

PRODUCT: AZITHROMYCIN 8% GRANULES / POWDER (TASTE MASKING GRANULES/POWDER)

COMPOSITION:

Each 100 gm Taste Masked Granules Contains:

Azithromycin Dihydrate USP

Eq. to Azithromycin ----- 8.0 gm

Excipients Q.S

SPECIFICATIONS:

S. No.	TEST	SPECIFICATION
1	Description	White to slightly off white free flowing powder, which after reconstitution gives a white to off white coloured & flavoured suspension.
2	Identification	The retention time for Azithromycin test preparation in test corresponds to that exhibited in the Chromatogram of the standard preparation of the Assay.
3	Water (By Karl Fischer) (Reagent used: ethylene glycol monomethyl ether)	Limit: not more than 1.5%
4	pH (reconstituted Suspension)	Limit : 8.5 to 11.0
5	Bulk density	0.5 g/cc to 0.8 g/cc
6	Assay: Each 100gm contains Azithromycin dihydrate USP/BP Eq. to Azithromycin8.0 gm	7.20 gm to 8.80 gm (90.0 % to 110.0 %)

NOTE: Customized specification & flavour will be available on request.