RESEARCH PAPER

Design And Development Of Mannose Receptor Targeted Strip Loaded Nano Formulation For Female Genital Tuberculosis

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Abstract

Objective: To develop mannose receptor-targeted Clofazimine nanoparticles incorporated into vaginal strips for localized treatment of female genital tuberculosis (FGTB), enhancing drug solubility, macrophage-specific uptake, site-specific delivery, and sustained release with minimal systemic toxicity.

Methods: Clofazimine nanoparticles were prepared and mannose-functionalized. Vaginal strips were formulated using Eudragit RL-100, Eudragit RS-100, HPMC K100M/E50, and PEG 400 via solvent casting. A 3-factor, 3-level Box–Behnken design optimized Eudragit RL-100, HPMC K4M, and magnetic stirring speed for thickness, folding endurance, and drug release. Evaluations included weight/thickness uniformity, folding endurance, surface pH, particle size, PDI, zeta potential, drug content, moisture content, swelling index, in-vitro drug release, SEM, DSC, and XRD.

Results: All strips exhibited uniform weight and thickness, good flexibility, and slightly acidic pH (3.83–4.47). Particle size ranged 80–97 nm (ST7: 80 nm), PDI 0.147–0.252, zeta potential −15.4 to −29.7 mV. Drug content (78.3–95%), moisture (4.25–8%), and swelling index (20.93–31.25%) were acceptable. In-vitro release was sustained over 8 h, with ST7 achieving 94.93% cumulative release. SEM showed uniform morphology; XRD indicated high crystallinity.

Conclusion: Mannose receptor-targeted Clofazimine strips exhibited consistent physicochemical properties, mechanical strength, and sustained release. ST7 demonstrated optimal size, stability, and macrophage targeting, providing a promising localized therapy for FGTB with reduced systemic toxicity.

Keywords: Female genital tuberculosis, Clofazimine, Mannose receptor, Nanoparticles, Vaginal strips

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1. Introduction

Tuberculosis (TB) remains a major global health issue, with extrapulmonary forms like female genital tuberculosis (FGTB) causing infertility and severe reproductive complications. Conventional therapy often fails due to poor tissue penetration, intracellular survival of Mycobacterium tuberculosis, and systemic toxicity. Nanotechnology-based drug delivery can enhance solubility, intracellular penetration, and sustained release, while active targeting via mannose receptors enables macrophage-specific drug delivery. Clofazimine (BCS Class II drug) is effective against drug-sensitive and resistant TB but suffers from poor solubility. Incorporating Clofazimine nanoparticles into vaginal strips ensures localized delivery, prolonged residence, and improved patient compliance, aiming to enhance therapeutic outcomes while minimizing systemic exposure [1, 2].

2. Materials and Methods

2.1 Materials

Clofazimine, Eudragit RS-100/RL-100, HPMC K100M/E50, PEG 400, Chitosan, STPP, Mannose, ethanol, distilled water all analytical grade.

2.2 Vaginal Strip Preparation

Polymers were dissolved in appropriate solvents; Clofazimine nanoparticles added. PEG 400 added as plasticizer; solution cast on plates and dried at 40 °C for 24 h [3].

2.3 Experimental Design

Box–Behnken 3-factor, 3-level design optimized: Eudragit RL-100 (A), HPMC K4M (B), stirring speed (C). Responses: thickness, folding endurance, drug release.

Table 1: DOE Suggest and Experimental batches

Formulation code	Eudragit RL 100(mg)	HPMCK4M(mg)	Magnetic stirring speed(RPM)
ST1	200	500	1500
ST2	300	500	1500
ST3	250	500	1000
ST4	200	450	1000
ST5	200	450	2000
ST6	300	450	1000
ST7	300	450	2000
ST8	250	450	1500
ST9	250	400	2000
ST10	250	400	1000
ST11	300	400	1500
ST12	250	500	2000
ST13	200	400	1500

2.4 Evaluation

- **Weight & Thickness:** Micrometer; mean ± SD.
- **Folding Endurance:** Repeated folding until breakage.
- **Surface pH:** Films swelled in distilled water; measured with pH meter.
- **Particle Size, PDI, Zeta Potential:** Dynamic light scattering (Malvern).
- **Drug Content:** UV spectrophotometry at 488 nm in SVF.
- **Moisture Content & Swelling Index:** Gravimetric method in desiccator and SVF.
- **In-vitro Release:** Franz diffusion cell; phosphate buffer pH 4.5; 8 h sampling.
- **SEM, DSC, XRD:** Surface morphology, thermal behavior, and crystallinity analysis [4, 5].

