Accurately

weigh 20 capsules of new formulation on Electronic Balance FX-400. Calculate the weight of each capsule that must be within official limits .USP/ BP states that the capsules containing less than 300 mg of the total weight may be outside  $\pm 10\%$  of the average (NMT two capsules out of the sample) and all must be within 20%.

#### 2.3.2. Disintegration Test

Disintegration apparatus Curro model no DS-0702 was used for this test. Place one capsule in each of the six tubes of the basket and add a disc (if specified). Using water or another liquid (unless specified) as the immersion fluid, operate the apparatus by maintaining its temperature at 35-39 °C. Finally at the specified time, pick up the basket from the fluid and check whether all of the capsules have disintegrated completely. The test is repeated on 12 extra capsules if one or two capsules fail to disintegrate. The requirements are met when out of 18 capsules 16 are disintegrated. According to USP, capsule should disintegrate in not more than thirty minutes.

#### 2.3.3. Dissolution test

Dissolution test was carried out on GDT-7L of Galvano Scientific dissolution apparatus. Assemble the equipment, pour 900ml of water in the vessel and place it in the water-bath. Maintain the temperature of water bath at  $37 \pm 0.5^\circ\text{C}$ . Place one capsule of new formulation in a dry basket and lower the basket into position before rotation. The rotation of the basket was set at 50RPM. A sample of 10 ml is withdrawn each time from the vessel at 15, 30, 45 and 60 min respectively. The sample must be taken from a zone midway between the surface of the dissolution medium and the top of the rotating basket, at least 10 mm from the vessel wall and not less than 10 mm below the surface. The quantity of lincomycin dissolved was determined as specified in official books.

## 3. Results and Discussion

### 3.1. Weight Variation Test

Wt. variation test of new formulation capsules proved statistically that all the capsules were in accordance to the BP/USP requirements. (Table 1)

### 3.2. Disintegration Test

was conducted on new formulation. And our results were in accordance to BP/USP (Table 2)

### 3.3. Dissolution Test

The absorbance and percentage of new formulation of Lincomycin dissolved in 30 min are shown in Table-. As per U.S.P official limits for Lincomycin capsules, dissolved amount of Lincomycin should NLT 80% (Q) of the labeled amount in 30 min and new formulation is under the specified limit.

## 4. Discussion

Comparative analysis of different drugs is carried out to check, analyze, compare and evaluate the (QS) quality standards of commercially available local pharmaceutical brands with multinational pharmaceutical brands in Pakistan as prescribed by U.S.P & B.P. Local and Multinational brands of drugs were evaluated comparatively for their physical and chemical parameters. It is said that marketed oral drugs will generally possess favorable physiochemical properties with respect to (ADME) absorption, distribution, metabolism, elimination and clearance. In the present study new of Lincomycin capsule was manufactured. All parameters of (wt. variation, dissolution, disintegration) of new formulation were carried out and results showed that they are in accordance with the BP/USP limits. In our trials Disintegration time was found to be 4.30 minutes which is within specified BP\USP limit. And the dissolved amount of Lincomycin should NLT 80% (Q) of the labeled amount in 30 min. Our research group has done these types of comparative studies which are very useful for pharmacy profession. [5-16]

## 5. Conclusion

All parameters (wt. variation, dissolution, disintegration,) of new formulations were carried out and results showed that wt. variation, disintegration and dissolution are in accordance with BP/USP limits. The advantage of this method is that this method is quite simple; less time consuming and economical therefore we use this method.

*Table 1. Statistical Weight variation*

No of tablets	Average (mg)	standard deviation	Upper Limit (X+3S)	Lower Limit (X-3S)
20	379.181	5.913	396.92	361.44

*Table 2. Disintegration test*

Disintegration time (min)	Limits	Deviation from USP
4 min 30 Sec	NMT 15 Min	PASS

*Table 3. Absorbance At Different Time Interval*

No. of capsules	Absorbance of drug			
	15min	30min	45min	60min
10	2.143	2.152	2.177	2.186

*Table 4. Dissolution Test*

No. of capsules	Dissolution at 30 min	USP Spec	Deviation from USP
10	100.00%	Not less than 80%(Q) of the labeled amount dissolved in 30 min	pass

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