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ORIGINAL ARTICLE

Advancement of Stabiility Showing Strategy for The Assurance of Ibandronate Sodium by Utlizing HPTLC Strategy

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ABSTRACT
The show study describes a straightforward, precise, exact and HPTLC strategy for the determination of Ibandronate sodium (IBN). The assurance of Ibandronate sodium (IBN) was performed by HPTLC method using 218 nm as the assurance wavelength. A straight response was observed in the range for HPTLC the linear response was observed in the range of 2-100 µg ml. The test was performed on silica gel 60 F_{254} (0.2mm thickness) HPTLC plate 10×10cm without prewashing. Sample were spotted in the forms of spots with a Camag Nanomat (2µL). The plates were created by the rising method, to a separate of 80 mm at 26± 5º C, relative humidityof 36% ± 5, in a Camag twin trough glass chamber with a stainless-steel cover, employing a mobile phase. N-Butanol: Methanol: Water in ratio of (3:1:1) as a mobile phase. These strategies were at that point successfully applied for the estimation of IBDROS (tablet) and the comes about were obtained agreeing to nominal substance.
Keywords: *Ibandronate sodium (IBN),HPTLC, Calibration curve.*

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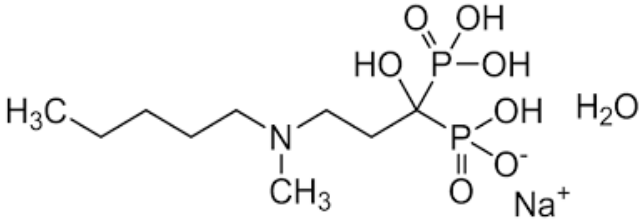
INTRODUCTION

The course of drugs that maintain a strategic distance from the misfortune of bone thickness and utilized to treat osteoporosis and comparative diseases are known as Bisphosphonates. They have two phosphonates (PO (Oh) 2) groups, consequently they are moreover known as diphosphonates. Ibandronate sodium contain because it were one nitrogen molecule.The IUPAC name of Ibandronate sodium is 3-(N-methyl-N-pentyl) amino-1-hydroxypropane-1, 1-diphosphonic acid with sodium salt, molecular weight 359.23. And molecular formula is C_9 H $_{22}$NO $_7$P $_2$Na.H $_2$O.It also prevent osteoclast bone resorption. It is also treated hypercalcemia of malignancy, Paget's disease, postmenopausal osteoporosis, and corticosteroid-induced osteoporosis metastatic bone infection. These strategies were then successfully applied for the estimation of IBDROS (tablet) and the results were obtained.The aim of our consider was to develop a precise and exact strategy for assurance of Ibandronate sodium in pharmaceutical details and bulk drugs utilizing HPTLC [1-10].



STRUCTURE OF IBANDRONATE SODIUM

MATERIAL AND METHODS

Chemicals and reagents

All chemicals and reagentss used to develop HPTLC method are analytical grade.Pure drug of Ibandronate sodium was gifted by JPN pharma Pvt Ltd, Mumbai.

Instrumentation

The test was performed on silica gel 60 F254 (0.2mm thickness) HPTLC plate 10×10cm without prewashing. Test were spotted within the shapes of spots with a Camag Nanomat (2µL). The plates were created by the climbing strategy, to a remove of 80 mm at 26± 5º C, relative mugginess of 36% ± 5, in a Camag twin trough glass chamber with a stainless-steel cover, employing a versatile stage. The chamber immersion time was kept as 20min. after improvement plate were dried with a hot-hair dryer, the filtered with a Camag TLC scanner HPTLC scanner III in all recognized crests mode worked by WIN-CATS program [11-17].

Preparation of working Standard solution [18]:

An precisely weighed amount of Ibandronate sodium (10 mg) was exchanged in volumetric flask (10ml) and was made from the coming about arrangement with water. Suitable dilutions were made from the coming about arrangement mobile phase so as to induce a concentration of 100µg/ml. The determination of wavelength 218 nm was identified. The Rf value for Ibandronate sodium is 0.71 individually. The optimized TLC plate containing run using n-Butanol: Methanol: Water in the proportion of (3:1:1) as a portable stage. The plate was created and checked. Normal chromatogram of standard arrangement of Ibandronate sodium are appeared in Fig.1.

