Angelini Pharma

QUALITY CERTIFICATE № 12507538

Product: LATUDA® film-coated tablets 80 mg
(Lurasidone hydrochloride - 80 mg)

Batch №:	03VA	**Internal code:**	130202
Manufacturing date:	June 2024	**Batch q-ty released:**	8400 Pieces
Expiry date:	May 2029		

TEST	SPECIFICATION	RESULTS
APPEARANCE *Visual*	Pale green, oval film-coated tablets, pale green in the outer borders and white to off- white in the inner part in cross-section, debossed with "L 80" on one side.	Pale green, oval film-coated tablets, pale green in the outer borders and white in the inner part in cross-section, debossed with "L 80" on one side.
IDENTIFICATION		
HPLC *(EAEU Ph., GMP 2.1.2.28. or Rus. Ph. GMP.1.2.1.2.0005.15, or Ph. Eur.[1] 2.2.29 and 2.2.46, or USP[1] mon. 621)*	Retention time of the main peak on the chromatogram of test solution should correspond to retention time of lurasidone peak on the chromatogram of standard solution.	Compiles
UV-SPECTROPHOTOMETRY *(EAEU Ph., GMP 2.1.2.24 or Rus. Ph. GMP.1.2.1.1.0003.15, or Ph. Eur.[1] 2.2.25, or USP[1] mon. 857)*	UV absorption spectrum of test solution should correspond to the UV absorption spectrum of standard solution in the wavelength range of 210 to 350 nm.	Compiles
DISSOLUTION *Ph. Eur.[1] 2.9.3 u 5.17.1 or USP[1] mon. 711, HPLC (EAEU Ph., GMP 2.1.2.28. or Rus. Ph. GMP.1.2.1.2.0005.15, or Ph. Eur.[1] 2.2.29 or 2.2.46, or USP[1] mon. 621)*	Not less than 80 % (Q) of lurasidone hydrochloride label claim within 20 min.	96 %
RELATED SUBSTANCES *HPLC (EAEU Ph., GMP 2.1.2.28. or Rus. Ph. GMP.1.2.1.2.0005.15, or Ph. Eur.[1] 2.2.29 u 2.2.46, or USP[1] mon. 621)*		
ANY INDIVIDUAL IMPURITY	Not more than 0,2 %	<0,03 %
TOTAL IMPURITIES	Not more than 0,4 %	0,0 %
UNIFORMITY OF DOSAGE UNITS *EAEU Ph., GMP 2.1.9.14 or Rus. Ph. GMP.1.4.2.0008.15, USP[1] mon. [1] 905, or Ph. Eur.[1] 2.9.40 direct definition HPLC (EAEU Ph., GMP 2.1.2.28. or Rus. Ph. GMP.1.2.1.2.0005.15, or Ph. Eur.[1] 2.2.29 and 2.2.46, or USP[1] mon. [1] 621)*	AV ≤ 15 (n = 10), if this requirement is not met then AV ≤ 15 (n = 30), and for 30/30 tablets assay of lurasidone hydrochloride should be within the range of 0.75xM - 1.25xM.	1,0
MICROBIOLOGICAL PURITY. Category 3A *EAEU Ph., GMP 2.3.1 or Rus. Ph. GMP.1.2.4.0002.18, or Ph. Eur.[1] 5.1.14, 2.6.12 u 2.6.13, or USP[1] mon. 61 and 62*		
TAMC	Not more than 10^3 CFU /g	<10 CFU/g
TYMC	Not more than 10^2 CFU /g	<10 CFU/g
ESCHERICHIA COLI	Absent/g	Absent
LURASIDONE HYDROCHLORIDE ASSAY *HPLC (EAEU Ph., GMP 2.1.2.28. or Rus. Ph. GMP.1.2.1.2.0005.15, or Ph. Eur.[1] 2.2.29 and 2.2.46, or*	From 93.0% to 107.0% of lurasidone hydrochloride label claim	101,4 %

USP[1] mon. 621)		

[1] References to Rus. Ph. and EAEU Ph. are provided in accordance with requirements adopted in the Russian Federation and EAEU. The quality control procedures at the manufacturing site are conducted according to the requirements of USP or Ph. Eur.
EAEU Ph. –Pharmacopoeia of Eurasian Economic Union, current edition.
Rus. Ph. - State Pharmacopoeia of the Russian Federation, current edition.
Ph. Eur. – European Pharmacopoeia, current edition.
USP – United States Pharmacopoeia, current edition.

