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FORMULATION AND EVALUATION OF MOXIFLOXACIN TASTE-MASKED CHEWABLE TABLES FOR PEDIATRIC TUBERCULOSIS

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Keywords:

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ABSTRACT: Moxifloxacin (MOX) is a second-line treatment for drug-susceptible and multidrug-resistant tuberculosis (MDR TB). MOX has poor patient compliance due to taste and odour concerns, particularly in the pediatric population. MOX taste-masked chewable tablets were developed by direct compression method using mannitol, aspartame, and sucralose as sweetening agents and lemon and peppermint flavor as flavoring agents. The lubricated granules were evaluated for flow properties, and compressed tablets were evaluated for hardness, friability, content uniformity, weight variation, DT and *in-vitro* drug release. FTIR, DSC, and XRD analysis were performed to detect any possible drug excipient compatibility issues and the nature of the drug molecule in the formulation. F6 formulation granules showed excellent flow properties, and batches manufactured with these granules showed physicochemical properties within acceptable limits. Complete drug release was observed within 8 minutes from the F6 formulation. FTIR and DSC studies demonstrated no drug excipient compatibility issues. According to XRD, the MOX in the final formulation was present in crystalline form. The dispersible MOX pills would be a superior alternative for treating pediatric TB.

INTRODUCTION: Fluoroquinolone antibiotic moxifloxacin (MOX) is a second-line therapy for multidrug-resistant tuberculosis (MDR TB) and drug-susceptible TB [1]. Fluoroquinolones are an integral element of current MDR TB therapy regimens for adults and children due to their potent *in-vitro* and *in-vivo* action against Mycobacterium tuberculosis. MOX, which is presently thought to be the most effective fluoroquinolone against *M. tuberculosis*, exhibits early bactericidal action that is comparable to that of isoniazid.

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Its clinical effectiveness in treating pediatric TB is well supported by data [2]. For children with multidrug-resistant (MDR) TB, moxifloxacin is recommended at 7.5–10 mg/kg [3]. However, fluoroquinolones and MOX are limited due to bad taste and smell issues with low patient compliance, especially in the pediatric population [4]. In this scenario, new drug delivery technology with improved patient compliance in children requires the hours.

Drug-resistant tuberculosis (DR-TB), characterized by increased morbidity and mortality, sequelae, higher cost, and complexity, is still a challenge to world health today. Rifampicin resistance was assessed in 71% of individuals with bacteriologically proven pulmonary TB in 2020. Between 2019 and 2020, 157,903 new cases of DR-TB were discovered, a 22% drop in the overall

number of people with the disease [5]. Approximately 95% of those exposed to *M. tuberculosis* already have the primary infection and do not develop active TB disease after that [6]. However, children do not experience this. Children's immune systems are less developed than those of adults, thus they are unable to develop a strong enough inflammatory response to inhibit the spread of TB disease [7]. There is a need to have better dosage forms for pediatric patients suffering from TB. Available marketed formulations with second-line anti-TB drugs are liquid solutions and suspension forms with various stability issues leading to lower patient compliance. Unfortunately, pediatric TB therapies are still in their infancy compared to adult treatments. Adult oral immediate-release tablets are commonly unsuitable for children. An excellent case of how children are not little adults and require formulations that are specifically tailored and assessed for this market is the pediatric TB treatment case [8].

Chewable tablets are a customizable dosage form with several benefits, including patient-centered drug delivery, ease of swallowing, the stability benefits of solid dosage forms, and oral drug delivery without the requirement for water [9]. They provide a convenient means of pediatric drug delivery. In terms of manufacturing, dosage precision, portability, and long-term stability, chewable tablets are superior to conventional tablets [10]. Chewable tablets also make swallowing easier since the substance is first broken down into small particles in the oral cavity. Chewable tablets are quite beneficial for patient-centered groups like pediatrics, where the ingestion of conventional tablets is an issue. Because sweeteners are included in chewable tablets, taste-masking is made simple and required for most formulations [11]. The best solution for the effective treatment of pediatric TB would be to use flavor- and sugar-masked chewable MOX tablets, taking into account all these possible MOX taste-related problems and the available therapeutic options. Potentially overcoming the difficulties in treating pediatric TB would be the taste-masked chewable tablets of MOX.

