



Purilex[®] Compacted

(Cefalexin Monohydrate)



Therapeutical category:

Oral broad-spectrum cephalosporin



Characteristics:

Granules obtained by means of dry compaction of the crystalline powder without adding any excipients. No solvents are used in the process for higher purity and improved odor of the product, with the exception of acetone used for the final product wash.



Applications:

The product is suitable for the manufacture of solid dosage forms, such as capsules, after addition of excipients.

This product is part of our PureActives[®] range.

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.



Key parameters: Purilex[®] Compacted (Cefalexin Monohydrate)

Pharmacopeia quality	USP, EP, IP	
Regulatory information	USA: FDA EU:EDQM Canada: HPB Japan: PMDA India: MoH South Korea: KFDA	Australia: TGA China: CFDA Japan: PMDA Taiwan: DoH Bangladesh: Moh Brazil: ANVISA
Appearance	White or almost white powder with granules	
Assay (anhydrous basis)	Cefalexin: 97.0–102.0% (at release)	
pH	4.0 - 5.5	
Water	4.0% - 8.0%	
Tapped bulk density	≥ 0.75 g/ml	
Total impurities	≤ 3.0%	
Residual solvents	Acetone <0.2% (washing step)	
Dimethylaniline	Not used in the process	
Shelf-life	Minimum 4 years (prod. DSP Spain) or 3 years (prod. DSP China) in the original packaging under storage conditions	
Batch size	Approximately 1500 - 2400 kg (depending on manufacturing site)	
Storage conditions	Below 25°C	
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	

Contact and information

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VAPFS 25.08.2017