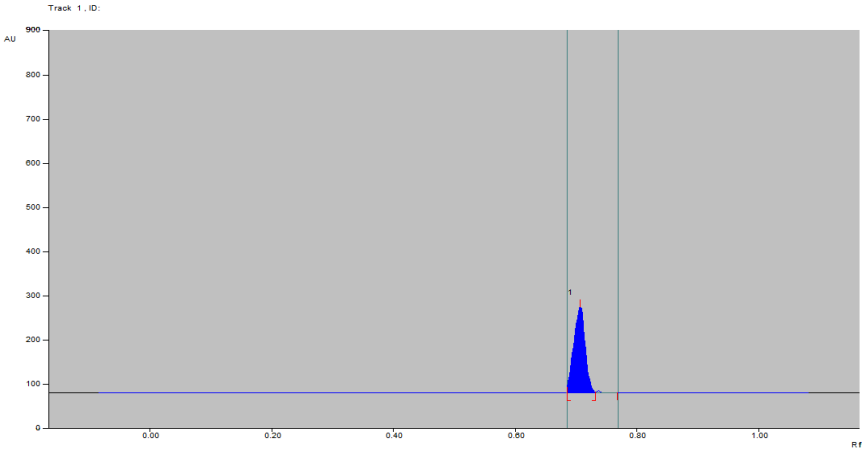


Figure 1. Chromatogram of Ibandronate sodium

Preparation of calibration curve for Ibandronate sodium

Calibration bend was arranged by plotting the top range against concentration of Ibandronate sodium. The standard arrangement 2-10 µg/ml was spotted on the HPTLC plate to get last concentration 2, 6, 8, 10 µl/spot of Ibandronate sodium and encourage it was created and filtered as per chromatographic condition. The crest zone was recorded. Calibration bend was arranged by plotting top against concentration was appeared below in Fig 2 [19].

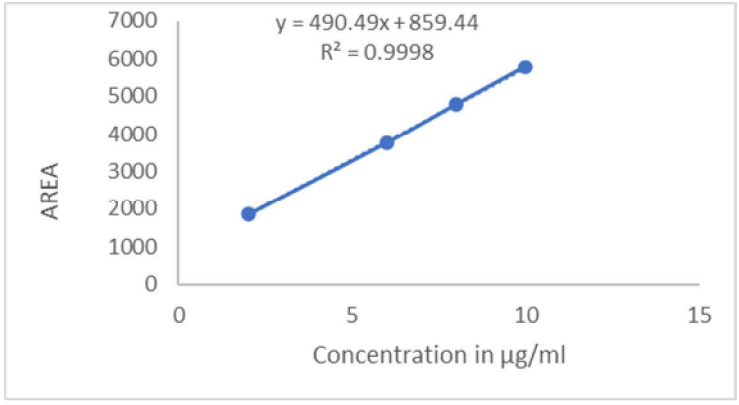


Figure 2. Calibration curve of Ibandronate sodium

RESULTS AND DISCUSSION

System suitability parameters (HPTLC)

The framework appropriateness is required and utilized to confirm the determination and reproducibility of the chromatograph.The collecting data from five replicate of standard solution spotting on plate t was tested performed accordingly. The comes about are appeared in Table 1.

Table 1. Table of System suitability parameter (HPTLC)

Sr.no	Weight of standard(µg/mL)	Retention factor	AUC of standard
1	10	0.71	2534.7

Analysis of tablets

The twenty tablets was weighed and crushedwas converted into fine powdered. Weigh accurately quantity of the powder equivalent to 100mg of drug. Then the powdered was taken in volumetric flask (10ml) and broken up it in 10ml of water. At that point the arrangement was sonicated for 15 minutes,it was further diluted up to the mark with water. The final solution was filtered through Whatmann filter paper no.41 and the filtrate was diluted with water to obtain concentration of about 10(µg/ml). The chromatogram was recorded. The result of assay is given in Table 2.

Table 2. Table of Analysis of tablet by proposed method

Average weight of tablet=0.601g (each tablet contains 150 mg)

Sr.no	Sum **of tablet powder taken(g)**	**Sum of drug estimated (g/tablet)**	**% labeled claim**
1	0.0403	0.146	97.33
2	0.0400	0.148	98.66
3	0.0405	0.150	100.00
4	0.0403	0.146	97.33
5	0.0401	0.147	98.00

Statistics

Mean	98.79
Standard deviation	1.1436
Relative standard deviation	1.1576

The stability testing of Ibandronate sodium were carried out as per ICH Q1A (R2) and photostability as per ICH Q1B rules. All the stress tests were dissected by proposed strategy and % medicate remained was calculated from the standard calibration curve.

