



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

20/06/2018

ADMISSION NOTICE FOR POST GRADUATE DIPLOMA PROGRAMS 2018-2019

DEGREE COLLEGE

The admissions of Post Graduate Diploma programs in-

1. Dietetics and Applied Nutrition
2. Regulatory Affairs
3. Clinical Studies Data Management and Medical Writing
4. Horticulture and Landscape Designing

will commence from 1st July 2018. Students must fill the form. The eligibility criteria and fee structure is available on the college website. Admission will be on fulfilment of criteria. Students must pay the fees.



Usha Principal

PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

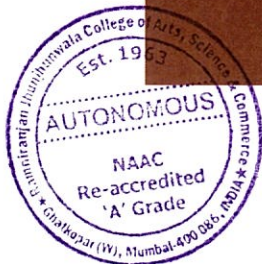
Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

BROCHURE



Postgraduate Diploma in

Regulatory Affairs




PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt. of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's) RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI II NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

O 5894	Title	:	Post Graduate Diploma in Regulatory Affairs
O 5895	Eligibility	:	B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemistry, Biotechnology, Microbiology, Life Sciences), PhD's and Pharmaceutical Professionals
R 8196	Duration of the Course	:	1 Year
R 8197	Fee Structure	:	Rs. 20,000/-
R 8198	Intake Capacity	:	40 Students
R 8199	Teacher Qualifications	:	B.Pharm, M.Pharm, Science Graduate, Post graduate, PhD's and Pharmaceutical Professionals
R 8200	Standard of Passing	:	

- Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.
- A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.
- Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.
- Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.
- Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.



Ushve

PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

Syllabus for Post Graduate

Diploma in Regulatory Affairs

Scheme of Examination

Paper	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	PAPER CODE
I	Regulatory Affairs	300	150	24 Credits	PGDRA001
II	Regulatory Affairs	300	150	24 Credits	PGDRA002
	Total	600	300	48 Credits	




PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt. of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

Syllabus for Post Graduate Diploma in Regulatory Affairs

Important to Regulatory Affairs in Pharma Industry

- Basic regulatory framework with respect to Regulated and Non-regulated market practices and procedures.
- Global Pharmaceutical Industry Scenario.

Paper I

24 Credits

Basic ICH Requirement

- ICH Topics
- Q1 -Stability
- Q2 -Analytical Validation
- Q3 -Impurities
- Q4 -Pharmacopoeia
- Q6 -Specifications
- Q7 -GMP API
- Q8 -Pharmaceutical Development
- Q9 -Quality Risk Management
- Q10 -Pharmaceutical Quality System
- Q11 -Development and manufacture of drug

Regulatory Filing systems for Active Pharmaceutical Ingredients in different countries.

- EU - ASMF, CEP, EU DMF
- US - DMF application, preparation and annual report.
- Semiregulated Markets- Requirement of API.
- Genotoxic Impurities, Elemental Impurities, Polymorphic form and characterization.
- Various types of DMF
- CTD -Module 1,2,3
- Quality Overall Summary (QOS)
- Quality by design concept applicable to API
- Post approval changes and handling deficiencies

Regulatory Filing systems in Europe.

- EMEA Procedures -Centralized, Decentralized, Mutual recognition and National procedure.
- CTD-Module 1, 2, 3, 4, 5 (including QOS, quality design concept and bioequivalence).
- Variation and Renewals
- Query-Response.



Usha

PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

Paper II

24 Credits

Regulatory Filing systems in US.

- Various Types of application - IND, NDA and ANDA.
- CTD- Module1, 2, 3 and CTD Overall summary -Module1, 2, 3 including quality overall summary and Quality by design CTD module. Module 4 and 5 (including Bioequivalence).
- Post approval changes.

Registration procedures in various countries:

- Australia
- New Zealand
- Canada
- South Africa/Africa
- Latum
- DCGI(India)
- Asia
- Russia/CIS

Pharmacovigilance in EU/US

- Interviews for Regulatory Opening.
- Case study for both US and EU

AUDIT Checklist

- Prior Approval Inspections (PAI)
- Out of Specifications (OOS), Inspection and Audits, Deviations and Change Controls
- Annual Product Reviews (APRs) for Pharmaceuticals



Usha
PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's) **RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce**

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

References:

- Stability Testing of New Drug Substances and Products Q1A(R2)
- Validation of Analytical Procedures: Text and Methodology Q2(R1)
- Impurities in new drug substance Q3A(R2)
- Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (Q6A)
- Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Q7)
- Organization of the Common Technical Document For the Registration of Pharmaceuticals for Human Use M4
- DISSOLUTION Guidance (USP pharmacopoeia Chapter 711)




PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt. of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

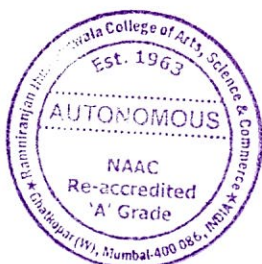
College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI II NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

PG Diploma in Regulatory Affairs

REPORT

The PG Diploma in Regulatory affairs commenced on 10th August 2018. All industries follow rules laid down by the regulatory authorities. These have to be followed strictly and all rules must be complied upon. Dr. Dilip Tripathi an expert in regulatory affairs was the coordinator of the program. Students enjoyed the interactive sessions in the premises and looked forward to his guidance. He also helped the students to prepare for interviews and in placements by informing them about the vacancies. They were trained in making dossier and were evaluated continuously on successful completion of the course students were given Post Graduate Diploma certificates.