3. Results and Discussion

3.1 Uniformity of Weight and Thickness, Folding endurance, Particle Size, PDI, Zeta potential

Table 2: Weight, Thickness, Folding Endurance, Particle Size, PDI, Zeta Potential

Formulation code	Weight variation (mg)	Thickness (mm)	Folding endurance	Particle Size (nm)	PDI	Zeta potential
ST1	29 ± 0.0011	0.11 ± 0.0024	207.03 ± 0.0010	92	0.232	-21.2
ST2	57 ± 0.0025	0.12 ± 0.0014	163.03 ± 0.0061	89	0.222	-25.8
ST3	43 ± 0.0001	0.08 ± 0.0066	143.65 ± 0.0011	84	0.229	-26.4
ST4	58 ± 0.0002	0.17 ± 0.0074	204.78 ± 0.0008	87	0.230	-18.1
ST5	50 ± 0.0047	0.06 ± 0.0210	287.53 ± 0.0087	96	0.244	-22.3
ST6	26 ± 0.0312	0.04 ± 0.0318	160.78 ± 0.0061	83	0.219	-20.4
ST7	32 ± 0.0574	0.23 ± 0.0102	243.53 ± 0.0047	80	0.147	-29.7
ST8	25 ± 0.0610	0.12 ± 0.0001	224.15 ± 0.0099	86	0.164	-15.4
ST9	56 ± 0.0009	0.08 ± 0.0005	304.65 ± 0.0061	82	0.159	-20.2

ST10	47 ± 0.0003	0.08 ± 0.0030	221.9 ± 0.0084	97	0.252	-27.8
ST11	30 ± 0.0014	0.1 ± 0.0000	241.28 ± 0.0001	91	0.231	-19.2
ST12	44 ± 0.0010	0.08 ± 0.0025	226.4 ± 0.0058	83	0.227	-28.4
ST13	52 ± 0.0008	0.07 ± 0.0010	285.28 ± 0.0025	94	0.248	-17.2

Conclusion: Uniform weight, thickness, and good mechanical strength; ST7 optimal.