Acid hydrolysis

It was performed in 0.1 N HCl at 70º C for 2 hours.The chromatogram was recorded. The % content of Ibandronate sodium remained were calculated.The comes about are appeared in Table 3.

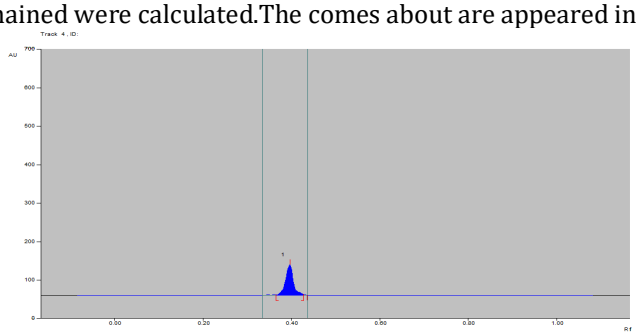


Figure 3. Chromatogram of acid hydrolysis

Table 3. Table of acid hydrolysis

Sr.no	Testing interval(h)	% labeled claim
1	0	99.91
2	1	98.85
3	2	89.55

Alkali hydrolysis

It was performed in 0.1 N NaOH at 70º C for 2 hours.The chromatogram was recorded. The % content of Ibandronate sodium remained were calculated.The comes about are appeared in Table 4.

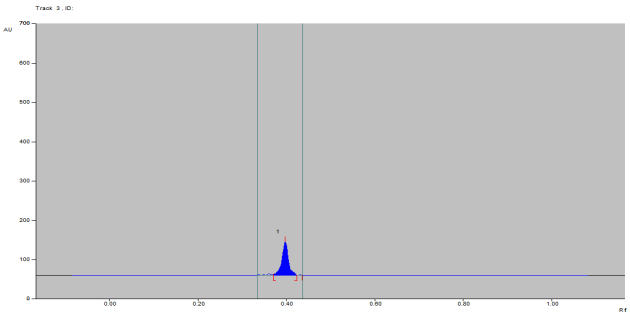


Figure 4. Chromatogram of alkali hydrolysis

Table 4. Table of alkali hydrolysis

Sr.no	Testing interval(h)	% labeled claim
1	0	98.86
2	1	98.75
3	2	93.23

Oxidative degradation

It was performed in 3%H_2O_2 at 70º C for 2 hours.The chromatogram was recorded. The % content of Ibandronate sodium remained were calculated. The comes about are appeared in Table 5.

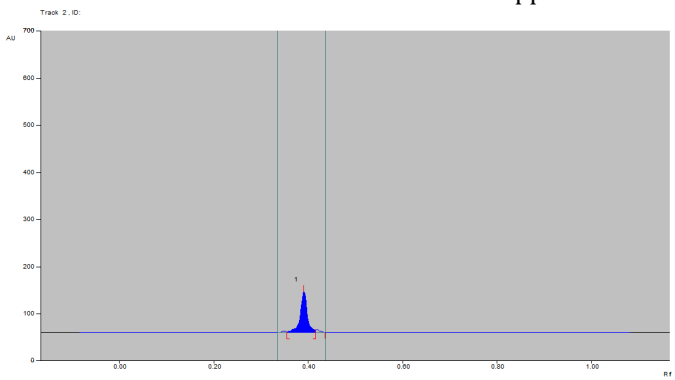


Figure 5. Chromatogram of oxidative degradation

Table 5. Table of oxidative degradation

Sr.no	Testing interval(h)	% labeled claim
1	0	96.59
2	1	93.46
3	2	81.28

Neutral hydrolysis

It was performed in H_2O at 70º C for 2 hours. The chromatogram was recorded. The % content of Ibandronate sodium remained were calculated.The comes about are appeared in Table 6.

