

Flucloxacillin Sodium Compacted

Therapeutical category:

Oral narrow spectrum penicillin

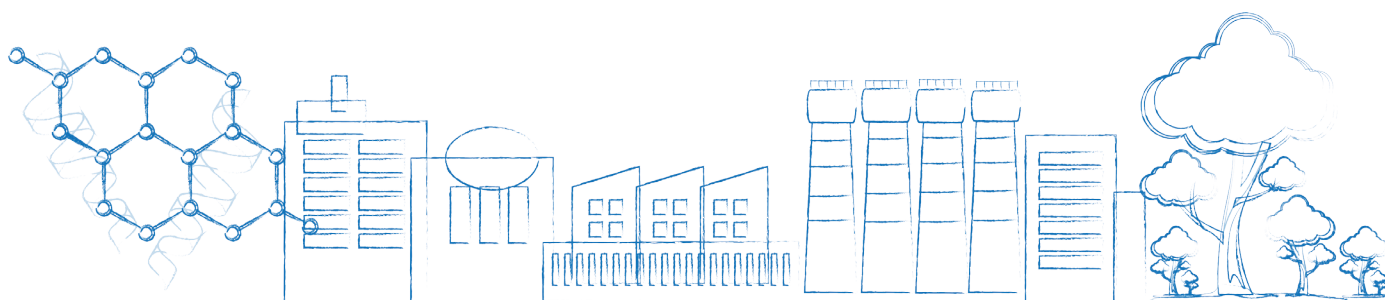
Characteristics:

Granules obtained by means of dry compaction of the crystalline powder without adding any excipients.

Applications:

The product is suitable for the manufacture of capsules and tablets after the addition of appropriate excipients.

All our manufacturing sites use the best available technology and operate dedicated waste water treatment plants, 24/7 throughout the year. Effluents are regularly sampled and checked for antimicrobial activity.



Key parameters: Flucloxacillin Sodium Compacted

Pharmacopeia quality	EP, IP	
Regulatory information	EU: EDQM India: Ministry of Health	Bangladesh: Ministry of Health Australia: TGA
Appearance	White to almost white granules, hygroscopic	
Assay (anhydrous basis)	Flucloxacillin: 95.0–102.0 %	
pH	5.0 – 7.0	
Water	3.0 – 4.5 %	
Tapped bulk density	≥ 0.78 g/ml	
Total impurities	≤ 5.0%	
Residual solvents	2-EHA: ≤ 8000 ppm Ethyl acetate: ≤ 5000 ppm	
Dimethylaniline	Not used in the process	
Shelf-life	Minimum 4 years in the original packaging under storage conditions	
Batch size	Approximately 750 kg	
Storage conditions	Below 25°C, protected from light and moisture	
Packaging	Primary packaging: polyethylene bag	
	Secondary packaging: thermo-sealed aluminum polyethylene bag	
	Outer packaging: corrugated box or HDPE drum	
	Fixed quantity of 25 kg packed in each bag	

Contact and information

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