



PJ. HEALTHCARE

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**PRODUCT: AZITHROMYCIN 7.5% GRANULES/POWDER** (TASTE MASKING GRANULES/POWDER)

**COMPOSITION:**

Each 100 gm Taste Masked Granules Contains:

Azithromycin Dihydrate USP

Eq. to Azithromycin ----- 7.5 gm

Excipient Q.S

**SPECIFICATIONS:**

S. No.	TEST	SPECIFICATION
1	Description	White to slightly off white free flowing powder and free from any visible foreign particles, which after reconstitution gives a white to off white coloured, flavoured & bitterless Suspension.
2	Identification	The retention time of the major peak in the chromatogram of the preparation corresponds to that exhibited in the Chromatogram of the standard preparation as obtained in Assay.
3	Bulk density	Not less than 0.60 gm/ml
4	Water	Not more than 1.5% w/w
5	Sieve Test	A) Not less than 95% pass through 250µm sieve B) Not more than 50% pass through 45 µm sieve
6	pH (after reconstitution)	Limit: 8.5 to 11.0
7	Assay: Each 100 gm Contains Azithromycin Dihydrate USP/BP Eq.to Azithromycin.....7.5gm	(6.75 gm to 8.25gm) (90.0% to 110.0 %)

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

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