

## Research Article

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## Manufacturing of new formulation of Pyridoxine HCL by direct compression method

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### Abstract

Vitamins are widely used as a prescription medicine. The aim of the study is to prepare pyridoxine HCl tablets (200 mg) using direct compression technique which is now a days considered a cost effective and simple method of formulation. It can be considered as an appropriate method for hygroscopic and thermolabile substances. In the present study new formulations of Pyridoxine HCl was manufactured by direct compression method using Lactose, magnesium stearate. The present study is divided into two phases. In the first phase new formulation of Pyridoxine HCl was prepared by direct compression method. In the 2<sup>nd</sup> phase of study new formulation is evaluated for their average weight variation, friability, hardness and other parameters like disintegration. The results showed that all parameters of new formulations are in accordance with the BP/USP limits.

**Keywords:** Pyridoxine HCl, Hardness, Thickness Friability, Disintegration.

### Introduction

Pyridoxine HCl (Figure 1) being the usual form of vitamin B<sub>6</sub> is included in pharmaceutical products. Vitamin B<sub>6</sub> is collectively named for, pyridoxal, pyridoxamine and pyridoxine. They are related to natural compounds having similar biological properties.<sup>1</sup> Pyridoxine readily absorbs from the GI tract, mainly in the jejunum part of the intestine. This drug primarily metabolized in the liver into its four active metabolites that are: pyridoxal, pyridoxal-5-phosphate (PLP), pyridoxamine, and pyridoxamine-5-phosphate. By phosphorylation, its main metabolite, PLP, releases into circulation and highly protein bound. PLP acts as a cofactor in about 160 enzyme activities which are involved in many metabolic processes of amino acids, neurotransmitters, nucleic acids, unsaturated fatty acids, glycogen, carbohydrates, and porphyrin. The major metabolite 4-pyridoxic acid is inactive, and excretes by the kidney.<sup>1, 2</sup> The only drug which is approved and also indicated for treatment of NVP (nausea and vomiting of pregnancy) is delayed-release formulation of doxylamine succinate 10 mg and pyridoxine hydrochloride (HCl) 10 mg, because it has been shown as effective and safe.<sup>3, 4</sup> Pyridoxine 4-oxidase is an enzyme which participates in the degradation of vitamin B<sub>6</sub> (pyridoxine). It contains the FAD and catalyzes the oxidation of pyridoxine to pyridoxal.<sup>5</sup> Folate-activates one-carbon units which are derived from serine by the activity of the pyridoxal-phosphate -dependent isozymes of serine hydroxymethyltransferase.<sup>6</sup>

Pharmaceutical drug manufacturing, from formulation development to final product, is very complex because the process includes interactions between raw materials and

process conditions. These interactions are very important for the processability and quality of the final product. Therefore these interactions should be taken into account as early on, because later loss of time and money is not incurred.<sup>7</sup>

There are 3 ways by which tablet can be manufactured. The selection of the method by which tablet is manufactured depends upon the dose and the drug's physical properties, such as, flow of the blend and compressibility.<sup>8</sup> Wet granulation methods used for tablet formulation is multistep and time consuming processes while direct compression is more economic, less time consuming and straightforward in terms of good manufacturing practice requirements. Tableting by Direct compression process involves compression of the tablets directly from mixtures of excipients and the drugs, without any preliminary treatment.<sup>9</sup> A simple formula is composed of a lubricant, a diluent and an active pharmaceutical ingredient API.<sup>10</sup>

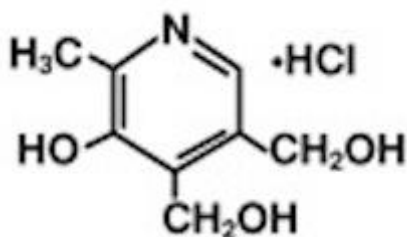


Figure 1: Structure of Pyridoxin HCl

## Materials and Methods

### Chemicals

Pyridoxine HCl, lactose, magnesium stearate, aerosol 200 and starch. All reagents used were analytical grade. Pyridoxine HCl (B.P grade, 93-101%) was used as the standard in quantitative analysis.

