

**ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON
PHARMACOPOEIAL PRODUCT**

DEPARTMENT OF DRUG ADMINISTRATION

Rabeprazole Capsules

Reference: IP 2014 (Rabeprazole Gastro resistant Tablets)

S.N	Test Parameter	Limit
1.	Identification	Positive for Rabeprazole
2.	Weight variation per capsule	as per Pharmacopoeia (Uniformity of weight of single dose preparation)
3.	Assay: Rabeprazole sodium	90-110% of the stated amount
4.	Uniformity of content (For capsules containing 10 mg or less)	85 % to 115 % of the stated amount
5.	Dissolution (%): Rabeprazole Acid Stage: Buffer Stage	Not more than 10 % of the stated amount Not less than 70 % D of the stated amount

Analytical Profile of Rabeprazole Capsule: As per IP monograph of Rabeprazole Gastro-resistant Tablet (latest edition)