MATERIALS AND METHODS:

Materials: Moxifloxacin HCl (MOX) was obtained as a gift sample from Macleods Pharmaceuticals Ltd. Mumbai, India. Microcrystalline cellulose (MCC 101) was purchased from Maple Biotech Pvt Ltd., Pune, India. Crospovidone was obtained from Concertina Pharma Pvt., Ltd, Hyderabad, India. Mannitol 100 SD, Sucralose and Sodium chloride were purchased from signet excipients PVT ltd. Mumbai, India. Lemon and peppermint flavors were purchased from Bell flavors and fragrances. Magnesium stearate was purchased from S. D. Fine Chem Ltd., Mumbai, India.

Methods:

Development of MOX Chewable Tablets: The direct compression method was used to manufacture MOX chewable tablets as per the composition presented in **Table 1.** MOX, Mannitol 100 SD, Sucralose, and Aspartame were co-sifted through sieve # 40. MCC 101, crospovidone, and sodium chloride were co-sifted through sieve # 40. These all-sifted ingredients were blended in a suitable blender for 20 min.

All these ingredients were properly mixed in a polybag for 15 min. Lemon and peppermint flavors were passed through sieve # 40 and blended with previous material for 5 min. Magnesium stearate was passed through sieve # 80, mixed, and blended with the initial mixture in a blender. The powder blend was compressed into tablets on a ten-station rotary punch tableting machine using 8 mm round punch set.

TABLE 1: COMPOSITION OF MOX CHEWABLE TABLETS

Sr. no.	Name of ingredient	F1	F2	F3	F4	F5	F6
1	Moxifloxacin	100.0	100.0	100.0	100.0	100.0	100.0
2	Mannitol 100 SD	70	70	70	70	70	70
3	Microcrystalline cellulose (MCC 101	52.5	46.5	40.5	34.5	28.5	22.5
4	Crospovidone	6	12.0	18.0	24.0	30.0	36.0
5	Sucralose	12.5	12.5	12.5	12.5	12.5	12.5
6	Asparatame	2.0	2.0	2.0	2.0	2.0	2.0
7	Sodium chloride	1.0	1.0	1.0	1.0	1.0	1.0

8	Lemon flavor	2.0	2.0	2.0	2.0	2.0	2.0
9	Peppermint	1.5	1.5	1.5	1.5	1.5	1.5
10	Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5
11	Total	250.0	250.0	250.0	250.0	250.0	250.0

Characterization of Granules [12]:

Angle of Repose (θ): In the funnel, accurately weighed lubricated granules were poured slowly from a specific height so that the pile of powder barely touched the funnel's tip. The angle of repose was estimated using the following formula once the diameter of the heap was determined.

$$\tan \theta = h / r$$

Where, h = Height of the pile and r = radius of the base

Bulk Density (BD): A measuring cylinder of 50 ml was gently filled with accurately weighed lubricated granules, and the bed was made uniformly without being disturbed. The volume was expressed in milliliters, and the following formula was used to determine the BD.

BD = Mass of sample in g / Volume occupied by sample in ml

Tapped Density (TD): Accurately weighted lubricated granules were taken and poured into a measuring cylinder within a bulk density tester. The sample's original volume was recorded, then it was tapped (50–100–250 times) until no change in volume could be seen. This volume was then reported as the tapped volume. TD was determined using the following formula

TD = Mass of sample in gm) / Tapped volume occupied by sample in ml

Compressibility Index (CI): The CI was calculated using the formula below.

$$CI = TD\text{-}BD / TD) \times 100$$

Hausner's Ratio (HR): HR was calculated with the help of the below formula.

$$HR = TD / BD$$

Evaluation of Dispersible Tablets [13]:

Thickness and Diameter: The diameter and thickness were measured using a digital vernier caliper. Ten tablets were chosen at random for this test and dimensions were measured in millimeters with standard deviation.

Hardness: Using a Stokes Monsanto hardness tester, the hardness of ten randomly selected tablets was evaluated. Both the average and standard deviation were determined.

