CERTIFICATE OF ANALYSIS

Generated Date:
Oct 17, 2019
Generated by:
MAALVES

INOVAT Indústria Farmacêutica Ltda.
CNPJ: 27.864.378/0001-90
IE: 796.591.145.110
Av. Presidente Tancredo de Almeida Neves 1555
07112-070 - Guarulhos - SP - Brazil

Product:	6100844
Description:	RIMADYL SOL 50MG/MLX20ML VLX1
Expiry Date:	30.Sep.2022
Manufacture Date:	13.Sep.2019
Specification:	RP-02-53400-00 - Eff. date: 19-May-2010
Batch:	1939331
Associated Lots:	1937072

TEST NAME	TEST METHOD	SPECIFICATION	UNIT	RESULT
Description	EP	Not more opalescent than reference suspension Ph. Eur. II and practically free from particles.	n/a	Meets test
Colour - undiluted sample	EP 2.2.2	Yellow to maximum slightly brownish-yellow	n/a	Meets test
Colour - diluted sample	EP 2.2.2	Dilute 1.0mL of sample with 5mL of Ethanol. Not more colored than reference solution Ph. Eur. Y1 or GY1 (CO1).	n/a	Meets test
pH	P 24.0 (USP)	5.0 - 7.0 (undiluted sample)	none	6.1
Density - g/cm3	USP/EP	1.040 to 1.060 g/cm3	g/cm3	1.051
Benzyl alcohol assay - mg/ml	TM-01-0538A	9 to 11 mg/mL	mg/mL	10
Identification of carprofen - method II	TM-01-0706A	The retention time of the sample and standard solutions in the Carprofen HPLC assay correspond.	n/a	Meets test
Assay of carprofen method II - mg/mL	TM-01-0706A	47.5 to 52.5 mg/mL	mg/mL	49.9
Degrad product - Ro 21-2760 - method II	TM-01-0706A	Less than 0.2%	%	0.0
Degrad product - Ro 22-5152 - method II	TM-01-0706A	Less than 0.2%	%	ND
Degrad product - Ro 20-7302 - method II	TM-01-0706A	Less than 0.2%	%	ND
Degrad product - Ro 21-0537 - method II	TM-01-0706A	Less than 0.2%	%	ND
Degrad product - Ro	TM-01-0706A	Less than 0.2%	%	ND

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TEST NAME	TEST METHOD	SPECIFICATION	UNIT	RESULT
22-7280 - method II				
Total impurities - method II	TM-01-0706A	Less than 1%	%	0
Identification - carprofen - num	TM-01-0705A	Rf approx. 0.5	none	0.58
Identification - benzyl alcohol - num	TM-01-0705A	Rf approx. 0.75	none	0.75
Identification - glycocholic acid - num	TM-01-0705A	Rf approx. 0.1 - 0.2	none	0.14
Identification - lecithin - num	TM-01-0705A	Rf approx. 0.2 - 0.3	none	0.34
Determ of volume / Extractable volume	USP 1/EP 2.9.17	20.0mL to 21.5mL	ml	21.0
Bacterial endotoxins - final result	TM-01-0530A	Maximum 18 EU/mL	EU/mL	< 18
Sterility	TM-01-0528A	Complies with the requirements of the European Pharmacopoeia.	n/a	Meets test

After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Lot Release Signature: MARIA APARECIDA DE FARIA ALVES
Lot Release Local Timestamp: 17 Oct 2019 09:42:39 AM