




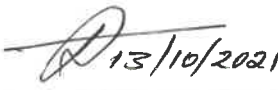
SOLARA
Active Pharma Sciences

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CERTIFICATE OF ANALYSIS

Name of the Product: Praziquantel USP	Page No. 1 of 3
Batch No: MBAL21046A	Analytical Report No: 1101-FP-210642
Batch Quantity: 418.6 Kg	Dispatch Quantity: 60 Kg
Manufacturing Date: SEPTEMBER 2021	Retest /Expiry Date: AUGUST 2024
Storage Condition: Preserve in well-closed, light-resistant containers. Store at 25°C (Excursions permitted between 15 to 30°C).	
Customer Name: LGM Pharma LLC	

Sl. No.	TESTS	RESULTS	SPECIFICATIONS
1	Description	Practically white powder	White to practically white powder
2	Solubility	Freely soluble in alcohol and in chloroform	Freely soluble in alcohol and in chloroform
3	Identification by IR	The infrared absorption spectrum of sample is concordant with spectrum obtained from standard	The infrared absorption spectrum of sample is concordant with spectrum obtained from standard.
4	Identification by HPLC	The retention time of major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation obtained in the test for assay	The retention time of major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation obtained in the test for assay
5	Melting range	138.1°C to 139.9°C	136°C to 142°C
6	Loss on drying	0.29%	Not more than 0.50%
7	Residue on ignition	0.01%	Not more than 0.10%
8	Phosphate	Less than 0.05%	Not more than 0.05%
9	Related compound by HPLC		
	Praziquantel related compound A (2-benzoyl-1,2,3,6,7,11b-hexahydro-4H-pyrazino[2,1-a]isoquinolin-4-one)	0.02%	Not more than 0.20%

	Prepared By:	Approved By:
Sign & Date:	 13/10/2021	 13/10/2021
Name:	Aishwarya	Brijesh Kumar
Designation:	Executive	Sr. Manager

A3/QC/076/F-01/R0

Solara Active Pharma Sciences Limited - CIN : L24230MH2017PLC291636



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Sl. No.	TESTS	RESULTS	SPECIFICATIONS
	Praziquantel related compound B (2-(cyclohexylcarbonyl)-2,3,6,7-tetrahydro-4H-pyrazino [2,1-a] isoquinolin-4-one)	BQL	Not more than 0.20%
	Praziquantel related compound C (2-(N-formyl hexahydrohippuroyl) -1,2,3,4-tetrahydroisoquinolin-1-one)	BDL	Not more than 0.10%
	Unspecified impurity	0.029%	Not more than 0.10%
	Total impurities	0.16%	Not more than 0.5%
10	Assay on dried basis (By HPLC)	100.1%	Not less than 98.5% & not more than 101.0%
11	Nickel content by AAS	BQL	Not more than 10ppm
12	Residual solvent		
	Methylene chloride	BQL	Not more than 600 ppm
	Methanol	BDL	Not more than 3000 ppm
	Toluene	BDL	Not more than 890 ppm
	Benzene	BDL	Not more than 2 ppm
13	Butylated hydroxytoluene by HPLC	BDL	Not more than 0.05%
14	Particle Size by Malvern		
	d90	8.6 µm	Not more than 10 µm

	Prepared By:	Approved By:
Sign & Date:	 13/10/2021	 13/10/2021
Name:	Aishwarya	Brijesh Kumar
Designation:	Executive	Sr. Manager

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Related Compounds – LOD and LOQ Data

Name of the Impurity	LOD	LOQ
Praziquantel related compound A	0.007%	0.020%
Praziquantel related compound B	0.008%	0.022%
Praziquantel related compound C	0.008%	0.022%

Residual solvents– LOD and LOQ Data

Name of the Solvents	LOD	LOQ
Methylene chloride	6.2 ppm	12.1 ppm
Methanol	30.1 ppm	60.2 ppm
Toluene	8.9 ppm	17.8 ppm
Benzene	0.21 ppm	0.65 ppm



BHT & Nickel – LOD and LOQ Data

Name of the reagent	LOD	LOQ
BHT	0.00075%	0.002%
Nickel	0.6 ppm	2.0 ppm

BQL - Below Quantifiable Limit, **BDL** – Below Detectable Limit.

LOD – Limit of Detection, **LOQ** – Limit of Quantification

REMARKS: The product complies as per the USP specification.

	Prepared By:	Approved By:
Sign & Date:	 13/10/2021	 13/10/2021
Name:	Aishwarya	Brijesh Kumar
Designation:	Executive	Sr. Manager

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