### Manufacturing of New Formulations

Tablets ingredients were accurately weighed. These powders were then passed through 20 mesh sieve. All the ingredients were transferred into the suitable polyethylene bag. Ingredients were mixed in a large size poly bag using tumbling action. Finally, adjust compression machine with die and punches. The blend was compressed using single punch tablet machine, having caplet shaped concave punches.

### Tablet Specifications

All parameters (wt. variation, thickness, hardness, friability disintegration,) of new formulations were carried out.

### Weight Variation Test

The average tablet weight was determined by weighing 20 units or tablets individually using an analytical balance. The mean  $\pm$  S.D. of formulation is mention in table 1.

### Thickness Test

20 tablets were taken and their thickness was determined individually by vernier caliper (VC). Mean and SD (standard deviation) were calculated.

### Hardness

20 tablets were taken randomly and hardness was measured using Hardness Tester. The mean  $\pm$  S.D of 20 tablets of each formulation is shown in table 4.

### Friability Test

20 tablets were taken randomly and took on a sieve. The dust, which is loose was removed with the air pressure or a brush. The tablet was weighed and placed in Friabilator After the given number of rotations (100 rotations/4 min) loose dust was removed from the tablets and finally tablets were weighed.

### Disintegration Test

Disintegration test was conducted on a new formulation of Pyridoxine HCl tablets. The official range in BP/USP for uncoated tablets is not more than 15 mins.

## Results

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

Table 1: Statistical Weight variation

No of tablets	Average (Gm)	standard deviation	Upper Limit (X+3S)	Limit	Lower Limit (X-3S)
20	0.5043	0.002793	0.5126		0.4959

Thickness Test: Thickness of all tablets of the new formulation is in accordance with BP/USP (Table-2-3).

**Table 2:** Thickness of 10 tablets

Tablet	1	2	3	4	5	6	7	8	9	10
Thickness (mm)	4.3	4.2	4.3	4.3	4.3	4	4.1	4.3	4.1	4.3

**Table 3:** Statistical Thickness

No of tablets	Average (mm)	standard deviation	Upper Limit (X+3S)	Lower Limit (X-3S)
10	4.22	0.114	4.562	3.878

**Hardness Test:** Hardness test of new formulation was found to be in conjunction with the stated guidelines as given in BP/USP (Table-4-5).

**Table 4:** Hardness of 10 tablets

Tablet	1	2	3	4	5	6	7	8	9	10
Hardness (Kg)	6.1	5.88	6.2	5.89	6.2	6.4	6.2	6.3	5.89	6.2

**Table 5:** Statistical Hardness

No of tablets	Average (Kg)	standard deviation	Upper Limit (X+3S)	Lower Limit (X-3S)
10	6.126	0.182525	6.6735	5.57842

**Friability Test:** Friability of new formulation tablets was less than 1%. Therefore, it is compliance with the BP/USP standards. It's data is given in (Table-6).

**Table 6:** Friability Test

No of Tablets	Result (%)	BP/USP Specification	Deviation from BP/USP Specification
10	0.586	Not more than 1%	In specified limit

**Disintegration Test:** was conducted on new formulation and we know the official range given in BP/USP is not >15 minutes and our results were in accordance with BP/USP (Table-7).

**Table 7:** Disintegration test

No of Tablets	Disintegration time (min)	BP/USP Specification	Deviation from BP/USP Specification
10	5.6	Not more than 15 min	In specified limit

## Discussion

In the present study new of Pyridoxine HCl was manufactured. For manufacturing of new formulations Direct compression method method was used. Direct Compression has the advantage over other methods in that it is a simple and less time consuming process. In addition the method is also economical. All parameters of (wt. variation, thickness, hardness, disintegration) of new formulation were carried out and results showed that they are in accordance with the BP/USP limits. In our trials, hardness varied from 5.88 kg to 6.3 kg. The average hardness for the optimised formulation was found to be 6.126 Kg. Friability is another important parameter that relates to hardness. According to the U.S.P the allowed limit of friability is not more than 1% of weight Loss. In our trials Disintegration time was found to be 5.6 minutes, which is within specified BP/USP limits.

## Conclusion

All parameters (wt. variation, thickness, hardness, friability, disintegration) of new formulations were carried out and results showed that wt. variation, thickness, disintegration and friability 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.

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