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madras pharma

**CERTIFICATE OF ANALYSIS – FINISHED PRODUCT**

Name of the Product: MYDAWA Clindamycin 300mg (Clindamycin capsule BP 300 mg)			
Batch No	R1316	Batch Size	100000 capsules
Mfg. Date	APR 2016	Exp. Date	MAR 2018
Report No.	MPB/0794/D1816	Date of Release	04/05/2016

RESULT OF ANALYSIS

S.No	TEST	OBSERVATION	SPECIFICATION				
1.	Description	Light Blue/white hard gelatin capsule filled with a white powder.	Light Blue/white hard gelatin capsule filled with a white powder.				
	Identification 1) By IR 2) By HPLC	Complies Complies	The infrared absorption spectrum of the sample residue, is concordant with the reference spectrum of Clindamycin hydrochloride. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak due to Clindamycin hydrochloride in the chromatogram obtained with solution (2).				
2.	Average fill weight	514.01 mg	520 mg ± 3.0% (504.4mg to 535.6mg)				
3.	Uniformity of fill weight	(-)4.15% to (+)2.76%	±7.5% of average fill weight				
4.	Disintegration time	8 minutes	Not more than 30 minutes				
5.	Water	5.519%w/w	Not more than 7% w/w				
6.	Related substances (By HPLC) Impurity B Impurity C Single Impurity Total Impurities	0.86% 0.35% 0.10% 0.39%	Not more than 2.0% Not more than 4.0% Not more than 1.0% Not more than 6.0%				
7.	Assay: Each hard gelatin capsule contains: Clindamycin HCL BP Equivalent to Clindamycin	293.13mg(97.71%)	<table><tr><td>Label Claim</td><td>Limit</td></tr><tr><td>300 mg</td><td>270 mg to 330 mg (90% to 110%)</td></tr></table>	Label Claim	Limit	300 mg	270 mg to 330 mg (90% to 110%)
Label Claim	Limit						
300 mg	270 mg to 330 mg (90% to 110%)						
8.	Microbial Limit test Total Aerobic microbial count Total yeast and mould count <i>E.Coli</i> <i>Salmonella</i> <i>Pseudomonas Aeruginosa</i> <i>Staphylococcus aureus</i>	40cfu/gm 20cfu/gm Absent/gm Absent/10gm Absent/gm Absent/gm	Not more than 2000 cfu/gm Not more than 200 cfu/gm Should be absent/gm Should be absent/10gm Should be absent/gm Should be absent/gm				

Remarks: THE SAMPLE CONFORMS TO BP /IHS WITH RESPECT TO TESTS PERFORMED

Approved by: **ARISHA**
Designation: **Manager QC**



THE MADRAS PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS OF WORKING STANDARD

Product Name	Clindamycin HCL	A.R Number	MPXR/0012/D0915
Working standard No	WS-245/15/01R	Effective Date	Nov 2015
Quantity	300 mg	Date of validity	Oct 2016

S.NO.	TEST	SPECIFICATION	RESULT
1.	Description	White or almost white crystalline powder	Almost white powder
2.	Identification (By IR)	The sample spectrum should concordant with standard spectrum	Complies
3.	Water	3.0% to 6.0%	4.06%
4.	Assay (on Anhydrous basis)	Clindamycin HCL contains not less than 91.0% and not more than 102.0% of Clindamycin HCL	97.80%
Store at Cool place Standardized against IPC reference standard Clindamycin HCL -Reference No:IPRS/184/12			

Prepared By	S. J. L. K.	Reviewed By	R. Srinivasan	Approved BY	
Date	15/11/15	Date	15/11/15	Date	15/11/15

