The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER:	RPP-SP-QC-RM-122
DOCUMENT TITLE:	SPECIFICATION OF MOLNUPIRAVIR (ITEM NO. 44111005)
DOCUMENT NOTES:	

Document Information

Revision:	01	Vault:	RPP STP_SP-rel
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Date Information

Effective Date:	15 Aug 2022	Next Review Date:	
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Control Information

Author:	NUANPRANG_C	Previous Number:	
Owner:	NUANPRANG_C	Change Number:	Packet-3791

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
TITLE	**SPECIFICATION OF MOLNUPIRAVIR (ITEM NO. 44111005)**	**Rev. 01**
DEPARTMENT	**QUALITY CONTROL DIVISION**	**PAGE 1 of 3**

REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release *Refer to the In-house specification, document no. RMS-RA-00314, Rev 01, Raw material specification of Molnupiravir, Research and Development Institute.	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description ($)	White to pale yellow powder.
02	Identification (*) A. By FT-IR ($)	The infrared absorption spectrum of the sample exhibits maxima only at the same wavenumbers as that of a similar preparation of the corresponding standard.
	B. By HPLC	The retention time of the major peak of sample solution corresponds to that of standard solution, as obtained in the Assay.
03	Water content ($,*)	Not more than 1.0%.
04	Residue on ignition (*)	Not more than 0.10%.
05	Related substances (*Procedure 1*) ($,*)	
	a. Impurity-A	Not more than 0.05%.
	b. Impurity-C	Not more than 0.05%.
	c. Impurity-E	Not more than 0.05%.
	d. Impurity-F	Not more than 0.05%.
	e. Highest individual impurity	Not more than 0.05%.
	f. Total impurities (Procedures 1&2)	Not more than 0.5%.
06	Related substances (*Procedure 2*) ($,*)	
	a. Impurity-B	Not more than 0.15%.
	b. Impurity-D	Not more than 0.10%.
07	Assay ($,*)	98.0-102.0%w/w of Molnupiravir ($C_{13}H_{19}N_3O_7$), calculated on the anhydrous basis.

B. Additional Test

No.	Test parameters	Requirements
01	Residual solvents *(As per manufacturer's COA)*	
	a. Methanol	Not more than 3000 ppm.
	b. Acetone	Not more than 5000 ppm.
	c. Isopropyl alcohol	Not more than 5000 ppm.
	d. Dichloromethane	Not more than 600 ppm.
	e. Methyl tertiary butyl ether	Not more than 5000 ppm.
	f. Ethyl acetate	Not more than 5000 ppm.
02	Solubility	Soluble in dimethyl sulfoxide.
03	Heavy metals (*)	Not more than 10 ppm.
04	Identification (XRPD) *(As per manufacturer's COA)* (*)	The X-ray diffractogram of the sample should exhibit 2θ values at about 3.3, 6.6, and 13.1 ± 0.2°.
05	Particle size (*) - d (0.9)	Not more than 20 µm.

$:Tests to be performed at retesting.

** : In-house specification.*

C. Storage condition

Do not store above 30°C. Store in the original container.

D. Reference

- USP-NF 2021 <197A>, FT-IR, <621>, HPLC and GC, <921>, Method Ia, Karl Fischer, <281>, Residue on ignition, <467>, Residual solvents, Procedure C for Water-Insoluble, <941>, X-ray powder diffraction, <429>, Light diffraction Measurement of particle size.
- Raw material specification of Molnupiravir, document No. RMS-RA-00314, Rev 01, Research and Development Institute.

E. Product Information

Approved source (s)	Refer to current version of Approved Supplier List (ASL) (as follow RPP-SOP-QA-029: Supplier Qualification) of Molnupiravir (Item No. 44111005).
Sampling plan	Identification : Every container. Other tests : $\sqrt{N}+1$.
Testing procedure	Test to be performed as per current version of Standard Testing Procedure of Molnupiravir (Item No. 44111005).
Retest period	1 year.

Signature Manifest

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All dates and times are in GMT +7.

RPP-SP-QC-RM-122 SPECIFICATION OF MOLNUPIRAVIR (ITEM NO. 44111005)

Step 1. Preparer

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