



Hekmat Medicinal Chemistry Development Co.

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Certificate of Analysis

Product Name: Ivacaftor Intermediate

CAS No.	1246213-45-5	Test date	2021.01.10
Batch No.	Iva-9910-21	Retest date	2023.01.09
Standard	In-house	Batch weight	200 g

Identification

Test items	Limit	Result
Description	Off- white powder	Conforms
Solubility	Freely soluble in DCM Insoluble in Water	Conforms
Minor Ivacaftor produced	—	0.8%
Individual impurities	NMT 1%	Conforms
Total Impurities	NMT 2%	Conforms
Purity	NLT 95%	98.6 %
LOD	NMT 0.5%	0.44%
ROI	NMT 0.5%	0.10%
Heavy Metal	≤ 20 ppm	Conforms

Conclusion: Conforms to In-house standard

Storage: Keep in dry and closed container

Reported by: Sara Arjomandi

Approved by: Mohammadreza Mirzahekmati



شرکت توسعه شیمی دارویی حکمت
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