



ALIVIRA

ALIVIRA ANIMAL HEALTH LIMITED

CERTIFICATE OF ANALYSIS

PRAZIQUANTEL

Batch No.	ASA04581SA	Quantity	100.00 Kg
Manufacturing Date	June-2024	Retest / Expiry Date	May-2029
A.R.No.	ALIV-FP-240236	Lot No.	40000077518
Storage Condition	Preserve in well closed, light-resistant containers, store at 25°C (Excursions permitted between 15°C to 30°C)		
Customer Name/Vender Name	SUAN FARMA INC.		

S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
1	Description	White to practically white powder.	White powder
2	Solubility	Freely soluble in alcohol and in chloroform.	Complies
3	Identification by IR	The infrared absorption spectrum of sample is concordant with spectrum obtained from standard.	Complies
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.	Complies
5	Melting Range	136°C-142°C	138.5°C-139.2°C
6	Loss on drying	Not more than 0.50% w/w	0.18% w/w
7	Residue on ignition	Not more than 0.10% w/w	0.05% w/w
8	Phosphate	Not more than 0.05%	Less than 0.05%
9	Related Substances by HPLC Praziquantel related compound-A Praziquantel related compound-B Praziquantel related compound-C Unspecified impurity Total impurities	Not more than 0.20% Not more than 0.20% Not more than 0.10% Not more than 0.10% Not more than 0.50%	BQL(LOQ:0.020%) 0.07% Not detected 0.06% 0.28%
10	Related compound by HPLC (Procedure-II) Any impurity	Not more than 0.10%	0.05%
11	Assay on dried basis (by HPLC)	98.5% to 101.0%	99.0%

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Asst. Manager-QC	Head-QC/Designee	Head-QA/Designee
SIGNATURE	<i>Ravi</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	21/06/2024	21/06/2024	21/06/2024

Format No.: QC/116/FMT-001/R1



Alivira Animal Health Limited

Regd.Off: 301, 3rd Floor, Dosti Pinnacle, Plot No. E7, Road No. 22, Wagle Industrial Estate, Thane (W), Mumbai - 400604 India Tel No.: +91-22-4111-4777
 Factory: Plot No: 104 to 109, Part of 112 & 113, Ramky Pharma City India Limited-SEZ, JNPC, Parawada Mandal, Anakapalli (District)-531019, A.P., India. Tel.: +9108924-660888 CIN: U74120MH2013PLC248708
 Website: <http://www.alivira.co> Email Id: Info@alivira.in



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S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
12	Nickel content by AAS	Not more than 10 ppm	Not detected
13	Residual solvents by GC		
	Methanol	Not more than 3000 ppm	Not detected
	Methylene chloride	Not more than 600 ppm	Not detected
	Toluene	Not more than 890ppm	Not detected
	Benzene	Not more than 2 ppm	Not detected
14	Butylated hydroxy toluene by HPLC	Not more than 0.05%	BDL(LOD:0.0007%)
15	Colour of solution	Solution not more intensely coloured than GY reference solution	Complies
16	Cyclohexane carboxylic acid content	Not more than 350 ppm	BQL(LOQ:59.5ppm)
17	Particle size by Malvern		
	D(10)	For information	1 µm
	D(50)	Not more than 8 µm	2 µm
	D(90)	For information	6 µm
	D(100)	Not more than 100 µm	11 µm

Remarks : The above batch complies as per the Ph.Eur/USP/IH Specifications.

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Asst. Manager-QC	Head-QC/Designee	Head-QA/Designee
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