

TODAY LETTER DATED 15.01.2019

NEW DRUG

S.NO.	NAME OF APPLICANT	DIARY NO.	TYPE OF LETTER
1.	M/S. LUPIN LTD	-	PERMISSION (FORM 46A)
2.	M/S. LAMBDA THERAPEUTIC RESEARCH LTD	-	CT NOC (2)
3.	M/S. SANOFI-SYNTHELABO (I) PVT LTD	-	LETTER
4.	M/S. WOCKHARDT LTD	-	LETTER
5.	M/S. HETERO LABS LTD	-	QUERY LETTER
6.	M/S. BAXTER (I) PVT LTD	-	QUERY LETTER
7.	M/S. NATCO PHARMA	-	QUERY LETTER
8.	M/S. WILLMAR SCHWABE INDIA PVT LTD	-	QUERY LETTER

SUBSEQUENT NEW DRUG

S. NO.	NAME OF THE FIRM	REFERENCE NO.	COMPUTER NO.	TYPE OF LETTER
1.	M/S UNICHEM LABORATORIES	30039	53112	LETTER
2.	M/S RUSAN PHARMA	36163	-	BE NOC, DEFICIENCY LETTER
3.	M/S MSN LABORATORIES	34457	1114951	AMENDMENT LETTER
4.	M/S MICRO LABS LIMITED	272	1182700	DEFICIENCY LETTER
5.	M/S MYLAN PHARMACEUTICALS	28675	-	LETTER
6.	M/S GELTECH	23126	-	APPROVAL LETTER
7.	M/S ZIM LABORATORIES	16963	-	APPROVAL LETTER
8.	M/S AKUMS	27533	-	APPROVAL LETTER

LETTER PERTAINING TO SHELF LIFE

S.NO.	NAME OF APPLICANT	DIARY NO.	TYPE OF LETTER
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1.	NECTAR LIFE SCIENCE LTD.	NIL	LETTER
2.	IND-SWIFT LABORATORIES LTD.	36284	LETTER
3.	MEENASKHI MISSION HOSPITAL AND RESEARCH CENTRE	34508	LETTER

GLOBAL CLINICAL TRIAL

SR. NO.	COMPANY NAME	REFERENCE NO.	STATUS
1	M/S. ROCHE	35684	PA APPROVAL LETTER
2	M/S. BMS	-	PA APPROVAL LETTER
3	M/S. CATALYST	36207	PA APPROVAL LETTER
4	M/S. FERMISH	35642/35643	TL APPROVAL LETTERS
5	M/S. B J. MEDICAL COLLEGE	-	TL APPROVAL LETTER

BE NOC FOR EXPORT

SR. NO.	COMPANY NAME	REFERENCE NO.	STATUS
1	M/S. ALEMBIC PHARMACEUTICALS LIMITED, VADODARA-390003	99	AMENDMENT LETTER
2	M/S. LAMBDA THERAPEUTIC RESEARCH LTD., GUJARAT-382481	98/ 143	CLARIFICATION LETTER
3	M/S. SUN PHARMACEUTICAL INDUSTRIES LTD., GUJARAT-390012	169	AMENDMENT LETTER
4	M/S. SUN PHARMACEUTICAL INDUSTRIES LTD., GUJARAT-390020	35501 (21)	ACKNOWLEDGEMENT LETTER
5	M/S. SYNCHRON RESEARCH SERVICES PVT. LTD., AHMEDABAD-380059, GUJARAT	36521	CLARIFICATION LETTER
6	M/S. TORRENT PHARMACEUTICALS LIMITED, GUJARAT-380009	31558/ 25	ACKNOWLEDGEMENT LETTER
7	M/S. WATSON PHARMA PVT. LTD., DIST. THANE-421506, MAHARASHTRA	72	ADDITIONAL STUDY SITES

FDC DIVISION

S.NO.	NAME OF COMPANY	DIARY NO.	DOCUMENT
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1.	M/S. AKUMS DRUG & PHARMACEUTICALS	5039	02 LETTERS
2.	M/S. NOVARTIS HEALTHCARE	32958	LETTER
3.	M/S. ERIS LIFE SCIENCES	NIL	02 LETTERS
4.	M/S. NOEL PHARMA	50531	LETTER
5.	M/S. KREBZ HEALTH CARE	NIL	LETTER
6.	M/S. MEYER ORGANICS	NIL	LETTER
7.	M/S. RAVIAN LIFE SCIENCES	NIL	LETTER
8.	M/S. SYNCOM HEALTHCARE	NIL	LETTER
9.	M/S. SUNCARE FORMULATIONS	NIL	LETTER
10.	M/S. UNIX BIOTECH	NIL	LETTER
11.	M/S. WALLACE PHARMACEUTICALS	NIL	LETTER
12.	M/S. ZUVENTUS HEALTHCARE	NIL	LETTER