Boehringer Ingelheim

Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Straße 173, 55216 Ingelheim am Rhein, Germany
Manufacturing Authorisation: DE_RP_01_MIA_2019_0025
Берингер Ингельхайм Фарма ГмбХ и Ко. КГ, Бингер Штрассе 173, 55216 Ингельхайм-на-Рейне, Германия Лицензия на производство: DE_RP_01_MIA_2019_0025

Certificate of Analysis and Conformance
Сертификат анализа и соответствия

Product name / Наименование лекарственного средства	Mirapex® 30 tablets 1 mg / Мирапекс® 30 таблеток 1 мг
Article No. / Lot No. / Артикул № / Серия №	59370386 / 006408
Marketing Authorization No. / Регистрационное удостоверение №	П N015908/01
API name / Наименование фармацевтической субстанции	Pramipexole dihydrochloride monohydrate / Прамипексола дигидрохлорида моногидрат
API Manufacturer / Производитель АФС	Boehringer Ingelheim Pharma GmbH & Co. KG
Dosage form / Лекарственная форма	Tablets / таблетки
Container Type / Вид упаковки	PA/Al/PVC blister / Блистер из ПА/алюминиевой фольги/ПВХ
Order-No. / № заказа	90279264
BIX No. / №-BIX	370386
BIX Version / BIX-версия	24
Quantity / Количество упаковок	70272
Date of Manufacture / Дата производства	07.09.2020
Date of Expiry / Срок годности	30.09.2023
Number of Normative Documentation: / Номер нормативной документации:	П N015908/01-091118 Var./ Изм. № var. 1, var. 2

I hereby certify that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and that the batch of the finished drug product for medical use conforms to the quality specifications established by the Normative Documentation.

Настоящим подтверждаю, что все стадии производства данной серии готового продукта выполнены в полном соответствии с требованиями GMP ЕС, а также что серия лекарственного препарата для медицинского применения соответствует спецификации нормативной документации.

Remarks: / Примечания:

Storage
At temperature below 30°C protected from light.

Хранение
При температуре не выше 30 °C, в защищенном от света месте.

Packaging conforms to the approved Normative Documentation.
Упаковка соответствует согласованной нормативной документации.

Labelling conforms to the approved Normative Documentation.
Маркировка соответствует согласованной нормативной документации.

Dr. Werner Faatz

06. Nov. 2020

Qualified Person/
Quality Assurance

Date / Name / Signature of the Qualified Person/Quality Assurance
Дата / Имя / Подпись уполномоченного лица, обеспечение качества

Boehringer Ingelheim Москва

Certificate of Analysis and Conformance

Boehringer Ingelheim

Product Name: Mirapex® 30 tablets 1 mg
Batch / Lot: 006408
Registration: Russia

Inspection Lot: 3549220

Test	Specification	Result
Description	White, round, flat, bevel-edged tablets. On one side the tablet is deeply scored and embossed with code P9 (on each half of this side), on the other side the tablet is scored and embossed with company symbol (on each half of this side).	Conforms
Water	Not more than 6.0 %	3,2 %
Disintegration	Not more than 15 min	3/2/2/3/2/2 min
Identification	Retention time of major peak in the chromatogram obtained with test solution should correspond to retention time of major peak in the chromatogram obtained with standard solution of pramipexole dihydrochloride monohydrate.	Conforms
	UV absorption spectrum of test solution prepared according to the procedure provided in Assay section should correspond to UV absorption spectrum of standard solution within the range of 220 - 330 nm.	Conforms
Related impurities	SND 919 CL2Y, degraded to BI-II 828 BS not more than 0.048 %, equivalent to 0.033 % BI-II 828 BS	<= 0,010 %
	SND 919 CL2Y, degraded to BI-II 820 BS not more than 0.38%, equivalent to 0.3% of BI-II 820 BS	<= 0,12 %
	SND 919 CL2Y, degraded to BI-II 786 BS not more than 0.41%, equivalent to 0.3% of BI-II 786	<= 0,12 %
	SND 919 CL2Y, degraded to Product V not more than 0.7%, equivalent to 0.7% of Product V	<= 0,1 %
	SND 919 CL2Y, degraded to Product Z not more than 2.0%, equivalent to 2% of Product Z	<= 0,1 %
	Any single unidentified degradation product not more than 0.3%	<= 0,1 %
	(BI-II 546 CL, BI-II 751 XX, 2-aminobenzothiazole, SND 1117 BS, BI-IO 460 BS, Product T) Sum of all related impurities equivalent to degraded SND 919 CL2Y not more than 3.5% of degraded SND 919 CL2Y	<= 0,1 %
Assay	0.90 - 1.05 mg /tablet	0,99 mg /tablet
Dissolution	Not less than 80 % (Q) of declared content of pramipexole dihydrochloride monohydrate should release in 30 min Requirement A (n=6) No individual value should be less than Q + 5 %. Requirement B (n=12) The average should be equal to or greater than Q and no individual value should be less than Q - 15 %.	conforms
Uniformity of dosage units	Requirement A (N = 10) Acceptance value (AV) should be not more than 15.0 % Requirement B (N = 30) Acceptance value (AV) should be not more than 15.0 % and no individual content of any dosage unit is less than 0.75M nor more than 1.25M.	Conforms

CoAC-370386-V03

Москва

Certificate of Analysis and Conformance

Boehringer Ingelheim

Product Name: Mirapex® 30 tablets 1 mg
Batch / Lot: 006408
Registration: Russia

Inspection Lot: 3549220

Test	Specification	Result
Microbiological purity		
Total aerobic microbial count(TAMC)	Not more than 10^3 cfu/g	< 10 CFU/g
Total combined yeasts/moulds (TYMC)	Not more than 10^2 cfu/g	< 10 CFU/g
Escherichia coli	Absent in 1 g	absent

or Rus. Ph. - Category 3A

- End of Report -

Общество с ограниченной ответственностью "Берингер Ингельхайм" ИНН 7714103413 Москва
Boehringer Ingelheim
CoAC- 370386-V03