Friability: For this test, 20 tablets were randomly selected and the test was carried out on an automated friabilator for 100 rotations. The weight of the dedusted tablets was recorded, and the mean of three readings for friability was calculated. Typically, tablets were considered acceptable when there was a weight loss of less than 1%.

Content Uniformity: On 10 tablets randomly selected from each batch, a content uniformity test was carried out in accordance with USP. These tablets were crushed, then left to soak for 24 hours in a buffer with a pH of 1.2. The solution was filtered through a 0.45-micron filter and MOX content was determined using UV spectroscopy at 240 nm.

Weight Variation: Twenty tablets were selected at random, and their weights were precisely recorded. Standard deviations and the mean were calculated.

Disintegration Test: Six tablets were subjected to the test utilizing the disintegration test apparatus. The time it took for the tablet to completely dissolve in 900 ml of distilled water at 37 ± 0.50C, with no perceptible bulk left in the device, was measured in seconds.

***In-vitro* Release Studies:** Dissolution test apparatus (USP type II) containing a pH 7.4 phosphate buffer (900 ml; 37 ± 0.50C) at 50 rpm for 15 minutes was used to evaluate the release of MOX. 5 ml samples were withdrawn and replaced with the same volume of freshly made buffer at predefined intervals (2, 4, 6, 8, 10, 12 and 15 min) to maintain the sink condition. The samples were filtered through 0.45 m filters to get clear solutions, and the MOX concentration was then assessed using UV spectroscopy at 240 nm.

FTIR Study: Utilizing FTIR analysis, it was possible to establish how well the MOX worked with additional components. A FTIR was used to

obtain the infrared spectra of MOX and the optimised formulation utilising the potassium bromide pellet technique. The dried samples were triturated and put in the sample container to compress the pellets after being mixed individually with potassium bromide in a 1:99 ratio. The resulting pellets were then scanned at 4000-400 cm-1. The functional groups' standard absorbance range was used to do the spectral analysis. The spectral analysis was carried out, by the standards absorbance range of the functional groups [14].

Differential Scanning Calorimetry (DSC) Studies: The pure MOX and optimised formulation were subjected to DSC analysis using a DSC device. 2-3 mg of the crushed formulation and a small quantity of MOX were precisely balanced in an aluminum pan before being hermetically sealed with a crimper. The sample was heated at a rate of 100C/min from an ambient temperature of 400C to 4000C. Purging nitrogen gas flowing at 100 ml/min was used to create inert atmospheres [15].

X-Ray Diffraction: X-ray Diffraction (XRD): XRD patterns of pure MOX and optimised formulation were recorded with the following settings: Cu Kα radiation with wavelength 1.54 Å, voltage = 45 kV, current = 40 mA. Measurements were made in the 2Θ range of 10 to 80° [16].

RESULTS AND DISCUSSION: MOX chewable tablets were developed by direct compression technique using mannitol as a major excipient. The granules obtained were evaluated for various flow properties presented in **Table 2**.

The F6 formulation batch showed excellent flow properties with an angle repose of 26.41 ± 0.21, while other batches showed good flow properties (31- 35). The granules with an angle of repose between 25-30 are considered excellent flow properties [17]. The BD of the granules ranged from 0.256± 0.02 to 0.382± 0.051. The higher BD values indicate the greater compressibility of the granules. TD was observed between 0.295± 0.0210.485± 0.024. The granules having HR of 1.00 to 1.11 and CI between 0-10 indicate the excellent flow properties of the powder [18]. Based on these criteria, F6 formulation granules showed excellent flow properties. The flow properties of batch F6 were excellent, considering all granule flow properties summarized in **Table 2.**