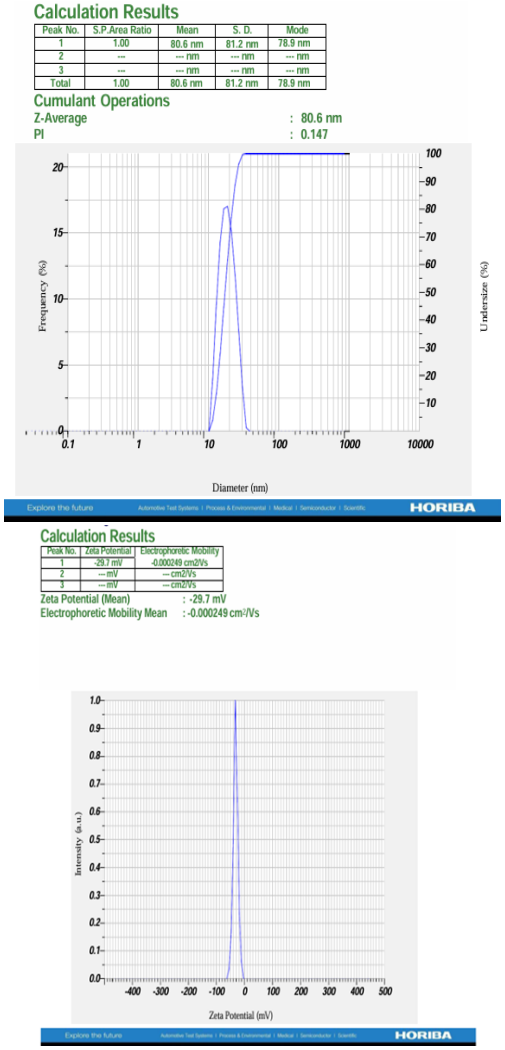


Figure 1: Particle size and Zeta potential of ST 7

3.2 Drug Content, Moisture, Swelling

Table 3: Drug content, Moisture, Swelling

Formulation code	Drug content (%)	Moisture content (%)	Swelling index (%)
ST1	86.6 ± 0.0020	6.89 ± 0.0018	24.13 ± 0.0016
ST2	93.3 ± 0.0036	5.26 ± 0.0058	22.80 ± 0.0091
ST3	80 ± 0.0002	4.65 ± 0.0028	20.93 ± 0.0087
ST4	78.3 ± 0.0014	5.17 ± 0.0033	24.14 ± 0.0009
ST5	91.6 ± 0.0022	6 ± 0.0074	26 ± 0.0002
ST6	85 ± 0.0007	7.69 ± 0.0003	23.07 ± 0.0047
ST7	95 ± 0.0014	6.25 ± 0.0031	31.25 ± 0.0051
ST8	85 ± 0.0047	8 ± 0.0003	24 ± 0.0007
ST9	88.3 ± 0.0048	5.36 ± 0.0070	23.21 ± 0.0011
ST10	90 ± 0.0000	4.25 ± 0.0001	23.40 ± 0.0024
ST11	85 ± 0.0017	6.66 ± 0.0088	23.33 ± 0.0056
ST12	91.6 ± 0.0009	4.54 ± 0.0093	22.72 ± 0.0082
ST13	81.6 ± 0.0051	5.77 ± 0.0058	25 ± 0.0091

Conclusion: ST7 optimal with highest drug content and swelling.

3.3 In-vitro Drug Release

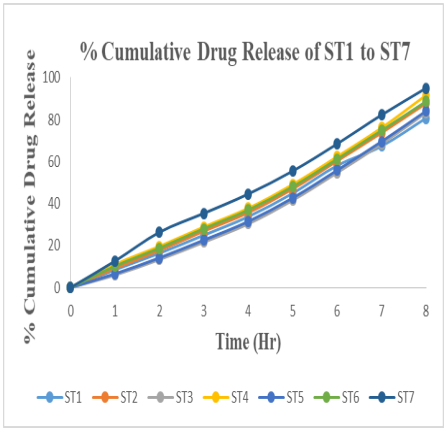
Table 4: In Vitro Diffusion Study of ST1 to ST7

Time in (HR)	ST1	ST2	ST3	ST4	ST5	ST6	ST7
0	0	0	0	0	0	0	0
1	8.47 ± 0.0015	9.13 ± 0.0047	5.93 ± 0.0107	11.00 ± 0.0947	6.53 ± 0.0018	10.13 ± 0.0009	12.60 ± 0.0047
2	16.33 ±	17.67 ±	13.33 ±	19.60 ±	14.13 ±	18.73 ±	26.33 ±

	0.0091	0.0019	0.0349	0.0358	0.0009	0.0064	0.0058
3	24.93 ± 0.0001	26.87 ± 0.0049	21.60 ± 0.0002	28.87 ± 0.0147	22.60 ± 0.0041	28.00 ± 0.0025	35.33 ± 0.0104
4	33.73 ± 0.0081	35.67 ± 0.0003	30.33 ± 0.0201	37.73 ± 0.0268	31.47 ± 0.0028	36.87 ± 0.0724	44.53 ± 0.0648
5	44.87 ± 0.0014	46.93 ± 0.0137	41.53 ± 0.0608	49.07 ± 0.0358	42.67 ± 0.0067	48.00 ± 0.0325	55.47 ± 0.0258
6	58.07 ± 0.0064	60.20 ± 0.0205	54.73 ± 0.000	62.33 ± 0.0618	55.87 ± 0.0011	61.13 ± 0.0025	68.40 ± 0.0602
7	67.33 ± 0.0014	73.67 ± 0.0327	68.40 ± 0.0261	76.07 ± 0.0987	69.53 ± 0.0058	74.73 ± 0.0001	82.20 ± 0.0487
8	85.67 ± 0.0083	87.67 ± 0.0619	83.20 ± 0.0825	91.60 ± 0.0022	84.07 ± 0.0064	88.60 ± 0.0259	94.93 ± 0.0216

