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Manufacturing Site:
Granules India Private
Survey No. 1607A, 1618 1622
& 1745A
Gagilapudi village
Qutbullapur mandal
Ranga Reddy Dist. 500043
TELANGANA State
Ph. No. 08418 306601
Fax: 08418 306600



Corporate Office:
Granules India Private
2nd Floor, 3rd Block
My Home Hub, Adj to Cyber Towers,
Madhapur, Hyderabad - 500 081
E-mail: mail@granulesindia.com
Telephone: 91-40-66760000
Fax: 91-40-23115145

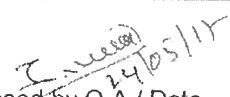
Certificate of Analysis

Product Name : COMPRESSO MF 90 P

Generic Name : METFORMIN HCl GRANULES DC 90%

Batch No	4010097	Mfg. Dt.	MAY' 2017			
A.R. No	FP/1113/0517	Exp. Dt.	APR' 2020			
Batch Size	6050.0 Kg	Spec. No	GGFPS044-R	Rev. No		02

S.No.	TEST	SPECIFICATION	RESULT
1.	Characteristics	White free flowing granules	White free flowing granules
2.	Identification i. Metformin a. Reaction with sodium hypochlorite solution.	Shall develop an orange-red color, which darkens on standing.	Developed an orange-red color, which darkens on standing.
	b. By Infrared Absorption Spectrum.	The IR spectrum of test sample shall be concordant with that of Reference spectrum.	Conformed to Reference Spectrum of Metformin Hydrochloride.
	ii. Povidone Acidified potassium dichromate.	Shall develop an orange –yellow precipitate.	Developed an orange – yellow precipitate.
3.	Moisture content (by K.F Method)	0.5% – 1.4% w/w	1.1% w/w
4.	Related Substances (by HPLC Method)		
	a. Cyanoguanidine	NMT 0.02%	0.004%
	b. Any other impurity	NMT 0.1%	0.005%
	c. Total impurities	NMT 0.5%	0.02%
5.	Metformin HCl Content (by UV Method) (On as is basis)	87.5 - 92.5% w/w	89.4% w/w
6.	Bulk Density (Tapped)	For Information	0.649 g/ml

Prepared by / Date W. 20/05/17	Approved by Q.C / Date  20/05/17	Released by Q.A / Date  24/05/17
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Granules India Ltd
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 Survey No. 160/A, 161/A, 162
 & 174/A
 Gagalapudi village
 Guntur District
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Batch Size	:	6050.0 Kg	Spec. No	GGFPS044-R	Rev. No : 02

S.No.	TEST	SPECIFICATION	RESULT
7.	Sieve Analysis (Particle size distribution) ASTM Mesh No.	% Cumulative retention	% Cumulative retention
	#12	NIL	NIL
	#20	NMT 10.0%	3.1%
	#40	NLT 15.0%	30.0%
	#60	NLT 45.0%	67.5%
	#100	NLT 75.0%	85.1%
	#200	NLT 85.0%	94.3%
*8.	Residual Solvents	Shall meet the requirement as per EP 5.4 and USP<467>	Complies
Formula:			
A) <u>Active Ingredient</u> Metformin HCl USP/Ph.Eur 90.00% w/w		B) <u>Excipients</u> 1. Povidone(PVP K-30) USP/Ph.Eur 2. Stearic Acid USP NF/Ph.Eur 3. Croscopovidone USP NF/Ph.Eur 4. Microcrystalline Cellulose USP/Ph.Eur	
Report : The product conforms to the above specifications.			

*Remarks: The following solvents are likely to be present: Methanol, Toluene, Dimethyl formamide, Mix-Xylene and Formic acid as they are present in the ingredients used in the manufacturing process of Compresso MF 90 P. Please refer to the Residual solvents declaration for the established limits. No solvents are used in the manufacturing process of Compresso MF 90 P.

20/05/17 Prepared by / Date	 20/05/17 Approved by Q.C / Date	 24/05/17 Released by Q.A / Date
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