

## Doxorubicin HCl

Synonym	Adriamycin HCl / (8S,10S)-10-[(3-Amino-2,3,6-trideoxy- $\alpha$ -L-lyxo-hexopyranosyl)oxy]-6,8,11-trihydroxy-8(hydroxyacetyl)1-methoxy-7,8,9,10-tetrahydrotetracene-5,12-dione hydrochlorid				
CAS. No.	25316-40-9				
Quality	EP / USP				
CMO / Manufacturer	Gemini PharmChem Mannheim GmbH Sandhofer StraÙe 96, 68305 Mannheim, Germany				
Pharmacological Group	Antineoplastic Agent, Anthracycline				
Application	Injection				
Manufacturing / Extraction	<i>Synthetic</i>	<i>Semi-Synthetic</i>	<i>Fermentation</i>	<i>Extractive</i>	
	-	■	-	-	
Project status	<i>Lab</i>	<i>Up-Scale</i>	<i>Validation</i>	<i>Commercial</i>	
	-	-	-	■	
Regulatory documentation	<i>CEP</i>	<i>EU-AP (Open Part)</i>	<i>US-DMF</i>	<i>J-DMF</i>	<i>Other</i>
	■	-	■	-	-
Technical product specification	<i>Samples</i>	<i>Batch size</i>	<i>Retest Period</i>	<i>Stability Data</i>	<i>Packaging</i>
	■	4-5 kg	3 years	■	glas bottle*
	<i>Lead Time</i>		<i>Shipping &amp; Storage Conditions</i>		<i>Other</i>
	to be agreed		no special		-
GMP status / Audit	<ul style="list-style-type: none"> <li>• EU-GMP approved (Authority: RP Tuebingen, Germany)</li> <li>• US-FDA inspected</li> </ul>				
Other information	<ul style="list-style-type: none"> <li>• * Primary pack size 500 g</li> <li>• CIP air or DDP delivery</li> </ul>				
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