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DSM Sinochem Pharmaceuticals

Puridrox® Compacted

(Cefadroxil Monohydrate)

Therapeutical category:

Oral broad-spectrum cephalosporin

Characteristics:

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

Applications:

The product is suitable for the manufacture of capsules after the addition of excipients such as magnesium stearate.

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: Puridrox® Compacted
(Cefadroxil Monohydrate)

Pharmacopeia quality	USP, EP, IP	
Regulatory information	USA: FDA EU: EDQM Canada: HC Bangladesh: MoH	China: CFDA Taiwan: DoH India: MoH South Korea: KFDA
Appearance	White to almost white crystalline powder	
Assay (anhydrous basis)	Cefadroxil: 95.0–102.0%	
pH	4.0 – 6.0	
Water	4.2% – 6.0%	
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 in the original packaging under storage conditions	
Batch size	Approximately 2,400 kg	
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

For more information, please visit www.dsm-sinochem.com or e-mail: info@dsm-sinochem.com or contact us at one of the addresses below:

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