Ushu

PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

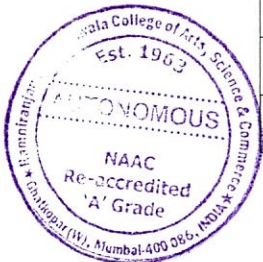
College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

PG Diploma in Regulatory Affairs

LIST OF STUDENTS WHO COMPLETED THE COURSE

SR NO	NAME	ROLL NO
1	BHELEKAR ARATI SANJAY SANGITA	1
2	DESAI SNEHA SHRIHARI	2
3	DUBEY SUNIL MATAPRASAD REKHA	3
4	KAMBLE NAYAN UTTAM BHARTI	4
5	KAMBLE PRAMOD PADMAKAR RANJANA	5
6	KAMBLE VISHAKHA RUPCHAND MEENAKSHI	6
7	KAVTHANKAR SIDDHESH SUDHIR SUPRIYA	7
8	KHOT PRATHAMESH BALKRISHNA PRIYANKA	8
9	LANDGE AKSHAY UTTARESHWAR RATNAPRABHA	9
10	MANDAVKAR SANDESH SAKHARAM SUGANDHA	10
11	MANGALE NIRAJ RAVINDRA RASHMEE	11
12	MEHTA KINJAL RAKESH RASEELA	12
13	MUKADAM SADAF ABDUL AZIZ REHANA	13
14	NAWALE KAVITA PRAKASH SINDHU	14
15	NIKAM SWAPNALI PRADIP ALKA	15
16	PAREKH VIDHI JITESH ANJANA	16
17	POWLE PUSHKAR DEEPAK	17
18	RAUT OMKAR PRABHAKAR PRATIBHA	18
19	RAVINDRAN PREETHI RAVINDRAN K ANITHA	19
20	SHAIKH AAYESHA ABDUL AZEEZ WASIM BANO	20
21	SINGH ANKIT PAVANKUMAR SASI	21
22	THORVE PRANALI NAVNATH ASHALATA	22
23	WAVAL AKSHAY PANDURANG SHASHIKALA	23




PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in

Email: rjcollege@rjcollege.edu.in

Tel No: +91 22 25151763

Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

24	YADAV GUDIYA RAMBALI MANJULA	24
25	MOURYA SONI KASHIRAM SHIVKUMARI	25
26	KHOKRALE PRIYANKA KISAN RANJANA	26
27	SHINDE SNEHA NARESH SWETA	27
28	BAVANE KAPIL MARUTI SUREKHA	28
29	JAGTAP POONAM UTTAM UJWALA	29
30	MAURYA NEHA KAILASH NATH MAURYA GEETA MAURYA	30
31	PAL JYOTI ASHOK SHIVADEVI	31
32	SHAIKH RABIYA NAAZ JABIR AHMED RUQAIYA JABIR AHMED	32
33	PATEL SAMREEN SADIQ NAJMA	33
34	RAI SONAM AKHILESH NIRAJ	34
35	DHEKANE TAPASYA PRASHANT SHABARI	35
36	DHURIYA PRIYANKA RAMDHIRAJ SUMITA	36
37	MOGAM MANASI VASANT VANDANA	37
38	D N ARUNKUMAR NINGRAJ JANAKI	38




PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt. of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2018: Autonomous Status by University Grants Commission (No. F. 22-1/2018(AC) - 28.05.2018) & by University of Mumbai (No. Aff./ICD/18-19/440 - 08.06.2018)

Hindi Vidya Prachar Samiti's
RAMNIRANJAN JHUNJHUNWALA COLLEGE
of Arts, Science & Commerce
(Autonomous)

Affiliated to **UNIVERSITY OF MUMBAI**

CERTIFICATE OF MERIT



This is to certify that

BHELEKAR ARATI SANJAY SANGITA

has secured

"A+" Grade

in Postgraduate Diploma in Regulatory Affairs
in the examination held in Aug, 2019.

Controller of Examination

**Certified as
TRUE COPY**

Principal

Ramniranjan Jhunjhunwala College,
Guatkopar (W), Mumbai-400086.

Principal