TABLE 2: FLOW PROPERTIES OF THE GRANULES

Batch	Angle of repose (θ)	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Hausner Ratio	CI
F1	34.11 ± 0.10	0.256 ± 0.02	0.295 ± 0.021	1.15 ± 0.017	13.22 ± 0.020
F2	32.12 ± 0.12	0.262 ± 0.06	0.382 ± 0.011	1.46 ± 0.012	31.41 ± 0.011
F3	32.24 ± 0.19	0.28 ± 0.05	0.375 ± 0.021	1.34 ± 0.027	25.33 ± 0.015
F4	33.27 ± 0.17	0.291 ± 0.034	0.365 ± 0.017	1.25 ± 0.023	20.27 ± 0.019
F5	31.10 ± 0.12	0.321 ± 0.045	0.485 ± 0.024	1.51 ± 0.014	33.81 ± 0.016
F6	26.41 ± 0.21	0.382 ± 0.051	0.4 ± 0.045	1.047 ± 0.011	4.5 ± 0.014

The tablets were compressed with 8 mm round flat punch so all the tablets were round with 8.01 ± 0.01 to 8.06 ± 0.03 diameter (**Table 3)**. The weight variation was observed due to the poor flow of the granules except for batch F6. Due to the uneven flow of the granules, complete die-filling did not occur, resulting in weight variation and content uniformity. However, all the batches comply with the weight variation test as per USP for uncoated tablets 7.5% weight variation for uncoated tablets (130-324 mg) is acceptable[19]. Also, all batches passed the content uniformity test because, as per BP the content uniformity limit is between 85 to 115% [19]. In our study, the batches with poor flow properties showed wide weight variation, while batch F6 showed lower weight variation due to the excellent flow of the granules. A similar observation was also found concerning content uniformity. The hardness of the tablets is one of the important parameters to be considered during the development of the tablet formulation. The compressibility of the granules determines the hardness of the tablets. The batches manufactured with a higher compressibility index showed greater hardness sufficient to withstand the physical abrasion. Also, the higher hardness of the tablets played a crucial role in withstanding in the friability test, as presented in **Table 3.** F5 and F6 formulations showed greater hardness and acceptable friability as per USP (NMT 1%). Other batches failed to pass the friability test due to relatively lower hardness observed during

compression. The disintegration time of tablets is the most crucial factor that needs to be adjusted in the development of chewable tablets [19]. All of the tablets in the study disintegrated between 35 to 160 seconds. The disintegration of the tablets was found directly related to the concentration of disintegrant used in the formulation. Crospovidone is a synthetic cross-linked PVP that is insoluble in water. Crospovidone exerts its effects through various mechanisms, such as swelling and wicking, followed by secondary swelling. The porous particle shape of the Crospovidone disintegrants in this study functions *via* a wicking mechanism, drawing water into the tablet by capillary action, causing subsequent swelling and breakdown of interparticle linkages and tablet disintegration [20]. Further, the presence of sodium chloride in the formulation has also helped in the rapid disintegration of the tablets due to its high-water solubility that helped to burst the tablets by erosion mechanism.

TABLE 3: POST-COMPRESSION PARAMETERS OF THE TABLETS

Batch	Weight variation (%)	Diameter (mm)	Content uniformity (%)	Hardness (kg/cm^2)	Friability (%)	DT (sec)
F1	1.12 ± 1.09	8.01 ± 0.01	92.11 ± 1.09	6.41 ± 0.10	1.3	160 ± 2
F2	0.956 ±1.20	8.03 ± 0.02	91.21 ± 1.12	6.45± 0.12	1.2	132 ± 5
F3	1.11 ± 1.24	8.02 ± 0.04	93.27 ± 1.24	7.18 ± 0.31	1.1	110 ± 2
F4	1.235 ±1.15	8.06 ± 0.03	94.24 ± 1.17	6.75 ± 0.45	1.0	85 ± 5
F5	0.954 ±1.24	8.02 ± 0.02	95.28 ± 1.21	8.12 ± 0.24	0.9	65 ±4
F6	0.125 ±1.08	8.01 ± 0.01	99.67 ± 0.95	8.97 ± 0.78	0.6	35 ± 4

***In-vitro* Release Studies:** Directly compressible tablets of MOX were studied for *in-vitro* release study in pH 7.4 phosphate buffer. The comparative release profile of all formulations is presented in **Table 4** and **Fig. 1**. The release study was performed for 30 minutes, and only two batches F5 and F6 showed 100 % release. F6 formulation showed very rapid release within 8 minutes, while the F5 batch showed in 15 minutes. It has been observed that crospovidone and sodium chloride helped improve the dissolution rate of MOX from chewable tablets.