Table 5: In Vitro Diffusion Study of F8 to F13

Time in (HR)	ST8	ST9	ST10	ST11	ST12	ST13
0	0	0	0	0	0	0
1	10.73 ± 0.0070	8.93 ± 0.0010	10.93 ± 0.0208	5.80 ± 0.0017	8.00 ± 0.0003	6.40 ± 0.0014
2	21.60 ± 0.0147	17.07 ± 0.0036	22.00 ± 0.0314	13.27 ± 0.0049	16.27 ± 0.0048	14.27 ± 0.0015
3	30.40 ± 0.0258	25.47 ± 0.0154	30.93 ± 0.0648	21.60 ± 0.0061	25.13 ± 0.0091	22.73 ± 0.0004
4	39.67 ± 0.0147	34.20 ± 0.0357	40.33 ± 0.0981	30.27 ± 0.0084	34.20 ± 0.0154	31.60 ± 0.0041
5	50.73 ± 0.0158	45.27 ± 0.0001	51.47 ± 0.0055	41.27 ± 0.0046	45.40 ± 0.0308	42.67 ± 0.0017
6	63.80 ± 0.0358	58.53 ± 0.0045	64.60 ± 0.0037	54.33 ± 0.0061	59.00 ± 0.0618	55.80 ± 0.0201
7	77.73 ± 0.0159	69.93 ± 0.0014	78.67 ± 0.0047	68.40 ± 0.0091	73.80 ± 0.0554	69.40 ± 0.0157
8	92.13 ± 0.0021	83.20 ± 0.0018	93.40 ± 0.0058	83.13 ± 0.0017	89.20 ± 0.0002	84.33 ± 0.0320



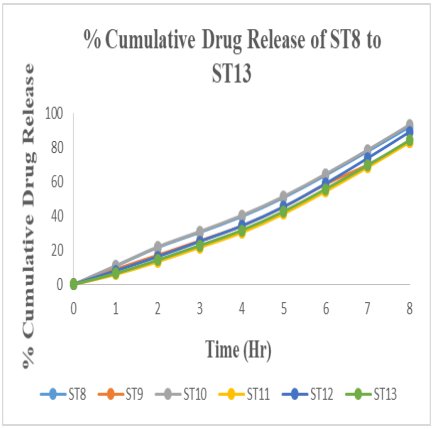


Fig 2: In vitro drug release of ST1 to ST 13

Conclusion: ST7 highest release (94.93%); others moderate-high (80–92%).

3.4 SEM

Fig 3: SEM of ST7

Conclusion: Uniform, spherical nanoparticles with smooth surface.

3.5 DSC

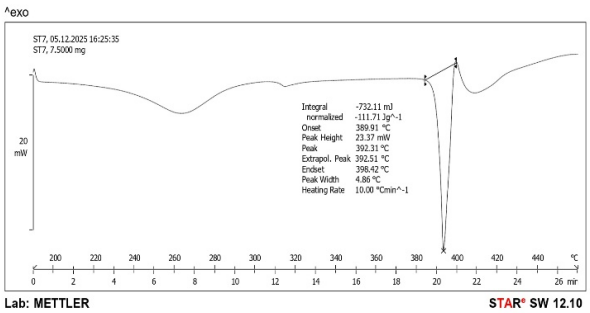


Figure 4: DSC of ST7

Conclusion: ST7 peak at 392.31 °C; drug retains crystallinity; no polymer interaction.

3.6 XRD

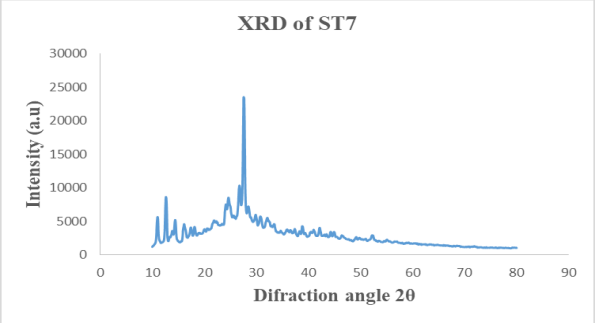


Figure 5: XRD of ST7

Conclusion: Sharp peaks indicate high crystallinity; stable formulation.

4. Conclusion

Mannose receptor-targeted Clofazimine strips were successfully formulated with uniform physicochemical properties, good mechanical strength, and sustained drug release. ST7 was identified as the optimized batch for macrophage-targeted delivery, offering a promising localized therapy for FGTB with reduced systemic toxicity.

5. References

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