MSN Laboratories Private Limited, Unit-II
Sy no. 50, Kardanur (Village), Patancheru (Mandal), Sangareddy District,
Telangana, Pincode: 502 300, India.
Tel: +91-8458-331200, Fax: +91-8458-331250, Alternate Fax: +91-40-30438799

CERTIFICATE OF ANALYSIS

Product	: **BINIMETINIB**	Customer Name	: **M/S.SANDOZ**
Batch No.	: EBMTN10B0011220	Mfg. Date	: December-2020
Batch Quantity	: 3.05 kg	Date of analysis	: 28.12.2020
A.R.No.	: ARFP201000	Re-test date	: May-2021
Reference	: **In-house**	Specification No.	: AR-FPBMTN10B-001/03

STORAGE: Store the material in a tightly closed containers at 2°C to 8°C temperature protected from light and moisture.

S.No.	TEST	RESULT	SPECIFICATION
1.0	Description	Pale yellow powder.	White to slightly yellow powder.
2.0	Solubility	Complies	Slightly soluble in 0.1N Methanolic Hydrochloride and Practically insoluble in water.
3.0	Identification By		
3.1	Infrared absorption	Complies	The IR absorption spectrum of the sample should be concordant with that of Binimetinib standard spectrum.
3.2	HPLC	Complies	The retention time of the major peak in the chromatogram of the sample preparation shall correspond to that in the retention time of the major peak in the chromatogram of the standard preparation, as obtained in the Assay by HPLC.
4.0	Water content by KFR	0.77%w/w	Not more than 5.0% w/w
5.0	Residue on ignition	0.05%w/w	Not more than 0.1% w/w
6.0	Related substances by HPLC		
6.1	Des ethanediol impurity	0.03%	Not more than 0.15%
6.2	Acid impurity	0.02%	Not more than 0.15%
6.3	Ethyleneglycol ester impurity	Not detected	Not more than 0.15%
6.4	Amide impurity	Not detected	Not more than 0.15%
6.5	Dimer impurity	Not detected	Not more than 0.15%
6.6	Highest individual unspecified impurity	0.04%	Not more than 0.10%

02.02.21

	Compiled by	Checked by	Checked by	Approved by
Sign				
Date	02/02/2021	02/02/2021	02/02/2021	02/02/2021
Name	**Sk.M.Vali**	**Dr.Ch.S.N.M.Rao**	**T.P.C.S.Reddy**	**Ch.V.S.Nagaraju**
Department	**AR&D**	**AR&D**	**R&D**	**AR&D**

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S.No.	TEST	RESULT	SPECIFICATION
6.7	Total impurities	0.14%	Not more than 1.0%
7.0	Assay by HPLC (On anhydrous and solvents free basis)	99.27%w/w	Not less than 98.0% w/w and not more than 102.0% w/w
8.0	Acetic acid content by HPLC		
8.1	Acetic acid	Not detected	Not more than 5000 ppm
9.0	Residual solvents by GC (Method-I)		
9.1	Methanol	15 ppm	Not more than 3000 ppm
9.2	Isopropyl alcohol	15 ppm	Not more than 5000 ppm
9.3	Acetonitrile	59 ppm	Not more than 410 ppm
9.4	Dichloromethane	153 ppm	Not more than 600 ppm
9.5	Ethyl acetate	Not detected	Not more than 5000 ppm
9.6	Tetrahydrofuran	Not detected	Not more than 720 ppm
9.7	Toluene	4 ppm	Not more than 890 ppm
10.0	Residual solvents by GC(Method-II)		
10.1	N,N-Dimethyl formamide	Not detected	Not more than 880 ppm
10.2	Dimethyl sulphoxide	30 ppm	Not more than 5000 ppm

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Name	Sk.M.Vali	Dr.Ch.S.N.M.Rao	T.P.C.S.Reddy	Ch.V.S.Nagaraju
Department	AR&D	AR&D	R&D	AR&D

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S.No.	TEST	RESULT	SPECIFICATION
#11.0	Polymorphic identification by PXRD	Complies	The PXRD pattern of sample should match with the PXRD pattern of Amorphous form.
#12.0	Particle size by Malvern		
12.1	Dv(90)	9.199 µm	For information.

The product CONFORMS to above specification.

 # Customer requirement.

MSN LABORATORIES PVT. LTD. UNIT-II * D.Q.A. Dept * 02.02.21

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Sign				
Date	02/02/2021	02/02/2021	02/02/2021	02/02/2021
Name	Sk.M.Vali	Dr.Ch.S.N.M.Rao	T.P.C.S.Reddy	Ch.V.S.Nagaraju
Department	AR&D	AR&D	R&D	AR&D