

## PHARMA APPLICATION LEAFLET

#17/11/ 005

### Ranitidine Hydrochloride, Direct Compression

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#### Abstract

Ranitidine Hydrochloride is belongs to histamine-2 blocker. It is used to treat ulcers i.e. peptic, gastrointestinal, stomach and duodenal etc. Ranitidine Hydrochloride is hygroscopic in nature. This formulation is manufactured with HiCel™XLM 200.

HiCel™XLM 200 gives very good tablet hardness with less disintegration time. The content uniformity is also found excellent. Ranitidine Hydrochloride tablet is available in the market with 150 mg and 300 mg dose.

#### Ingredient composition

Sr.No.	Name of ingredients	mg/tablet	Contribution (%)
1.	Ranitidine Hydrochloride	334.75	55.79
2.	HiCel™XLM200	250.00	41.67
3.	Magnesium Stearate	2.25	0.375
4.	Sodium starch Glycolate	12.00	2.00
5.	Purified Talc	1.00	0.17
<b>Total</b>		600.00	100

#### Procedure

Sodium starch glycolate, HiCel™XLM200 and Ranitidine Hydrochloride were blended for 15-20 minutes. Then added magnesium stearate and purified talc. Mixed them for 5-6 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:** Distilled water 900 ml.  $37 \pm 2$  °C temperature, at 50 rpm and using with USP dissolution type II apparatus.

Samples withdrawals after 10, 15, 20, 25, 30, 35, 40, 45, 50 and 60 minutes. Samples should be diluted if require and filtered. Check absorbance at  $\lambda = 314$  nm.

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#### Tablet Characteristics

Sr.No.	Name of Parameter	Result
1.	Tablet description	Round, Concave, Light yellowish color.
2.	Tablet weight (n=10)	600 mg
3.	Tablet Hardness(n=10)	85.5N
4.	Thickness (n=10)	5.5 mm
5.	Diameter	12.50mm
6.	Disintegration time (n=06)	45.60 Sec
7.	Friability (n=10)	<1%
8.	Dissolution Time	45 min

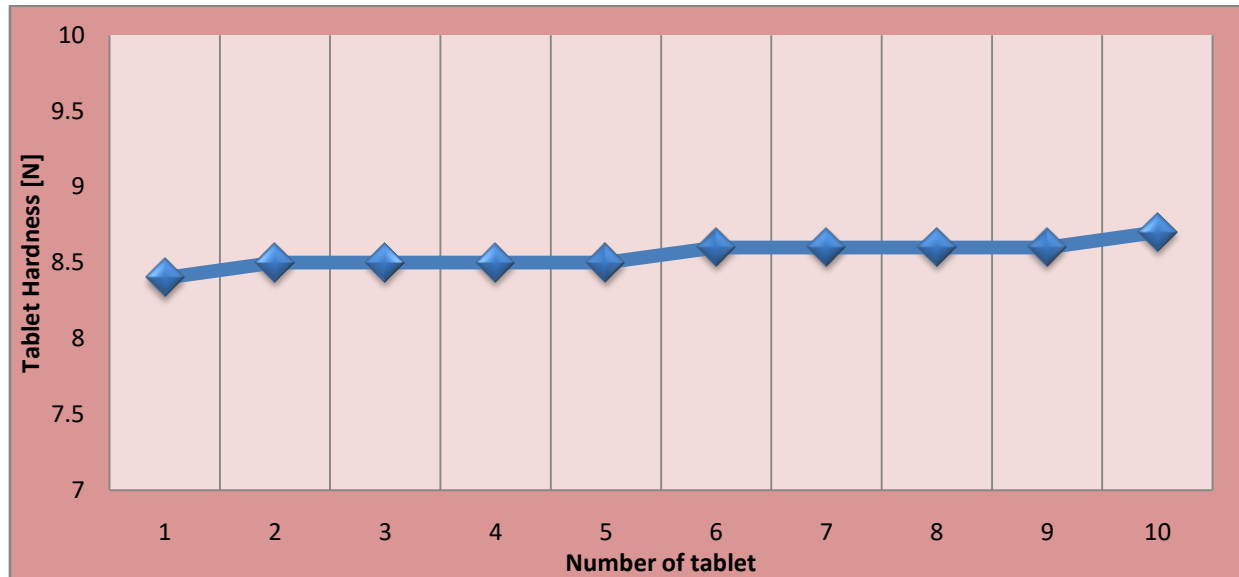


Fig.2. Hardness variation of Ranitidine Hydrochloride tablet

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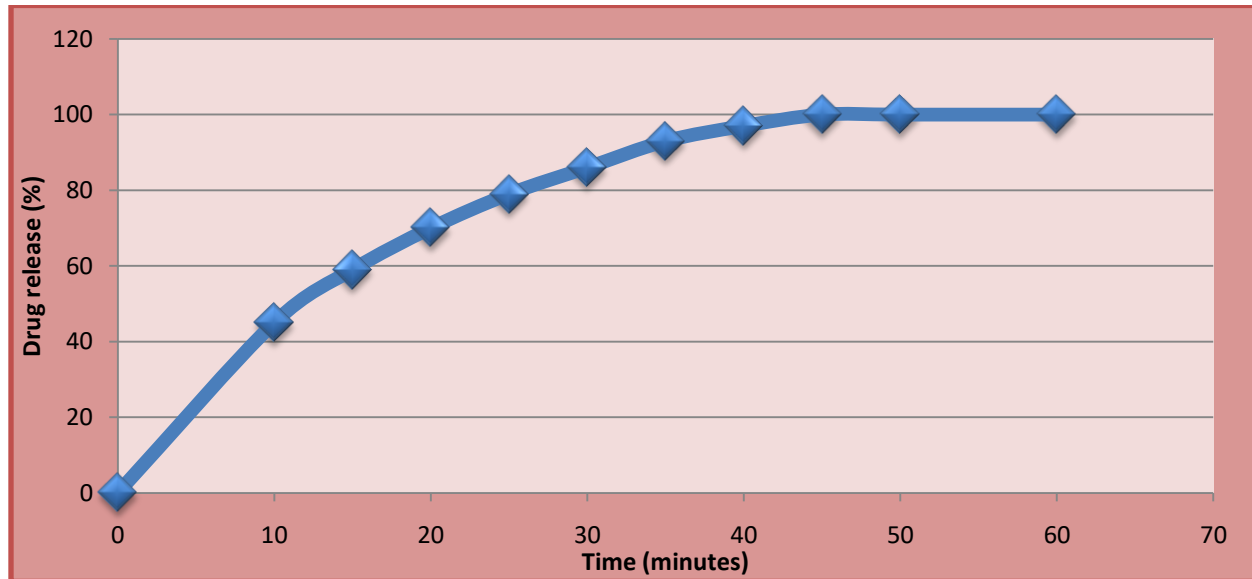


Fig.2. Dissolution profile of Ranitidine Hydrochloride tablet

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