



This product is part of our PureActives® range.

Purilex® Powder (Cefalexin Monohydrate)

Therapeutical category:

Oral broad-spectrum cephalosporin

Characteristics:

A crystalline powder. No solvents are used in the process for higher purity with the exception of acetone used for the final product wash. Methanol is used for the side chain activation.

Applications:

The product is suitable for the manufacture of powders and granules for oral suspensions and tablets, after addition of appropriate excipients.

PureActives, the enzymatic difference

All our PureActives® antibiotic products are produced using our proprietary, sustainable, and environmentally friendly enzymatic technology. They bring our brand promise to life through superior quality, outstanding reliability and leading sustainability performance.

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.



Quality



Reliability



Sustainability



Key parameters: Purilex® Powder (Cefalexin Monohydrate)

Pharmacopeia quality	USP, EP, IP, ChP	
Regulatory information	EU:EDQM USA: FDA Canada: HPB Brazil: ANVISA Australia: TGA	India: MoH Bangladesh: Moh South Korea: KFDA Japan: PMDA China: CFDA Taiwan: DoH
Appearance	White to almost white crystalline powder	
Assay (anhydrous basis)	Cefalexin: 97.0–102.0% (at release)	
pH	4.0 - 5.5	
Water	4.0% - 8.0%	
Tapped bulk density	≤ 0.65 g/ml	
Total impurities	≤ 3.0%	
Residual solvents	Acetone <0.2% (washing step)	
Dimethylaniline	Not used in the process	
Shelf-life	Minimum 5 years (prod. DSP Spain) or 4 years (prod. DSP China) in the original packaging under recommended storage conditions	
Batch size	Approximately 1000 - 2400 kg (depending on manufacturing site)	
Storage conditions	Below 25°	
Packaging	Primary packaging: polyethylene bag	
	Secondary packaging: thermo-sealed aluminum polyethylene bag	
	Outer packaging: corrugated box	
	Fixed quantity of 25 kg packed in each bag; 300kg per pallet	

Contact and information

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