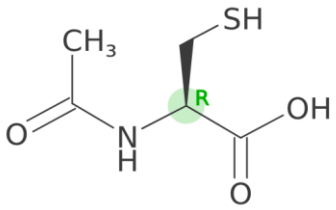
THE CONNECTING LINK TRANSO-PHARM

Revision No. 1.0 09/22/2023

Acetylcysteine

Synonym	N-Acetyl-L-cysteine
CAS. No.	616-91-1
Quality	EP / USP
CMO / Manufacturer	Seven Star Pharmaceutical Co.Ltd., 75 Fwu An Street, Tucheng District, New Taipei City, Taiwan
Phamacological Group	antidote, mycolytic, radical scavenger
Application	Acetylcysteine belongs to a group of medicines called mucolytics which work by thinning the mucus (phlegm) to facilitate easier coughing. Additionally, it can be used as an antidote for intentional or occasional acetaminophen poisoning.



Manufacturing / Extraction	*Synthetic*	*Semi-Synthetic*	*Fermentation*	*Extractive*	
	–	■	–	–	
Project status	*Lab*	*Up-Scale*	*Validation*	*Commercial*	
	–	–	–	■	
Regulatory documentation	*CEP*	*EU-AP (Open Part)*	*US-TDP*	*J-DMF*	*Other*
	■	–	■	–	–
Technical product specification	*Samples*	*Batch size*	*Retest Period*	*Stability Data*	*Packaging*
	■	approx. 500-650 kg	3 years	■	25 kg/drum or 50 kg/drum
	Lead Time		*Shipping & Storage Conditions*		*Other*
	tba		tbc		–

GMP status / Audit	• TFDA inspected / local GMP • US-FDA inspected
Unique features	Acetylcysteine has a direct antioxidant effect; it provides a free thiol group (nucleophilic -SH) that can interact with electrophilic oxidative groups. Particularly interesting is the recent confirmation that NAC can prevent the damage caused by hypochlorous acid (HOCL) to α1-antitrypsin and elastase. Hypochlorous acid is a potent oxidant produced by myeloperoxidase to activate phagocytes. Due to these actions, this product exhibits excellent efficacy in reducing the viscosity and purulent nature of secretions associated with acute and chronic respiratory infections.
Other information	Acetylcysteine is the nonproprietary name for the N-acetyl derivative of the naturally occurring amino acid, L-cysteine (N-acetyl-L-cysteine, NAC). The compound is a white crystalline powder and has a very slight odor. The molecular formula of the compound is C5H9NO3S, and its molecular weight is 163.2.
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