

Certificate Of Analysis

Product Name	Anastrozole					
Batch No	20200616	Report No.		2	20200616	
Package	1kg/foil bag	Report Date		20	2020/06/15	
MFG Date	2020/06/15 EXP Date		2022/06/15			
Quantity	15kg	Ref. Standard		USF	USP40 Standard	
Results Of Analysis Tests						
Item	Specifica	Specifications		Results		
Description	White or off-white cry	White or off-white crystalline powder			Conform	
Solubility	acetonitrile, ethy chloroform, slightly	Freely soluble in methanol, ethanol, acetonitrile, ethylacetate and chloroform, slightly soluble in water and 0.1M hydrochloric acid solution			Conform	
Identification	IR Reactive	IR			Conform with standard IR Conform	
Melting point	82.0~85.0°C	82.0 ~ 85.0°C			83.1 ~ 83.3 ℃	
Related substances Impurity B Impurity C Impurity D Impurity E Single Unknown Impuri Total Unknown Impurit Total Impurity	Not more than 0.2% Not more than 0.2% Not more than 0.1% Not more than 0.1% Not more than 0.1% Not more than 0.2% Not more than 0.5%			0.02% 0.03% 0.02% 0.03% 0.04% 0.08% 0.23%		
Residual solvent Dichloromethan Chloroform Ethanol Cyclohexane Ethylacetate	Not more than 0.006% Not more than 0.5% Not more than 0.08% Not more than 0.5%	Not more than 0.08% Not more than 0.5%			Not detected Not detected 0.04% 0.02% 0.1%	
Residue on ignition	Not more than 0.1%	Not more than 0.1%			0.03%	
Water	Not more than 0.3%				0.08%	
Heavy metals	Not more than 0.001%	Not more than 0.001%			<0.001%	
Assay(on dry basis)	98%~102%(HPLC)	98%~102%(HPLC)			99.77%	
Conclusion	The specification con	The specification conforms with UPS40 standard				
Q. C. Dept. Directo	r Checker			Identifier		