

Ajmaline

Development Product

Synonym	(17R,21-alpha)-Ajmalan-17,21-diol / Ajmalan-17,21-diol				
CAS. No.	4360-12-7				
Quality	in-house specification				
CMO / Manufacturer	ALKALOIDS CORPORATION, 8 Bentinck Street, 70001 Kolkata, India				
Pharmacological Group	Anti-Arrhythmia Agents / Cardiovascular Agents / Voltage-Gated Sodium Channel Blockers				
Application	injectable				
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-TDP</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 kg	tbd	-	1 kg
	<i>Lead Time</i>		<i>Shipping & Storage Conditions</i>		<i>Other</i>
	4 - 6 weeks		no special requirements		-
GMP status / Audit	<ul style="list-style-type: none"> • local GMP • site FDA inspected 				
Unique features	<ul style="list-style-type: none"> • only producer worldwide • secured plant material supply chain 				
Other information	<ul style="list-style-type: none"> • 6 m stability data available in August 2019 - ASMF compilation in September 2019 • commercialization by the end of 2019 				
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