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CERTIFICATE OF ANALYSIS

Batch Size : 100.12 Kgs. Exp. Date : Aug. 2017 R Batch Size : 100.12 Kgs. Exp. Date : Jul. 2022 A TEST OBSERVATION Description White crystalline powder, slightly hygroscopic 279.2°C to 280.4°C M. Solubility Complies Fr. Solution (A) By IR Spectroscopy Conformed The chromatographic purity (By HPLC) Clarity of solution Complies The solution of the chromatographic purity (By HPLC) Assay (Calculated on dry basis) Additional In-House Test / Customer Requirement Particle size (By Malvern wet method) Below Detection Limit (Scherichia Coli Residual solvent Propanol Columber (Scherichia Coli Residual solvent Propanol (Scherichia C	ampling Date: 26/08/2017 eleased Date: 30/08/2017
TEST OBSERVATION Description White crystalline powder, slightly hygroscopic 279.2°C to 280.4°C Mr. Complies Find Solution (A) By IR Spectroscopy Conformed The conformed Conformed The conformed Conformed The conf	
Description White crystalline powder, slightly hygroscopic 279.2°C to 280.4°C Mr. Complies Fr. sol Identification (A) By IR Spectrosc py Conformed The correct of the christ of t	.R. No. : ADS/17/0272
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Identification (A) By IR Spectroscopy Conformed The conformed (B) By HPLC Conformed Conformed Conformed Conformed Conglies The chr th	Its at about 2.34°C
(A) By IR Spectrosc ppy Conformed (B) By HPLC Conformed (C) By Flame test Colour of solution Ab.5% In MeOH/440rm/1cm Clarity of solution Complies The solution in water) 7.21 Bett O.22 % (w/w) Not Chromatographic purity Below Detection Limit Rela 0.01 % 100.7 % (w/w) Not Calculated on dry basis) Additional In-House **est / Customer Requirement Carticle size (By Malvern wet method) Calculated indication Clarity of solution Complies The correction Limit Not assay 1.21 Clarity of solution 1.22 Clarity of solution 1.23 Clarity of solution 1.23 Clarity of solution 1.24 Clarity of solution 1.25 Clarity of solution 1.25 Clarity of solution 1.26 Clarity of solution 1.27 Clarity of solution 1.28 Clarity of solution 1.29 Clarity of solution 1.25 Clarity of solution 1.26 Chromatographic purity Clarity of solution 1.27 Clarity of solution 1.28 Clarity of solution 1.28 Clarity of solution 1.29 Clarity of solut	ely soluble in methanol, soluble in ethanol, sparing uble in water, practically insoluble in chlopform other.
Conformed The chr the Chr	: Infrared absorption spectrum of the sample must be cordant with that of Dictorage coding
Colour of solution	rence/working standard spectrum. retention time of the Diclofenac peac in the matogram of the test solution corresponds to that a Resolution solution as obtained in the test for
Ab.5% In MeOH/440r nv/1cm	omatographic purity. dense precipitate is formed. Sodium empounart an intense yellow color to a non luminous flame
Clarity of solution Complies The solution Complies The solution Complies The solution in water) 7.21 Betwork Example D.22 % (w/w) Not Clarity D.22 % (w/w) Not Clarity Chromatographic purity Below Detection Limit Relation D.01 % Individual D.01 % Individual D.01 % Tota D.01 % D.01	solution should be colorless to faintly yellow
pH (1% solution in water) Loss on drying (At 105°C to 110°C for 3 hrs) Chromatographic purity By HPLC) Assay Calculated on dry basis) Additional In-House est / Customer Requirement Particle size (By Malvern wet method) Bacterial endotoxin Otal aerobic microb al count Otal yeast & Fungi Scherichia Coli Esidual solvent Propanol Oluene Compiles The solution water) Poly 1.21 Betw Detection Limit Not in the solution in water) Relating the properties of the properties o	more than 0.05
7.21 Beta	solution prepared as directed under colour of tion is not significantly less clear than an equa me of methanol contained in a similar vessel an nined similarly.
Act 105°C to 110°C for 3 hrs)	veen 7.0 to 8.5
By HPLC 0.01 % 100.7 % (w/w) Not	more than 0.5 % (w/w)
100.7 % (w/w) Not	ted compound-A Not more than 0.2 % ridual impurity Not more than 0.10 % impurities Not more than 0.5 %
Additional In-House "est / Customer Requirement Particle size (By Malvern wet method) Bacterial endotoxin Otal aerobic microb al count Otal yeast & Fungi Scherichia Coli Absent Below Detection Limit Not recording to the propanol Otal yeast & Below Detection Limit Below Detection Limit Not recording to the propanol Not recording to the propanol Below Detection Limit Not recording to the propanol Not recording to the propanol Below Detection Limit Not recording to the propanol Not recording to the propanol Below Detection Limit Not recording the propanol Not recording the propanol Below Detection Limit Not recording the propanol Not recording the propanol School Propanol Below Detection Limit Not recording the propanol Not recording the propanol School Propanol Below Detection Limit Not recording the propanol Not recording the propanol School Propanol School Propanol Below Detection Limit Not recording the propanol Not recording the propanol School Propanol School Propanol Below Detection Limit Not recording the propanol Not recording the propanol School Propanol School Propanol Below Detection Limit Not recording the propanol School Propanol	ess than 99.6 % and Not more than 101.0 %
Sacterial endotoxin Less than 4.67 EU/mg otal aerobic microb.al count otal yeast & Fungi scherichia Coli esidual solvent -Propanol oluene Description 1.38% 10 % Not < 10 cfu/g Not Absent Show Below Detection Limit Not in Below Detection Limit Not in	
1.38 % 10 %	< 20 micron
tacterial endotoxin otal aerobic microb, al count otal yeast & Fungi otal yeast & Fungi otal yeast & Fungi scherichia Coli esidual solvent -Propanol oluene Less than 4.67 EU/mg Not 10 cfu/g Not Absent Show Show Below Detection Limit Not in Below Detection Limit Not in No	between 20 to 40 micron
Odal peroble microb, al count Otal yeast & Fungi Scherichia Coli Absent Propanol Olimer Below Detection Limit Below Detection Limit Not residual solvent Below Detection Limit	more than 4.67 EU/ing
Scherichia Coli	note than 4.07 EO/mg
Absent Show desidual solvent -Propanol Below Detection Limit Not in Below Detection Limit Not in N	more than 10 cfu/g
-Propanol Below Detection Limit Not a Below Detection Limi	Id be absent
oluene Below Detection Limit Not a	id be abself
Oldene Below Detection Limit Not r	nore than 1000 ppm
	nore than 1305 ppm
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