





FINISHED PRODUCT SPECIFICATION

(For restricted circulation only)

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Product Name	TAXIM-O DRY SYRUP	Page No	Page 1 of 3	
Generic Name	Cefixime for oral suspension IP 50mg/5ml	Shelf life	24 Months	
P.C. No	FD4601	Effective Date	09.07.2009	
Specification No.	SPC/FD4601/024-02	Review Date	08.07.2012	
Reference STP No.	Follow the current version of STP/FD4601/024			
	Prepared By	Checked By	Approved By	Authorised By
Signature				
Name	VANDANA SHARMA	ASAY TIALI	BHUPESH KALDA	SHAILESH PATEL
Date	08.07.09	08.07.09	08.07.2009	09.07.2009





FINISHED PRODUCT SPECIFICATION FOR RELEASE

SR. NO.	TESTS	SPECIFICATION
1.	DESCRIPTION	An Off white free flowing granular powder filled in 30 ml bottles. On reconstitution with water, gives off-white coloured homogenous suspension.
2.	IDENTIFICATION TEST (BY HPLC)	The chromatogram of the sample preparation exhibit a major peak for cefixime, the retention time of the major peak should correspond to that exhibited in the chromatogram of the standard preparation as obtained in the assay.
3.	AVERAGE FILL WEIGHT	15gm \pm 5.0%
4.	UNIFORMITY OF WEIGHT	\pm 5% of the average fill weight
5.	pH	Between 2.5 and 4.5.
6.	WATER CONTENT (BY K.F.)	Not more than 2.0% w/w.
7.	WEIGHT PER ML	1.18 \pm 0.05gm/ml
8.	VISCOSITY	900 \pm 150cps
9.	UNIFORMITY OF DOSAGE UNITS (By weight variation)	Each individual content is between 85.0% and 115.0% of the average value.
10.	ASSAY: EACH 5ML CONTAINS: CEFIXIME 50MG	Not less than 50.0mg and not more than 55.0mg. Not less than 100.0% and not more than 110.0% of the labelled amount of cefixime.

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P.C. No	FD4601	Effective Date	09-07-2009	
Specification No.	SPC/FD4601/024-02	Review Date	08.07.2012	
Reference STP No.	Follow the current version of STP/FD4601/024			
	Prepared By	Checked By	Approved By	Authorised By
Signature				
Name	VANDANA SHARMA	AJAY TYAGI	BHUPESH KANDA	SHAILESH PATEL
Date	08.07.09	08.07.09	08.07.2009	09.07.2009





FINISHED PRODUCT SPECIFICATION FOR SHELF-LIFE

SR. NO.	TESTS	SPECIFICATION
1.	DESCRIPTION	An Off white free flowing granular powder filled in 30 ml bottles. On reconstitution with water, gives off-white coloured homogenous suspension.
2.	IDENTIFICATION TEST (BY HPLC)	The chromatogram of the sample preparation exhibit a major peak for cefixime, the retention time of the major peak should correspond to that exhibited in the chromatogram of the standard preparation as obtained in the assay.
3.	AVERAGE FILL WEIGHT	15gm \pm 5.0%.
4.	UNIFORMITY OF WEIGHT	\pm 5% of the average fill weight
5.	pH	Between 2.5 and 4.5.
6.	WATER CONTENT (BY K.F.)	Not more than 2.0% w/w.
7.	WEIGHT PER ML	1.18 \pm 0.05gm/ml
8.	VISCOSITY	900 \pm 150cps
9.	UNIFORMITY OF DOSAGE UNITS (By weight variation)	Each individual content is between 85.0% and 115.0% of the average value.
10.	ASSAY: EACH 5ML CONTAINS: CEFIXIME 50MG	Not less than 45.0mg and not more than 60.0mg. Not less than 90.0% and not more than 120.0%.

FINISHED PRODUCT SPECIFICATION

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Product Name	TAXIM-O DRY SYRUP	Page No	Page 3 of 3	
Generic Name	Cefixime for oral suspension IP 50mg/5ml	Shelf life	24 Months	
P.C. No	FD4601	Effective Date	09.07.2009	
Specification No.	SPC/FD4601/024-02	Review Date	08.07.2012	
Reference STP No.	Follow the current version of STP/FD4601/024			
	Prepared By	Checked By	Approved By	Authorised By
Signature				
Name	VANDANA SHARMA	AJAY TRALI	BHUPESH KALRA	SHAILESH PATEL
Date	08.07.09	08.07.09	08.07.2009	09.07.2009

REVISION HISTORY

SR. NO.	SPECIFICATION No.	REVISION No.	CHANGE MADE
1.	New Specification	-	-----
2.	SPC/FO4601/024-01 Supersedes SPC/FO4601/024	01	1.Updating the specification with respect to change in format.
2.	SPC/FO4601/024-02 Supersedes SPC/FO4601/024-01	02	1.Pharmacopoeia status has been changed from IH to IP.