GRACURE PHARMACEUTICALS LTD.

E-1105, RIICO Industrial Area, Phase-III, Bhiwadi, Alwar (Raj.) INDIA Phone : 01493-221316, 221387 Fax : 220659

CERTIFICATE OF ANALYSIS

PRODUCT NAME	: CELECOXIB CAPSULE 200 mg	**AR NO. :**	GPB/1819/QCP/FGQ/00689
PRODUCT CODE	: FG20107700310	**PACK SIZE**	: 3x10 CAPS.
BATCH NO.	: CE-2165	**BATCH SIZE**	: 30600.00 CTN
MFG. DATE	: 09/2018	**SAMPLE QUANTITY**	: 60.00 CAP
EXP. DATE	: 08/2020	**DATE OF RELEASE**	: 05/10/2018

TEST	ACCEPTANCE CRITERIA	RESULT
Description	Dark green / Dark green coloured hard gelatin capsules, containing white granular powder.	Dark green / Dark green coloured hard gelatin capsules, containing white granular powder.
Identification (By HPLC)	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.
Average weight	Between 265.00 and 285.00 mg.	268.68 mg.
Average Net Content	Between 200.00 and 220.00 mg	204.03 mg
Uniformity of fill weight	± 10.00% of average fill 18/20 ± 10% of average fill 2/20 ± 20% of average fill	-4.67% to 3.96%
Uniformity of dosage units (by weight variation)	The acceptance value of first 10 dosage units are less than or equal to 15.0.	7.7
Disintegration Time	Not More Than 30 minute.	4 minute.
Dissolution	Not less than 80.00%(Q) of the labelled amount of Celecoxib is dissolved in 30 minutes.	86.07% to 92.62%
Related Substances		
a). Related compound-A	Not more than 0.400%	0.003%
b). Related compound-B	Not more than 0.200%	Not detected
c). Individual unknown impurity	Not more than 0.200%	0.004%
d). Total Impurity	Not more than 1.000%	0.007%
Microbial Contamination		
Total bacterial count	NMT 1000 cfu / gm	20 cfu / gm
Total Yeast and mould count	NMT 100 cfu / gm	<10 cfu / gm
Escherichia coli	Should be absent / gm	Absent / gm
Salmonella	Should be absent / 10 gm	Absent / 10 gm
Pseudomonas aeruginosa	Should be absent / gm	Absent / gm
Staphylococcus aureus	Should be absent / gm	Absent / gm
Assay: Each capsule contains:		
Celecoxib BP....200mg	Between 95.0 and 105.0 %	99.9 %

CONCLUSION :The above product Complies as per specification no. FPS/CA/01077/01

PREPARED BY
05/10/18
BIBEKANANDA BISWAS
Executive-QC

REVIEWED BY
05/10/18
RANVIJAY SINGH
Team Leader-QC

APPROVED BY
05/10/18
PRITAM SHAH
Head-QC

Regd. Office : 251-254, IInd Floor, DLF Tower, 15, Shivaji Marg, New Delhi-110015 (INDIA)
Phone : 011-47770900 Fax : +91-11-47770999 e-mail : gracure@vsnl.com
CIN : U24232DL1992PLC049002

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CERTIFICATE OF ANALYSIS

PRODUCT NAME	: CELECOXIB CAPSULE 200 mg	AR NO. :	GPB/1819/QCP/FGQ/00674
PRODUCT CODE	: FG20107700310	PACK SIZE	: 3x10 CAPS.
BATCH NO.	: CE-2166	BATCH SIZE	: 20400.00 CTN
MFG. DATE	: 09/2018	SAMPLE QUANTITY	: 60.00 CAP
EXP. DATE	: 08/2020	DATE OF RELEASE	: 05/10/2018

TEST	ACCEPTANCE CRITERIA	RESULT
Description	Dark green / Dark green coloured hard gelatin capsules, containing white granular powder.	Dark green / Dark green coloured hard gelatin capsules, containing white granular powder.
Identification (By HPLC)	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.
Average weight	Between 265.00 and 285.00 mg.	269.37 mg.
Average Net Content	Between 200.00 and 220.00 mg	204.62 mg
Uniformity of fill weight	± 10.00% of average fill 18/20 ± 10% of average fill 2/20 ± 20% of average fill	-3.48% to +4.49%
Uniformity of dosage units (by weight variation)	The acceptance value of first 10 dosage units are less than or equal to 15.0.	7.3
Disintegration Time	Not More Than 30 minute.	6 minute.
Dissolution	Not less than 80.00%(Q) of the labelled amount of Celecoxib is dissolved in 30 minutes.	89.56% to 106.00%
Related Substances		
a). Related compound-A	Not more than 0.400%	Not detected
b). Related compound-B	Not more than 0.200%	Not detected
c). Individual unknown impurity	Not more than 0.200%	0.007%
d). Total Impurity	Not more than 1.000%	0.011%
Microbial Contamination		
Total bacterial count	NMT 1000 cfu / gm	25 cfu / gm
Total Yeast and mould count	NMT 100 cfu / gm	<10 cfu / gm
Escherichia coli	Should be absent / gm	Absent / gm
Salmonella	Should be absent / 10 gm	Absent / 10 gm
Pseudomonas aeruginosa	Should be absent / gm	Absent / gm
Staphylococcus aureus	Should be absent / gm	Absent / gm
Assay: Each capsule contains:		
Celecoxib BP....200mg	Between 95.0 and 105.0 %	97.1 %

CONCLUSION :The above product Complies as per specification no. FPS/CA/01077/01

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