TABLE 4: COMPARATIVE *IN-VITRO* MOX RELEASE FROM DISPERSIBLE TABLETS

Time (min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
2	20	22	28	32	45	60
4	25	38	45	56	59	80
6	40	46	52	65	72	92
8	50	57	65	80	85	100
10	62	70	73	85	90	
12	70	77	82	90	95	
15	75	82	85	92	100	
30	84	87	92	96		

The addition of crospovidone significantly improved the dissolution profile in formulations. This rapid rise in the dissolution profile might result from the tablets' quick swelling and breakdown.

Crospovidone has a strong capillary action, is highly hydrated, and exhibits significant agglomeration and a little propensity toward gel formation. The tablets break down fast but produce a larger aggregated mass of particles. For the treatment of TB to be effective, this fast-release pattern is necessary and preferred.

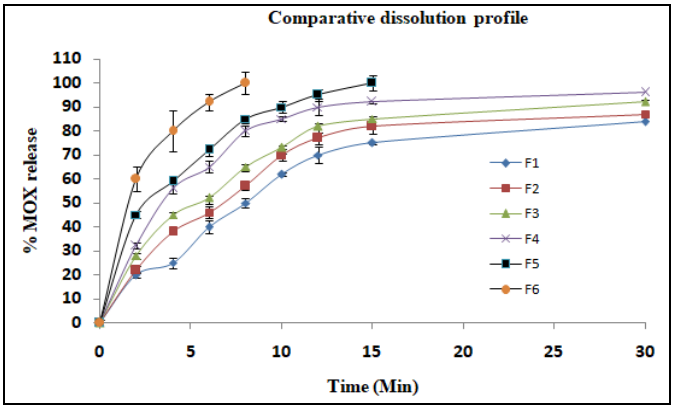


FIG. 1: COMPARATIVE *IN-VITRO* MOX RELEASE IN pH 7.4 PHOSPHATE BUFFER

IR: Fig. 2A and **2B** shows the FT-IR spectra of the optimized formulation F6 and pure OMX, respectively. FTIR spectra of MOX Hydrochloride revealed four distinctive peaks at 3522 cm^{-1} (secondary N-H stretching), 1699 cm^{-1} (CO stretching of keto group), 1499 cm^{-1} (OH bending of COOH) and 1617 cm^{-1} (CO stretching).

In the IR spectra of the F6 formulation, similar distinctive peaks with lesser intensity and a small shifting were also seen **Fig. 2B**. This suggests that the final formulation kept the MOX drug's distinguishing peaks. The drug and the excipients employed in the tablet formulation did not interact.

