

## Idarubicin HCl

Synonym	Idarubicin hydrochloride / 4-Demethoxydaunomycin HCl / 4-Demethoxydaunorubicin HCl / 5,12-Naphthacenedione				
CAS. No.	57852-57-0				
Quality	USP				
CMO / Manufacturer	Gemini PharmChem Mannheim GmbH, Sandhofer Straße 96, 68305 Mannheim, Germany				
Pharmacological Group	Antineoplastic Agent, Anthracycline				
Application	Injection, oral (capsule)				
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>
	■	up to 600 g	3 years	■	Glass 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: LASD, Germany)</li> <li>• US-FDA inspected</li> </ul>				
Other information	<ul style="list-style-type: none"> <li>• primary pack size upon demand</li> <li>• CIP air or DDP delivery</li> </ul>				
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