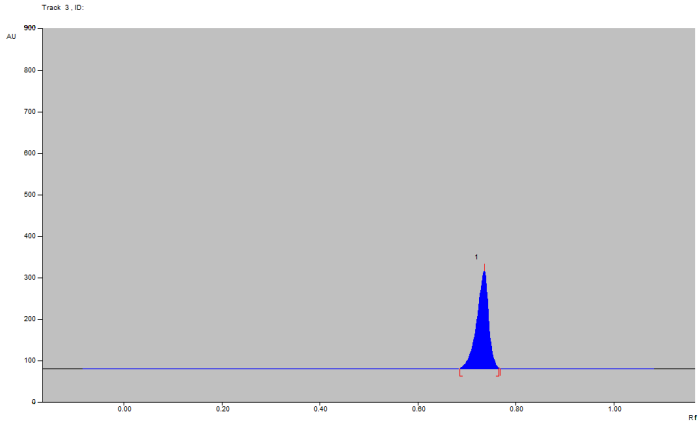


Figure 6. Chromatogram of neutral hydrolysis

Table 6. Table of neutral hydrolysis

Sr.no	Testing interval	% labeled claim
1	0h	99.99
2	1h	99.95
3	2h	99.94
4	4h	99.92
5	6h	99.91
6	8h	99.83
7	24h	99.81
8	2days	99.75
9	5days	99.52

Photolytic degradation

It was performed by exposing drug to 6.0×10^6 lux hr. The chromatogram was recorded. The % content of Ibandronate sodium remained were calculated. The comes about are appeared in Table 7.

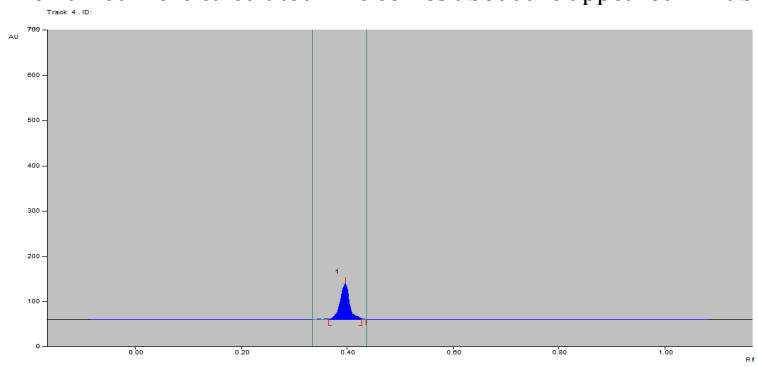


Figure 7. Chromatogram of photolytic degradation

Table 7. Table of photolytic degradation

Sr.no	Total exposure	% labeled claim
1	Initial	99.57
2	1.2×10^6	89.76
3	6.0×10^6	78.18

Thermal degradation

It was performed by exposing drug at 90º C .The chromatogram was recorded. The % content of Ibandronate sodium remained were calculated. The comes about are appeared in Table 8.

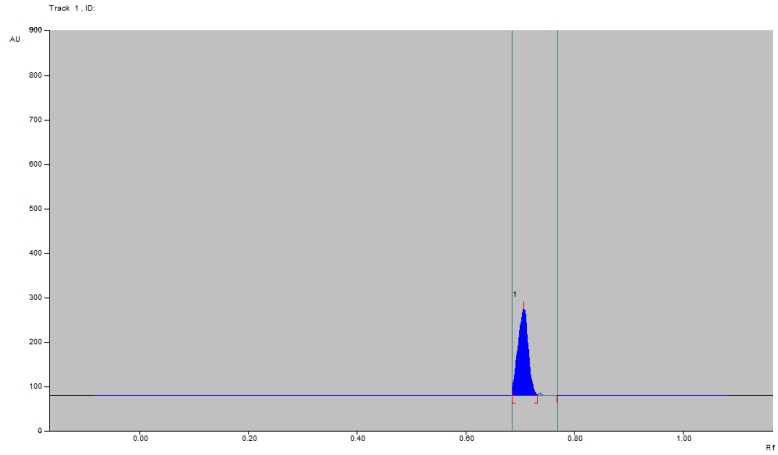


Figure 8. Chromatogram of thermal degradation

Table 8. Table of thermal degradation

Sr.no	Total exposure	% labeled claim
1	0h	98.85
2	24h	98.79
3	2days	95.76
4	5days	89.57

CONCLUSIONS

The chromatographic strategy (HPTLC) portrayed for the assurance of Ibandronate sodium in pharmaceutical detailing are straightforward, exact, delicate and reproducible. Measurable investigation demonstrates that the strategies are repeatable and specific for the examination of Ibandronate sodium in pharmaceutical detailing. The strategies were totally approved appearing palatable information for all the parameter tried. The proposed strategies may well be connected for the schedule investigation.

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