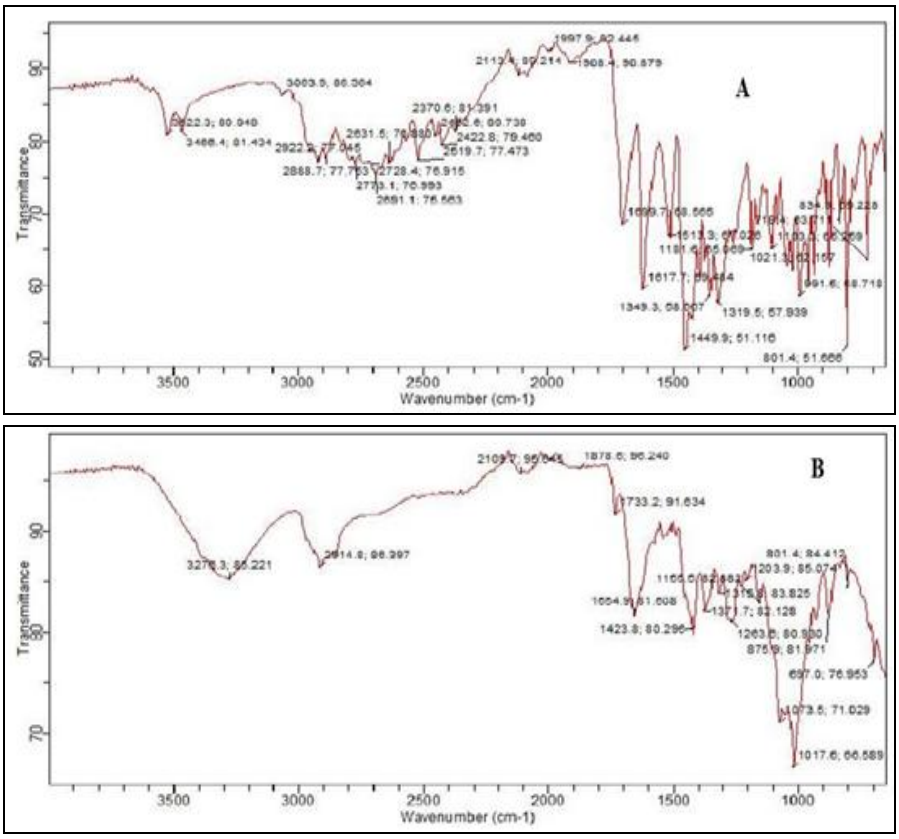
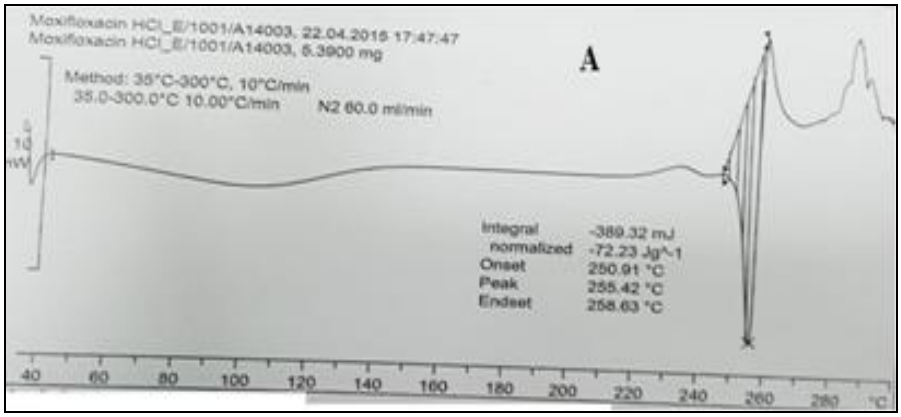


FIG. 2: FTIR SPECTRA OF (A): PURE MOX AND (B): OPTIMISED FORMULATION F6

DSC: DSC helps to identify transitions such as melting, glass transition, and crystallization during drug development activities. DSC thermograms of the pure MOX and F6 formulations are presented in **Fig. 3A** and **3B,** respectively. MOX exhibited an endothermic peak at 255.42°C, indicating pure crystalline nature. The DSC thermograph of optimized formulation F6 exhibited an endothermic peak at 167.30°C. Reduction in intensity and shifting of the MOX endothermic peak suggests an increase in the amorphous nature of MOX when formulated as chewable tablets.



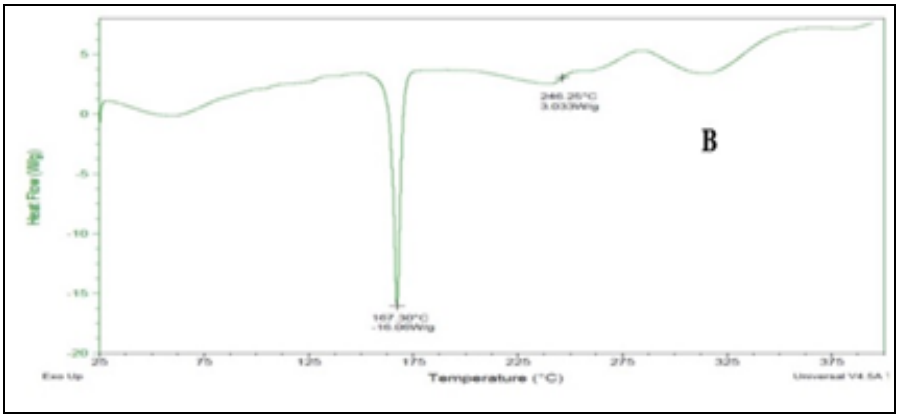


FIG. 3: DSC ENDOTHERMIC PEAK OF PURE DRUG (A) AND OPTIMISED FORMULATION F6 (B)

