



ISO 9001:2015 CERTIFIED CERTIFICATE OF ANALYSIS

Product Name	Droperidol EP Impurity C (Chloride)	
Molecular Formula	Free base: C ₂₂ H ₁₉ FN ₃ O ₂ ; Chloride salt: C ₂₂ H ₁₉ ClFN ₃ O ₂	The chemical structure shows the cation of Droperidol EP Impurity C. It consists of a benzimidazole ring system (a benzene ring fused to an imidazole ring) connected at the 2-position of the imidazole to the 4-position of a pyridine ring. The pyridine ring is in its cationic form (N⁺). A 4-(4-fluorophenyl)-4-oxobutyl chain is attached to the pyridine ring at the 1-position. The chain consists of a carbonyl group (C=O) connected to a CH₂ group, which is connected to a CH₂ group, which is connected to a CH₂ group. The terminal CH₂ group is connected to the N⁺ of the pyridine ring. A chloride ion (Cl⁻) is shown as the counterion. A large, faint watermark 'A' is visible in the background of the image.
Molecular Weight	Free base: 376.40; Chloride salt: 411.86	
Batch Number	XX-XXXX	
Batch Quantity	XXX	
Date of Manufacturing	DD-MM-YYYY	
Date of Analysis	DD-MM-YYYY	
Next Retest Date	DD-MM-YYYY	
Catalogue Number	XX	
CAS Number	705917-40-4 (Free base); 60373-76-4 (chloride)	
COA Number	PA-XXXX	
IUPAC Name	1-(4-(4-fluorophenyl)-4-oxobutyl)-4-(2-oxo-2,3-dihydro-1H-benzo[d]imidazol-1-yl)pyridin-1-ium chloride	
Storage and Handling	2 to 8°C	

Sl. No	* Test	Result
	Description	
1.	Identification i) By IR ii) By NMR iii) By MS	--
2.	Chromatographic Purity (% by HPLC)	--

Remarks: *Test or tests as mentioned above may vary as per the product nature or customer's requirement

Function	Compiled by	Reviewed by	Reviewed by	Approved by
Name	xxx	xxx	xxx	xxx
Department	Pharma Standards QC	Pharma Standards QC	Quality Assurance	Quality Assurance
Sign and Date				

Attachments	IR, NMR, MS spectra, HPLC Chromatogram.
Date of Shipment	DD-MMM-YYYY

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