

PHARMA APPLICATION LEAFLET

#16/09/001

Metformin Hydrochloride, Direct Compression

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Abstract

Metformin hydrochloride is a popular drug for diabetes. It is first line medication for the treatment of type II diabetes. It is high dose active pharmaceutical ingredient and it is available with 500 mg and 850 mg. Generally high dose metformin tablets are

manufactured by wet granulation. This tablet formulation manufactured with **HiCelTMMCC** by direct compression. Tablets got good tablet profile in terms of weight uniformity, hardness, friability, disintegration time and dissolution profile.

Ingredient composition

Sr.No.	Name of ingredients	mg/tablet	Contribution (%)
1.	Metformin Hydrochloride	500	79.24
2.	HiCelTMMCC90M (Microcrystalline Cellulose)	60	9.52
3.	HPMC-10 (Hydroxypropylmethyl Cellulose)	65.80	10.42
4.	Magnesium stearate	5.20	0.82
Total		631	100.0

Procedure

Metformin Hydrochloride was mixed with **HiCelTMMCC 90M** and HPMC-10 for 15 minutes. Then magnesium stearate was added and mixed them for 10 minutes. The powder mixture was ready for direct compression.

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Equipment

Sr.No.	Name of equipment	Application	Model/ make
1.	Tablet punching machine	Tablet Manufacturing	10 station, D tooling/ Proton mini press
2.	Weighing Balance	Weighing	MS204S/A01/ Mettler Toledo
3.	Tablet Hardness Tester	Hardness Test	TH 1050 M/ Labindia
4.	Tablet Friability Tester	Friability Test	FT1020 / Labindia
5.	Tablet Disintegration Tester	Disintegration Test	DT 1000 / Labindia
6.	Dissolution Apparatus	Percentage of drug release	DS 8000 / Labindia
7.	UV Spectrophotometer	Absorbance	1800/ Shimadzu

Dissolution Test Detail

Dissolution Medium: Potassium di-hydrogen Ortho phosphate buffer, 1000 ml. 37±2 °C temperature, at 50 rpm and using with USP dissolution type II apparatus.

Samples withdrawals after 5, 10, 15,20,25,30, 35 and 40 minutes. Samples should be diluted if require and filtered. Check absorbance at $\lambda=233\text{nm}$.

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Tablet Characteristics

Sr.No.	Name of Parameter	Result
1.	Tablet description	Concave, Elongated , white color
2.	Tablet weight (n=10)	631 mg
3.	Tablet Hardness(n=10)	61.7N
4.	Thickness (n=10)	5.2 mm
5.	Diameter	18.10mm
6.	Friability (n=10)	<1 %
7.	Disintegration time (n=06)	42 Sec
8.	Dissolution time (n=6)	30 min



Fig.1. Metformin Hydrochloride tablets

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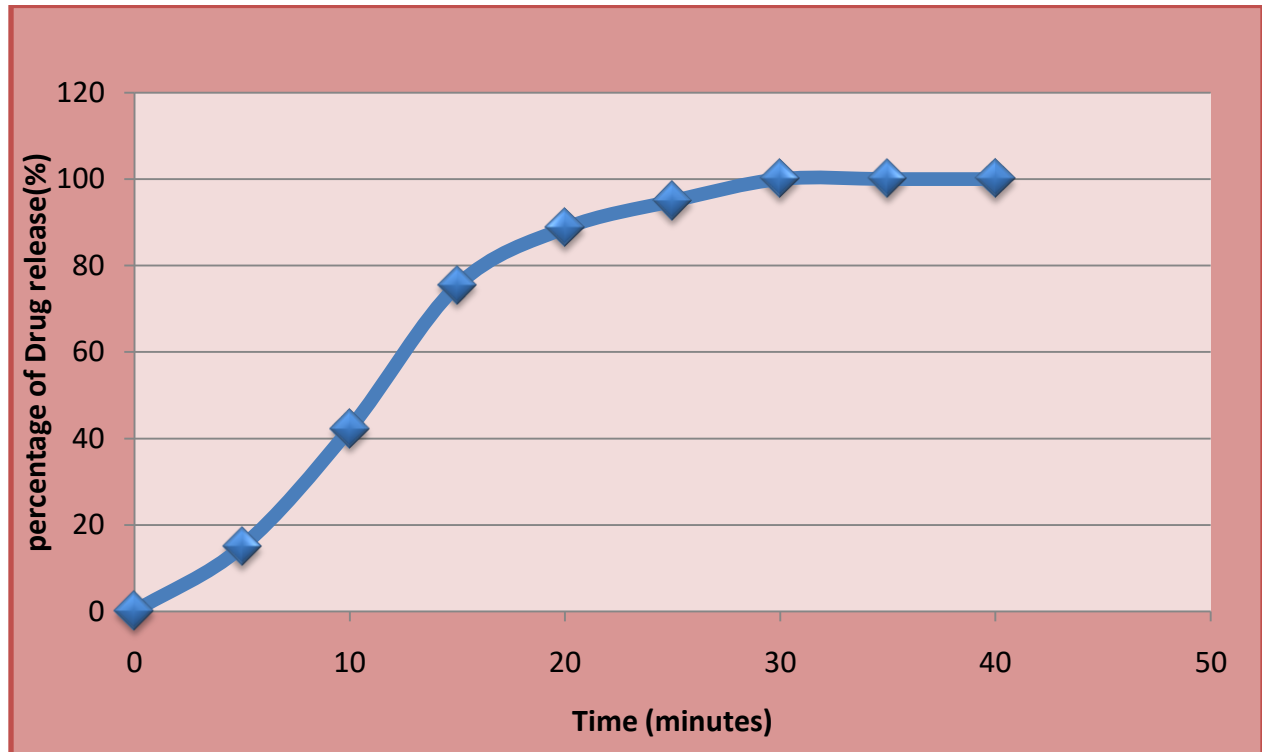


Fig.2. Dissolution profile of Metformin Hydrochloride tablet

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