X-Ray Diffraction: The XRD study revealed the crystalline nature of the pure MOX due to sharp peaks observed at diffraction angles of 8.44, 10.07, 15.11 and 19.06 **Fig. 4A**. The optimized formulation showed peaks at diffraction angles 45.37, 48.11 and 43.33 might be from other excipients present in the final optimized formulation **Fig. 4B**. The intensity of the peaks was slightly decreased in comparison to the pure drug MOX. These observations state that the MOX was present in crystalline form.

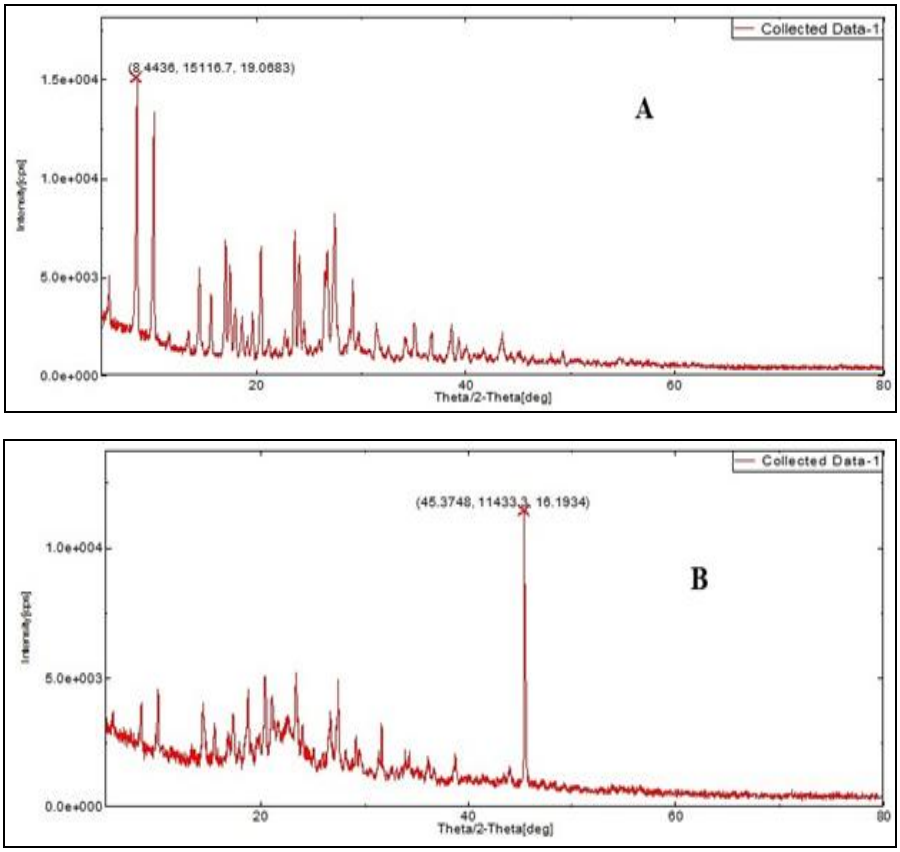


FIG. 4: X-RAY DIFFRACTION PATTERN OF (A): PURE MOX DRUG AND (B): OPTIMISED FORMULATION F6

CONCLUSION: Crospovidone, which acts as a super disintegrant, flavours and sugar, which serve as taste masking agents, may be used to develop chewable tablets of the MOX. The Crospovidone concentration and disintegration time were inversely correlated. The optimised batch demonstrated complete drug release within 8 minutes. The FTIR and DSC studies did not reveal drug excipient compatibility. XRD clearly showed the presence of crystalline MOX in the final formulation. The MOX chewable tablets may be an effective option for treating pediatric TB.

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