TESTS	SPECIFICATIONS	RESULT
PACKAGING	14 film-coated tablets in a blister of PA/Al/PVC and aluminium foil. 2 or 4 blisters and a patient information leaflet in a carton pack. Carton pack is sealed with two transparent stickers (tamper-evident).	14 film-coated tablets in a blister of PA/Al/PVC and aluminium foil. 2 blisters and a patient information leaflet in a carton pack. Carton pack is sealed with two transparent stickers (tamper-evident).
LABELING	**In accordance with paragraph 1.3.2 of the registration dossier's module 1** ***It is indicated on blister*** **in Russian:** trade name of the product with warning labelling ®; international nonproprietary name; dosage in mg; **in English:** international nonproprietary name, логотип logotype of marketing authorization holder (graphic image and name "Angelini Pharma"). Additionally, there are inscriptions "Batch №" or "Batch №:" with indication of the batch number and "Exp:" with indication of the expiration date, in-house digital/graphic technics codes of the product/pack components. ***It is indicated on the secondary package*** **in Russian:** trade name of the product with warning labelling ®; international nonproprietary name; pharmaceutical form; dosage in mg; number of tablets per package; composition in wording: "**1 TABLET CONTAINS: lurasidone hydrochloride - 80 mg**", administration route, "**Administration route: see instruction for medical use (package insert)**", "**Keep away from children.**", storage conditions – "**At the temperature below 25°C**"; prescription status - "**Distribute on medical prescription**"; name and country of marketing authorization holder; name and country of a company carrying out	***It is indicated on blister*** **in Russian:** trade name of the product with warning labelling ® - **LATUDA®**; international nonproprietary name - **Lurasidone**; dosage in mg – **80 mg**; **in English:** international nonproprietary name - **Lurasidone**, логотип logotype of marketing authorization holder (graphic image and name "Angelini Pharma"). Additionally, there are inscriptions "Batch №" with indication of the batch number 03VA and "Exp:" with indication of the expiration date 05/2029, in-house digital/graphic technics codes of the product/pack components. ***It is indicated on the secondary package*** **in Russian:** trade name of the product with warning labelling ® - **LATUDA®**; international nonproprietary name - **Lurasidone**; pharmaceutical form – **film-coated tablets**; dosage in mg – **80 MG**; number of tablets per package – **28 tablets**; composition in wording: "**1 TABLET CONTAINS: lurasidone hydrochloride - 80 mg**", administration route – **Oral**; "**Administration route: see instruction for medical use (package insert)**", "**Keep away from children.**", storage conditions – "**At the temperature below 25°C**"; prescription status - "**Distribute on medical prescription**"; name and country of marketing authorization holder - **Angelini Pharma S.p.A., Italy**; name and country of a company carrying out quality release control - **Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Italy,**

	quality release control, name and country of bulk manufacturer; **in English:** international nonproprietary name, logotype of marketing authorization holder (graphic image and name "Angelini Pharma"). Additionally, there are a barcode, batch number, expiry date, date of manufacturing, in-house digital/graphic technical codes of the product/pack components. An identifying tag for drug product movement monitoring system may be printed (2Q code – Data matrix, global identification number and individual serial number of trade unit) straightly on pack or on label (sticker).	name and country of bulk manufacturer - **Bushu Pharmaceuticals Ltd., Japan**; **in English:** international nonproprietary name - **Lurasidone**, logotype of marketing authorization holder (graphic image and name "Angelini Pharma"). Additionally, there are a barcode, batch number 03VA, expiry date 05/2029, date of manufacturing 06/2024, in-house digital/graphic technical codes of the product/pack components. An identifying tag for drug product movement monitoring system is printed (2Q code – Data matrix, global identification number and individual serial number of trade unit) straightly on pack.
STORAGE CONDITIONS	At the temperature below 25 °C.	At the temperature below 25 °C.
SHELF LIFE	5 years	5 years

Certification statement:

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the GMP requirements of the local Regulatory Authority, Technical Dossier and **Normative Document ЛП-№(002753)-(РГ-RU)-030524** and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

API batch number: 0007
API manufacturer: Sumitomo Chemical Co., Ltd., 2200 Oazatsurusaki, Oita, Oita 870-0106, Japan
Manufacturer: Bushu Pharmaceuticals Ltd., 1 Takeno, Kawagoe, Saitama 350-0801, Japan
Primary, secondary packager and quality release control: Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy

The batch is approved and released.

Qualified Person
Annarita Zacchilli

Ancona, 22nd April 2025

Aziende Chimiche Riunite Angelini Francesco – A.C.R.A.F. – S.p.A.

Manufacturing Authorization N. aM-201/2024 – GMP Certificate N. IT/272/H/2024

Legal address:
Viale Amelia, 70
00181 - Rome (RM), Italy

Manufacturing site:
Via Vecchia del Pinocchio, 22,
60131 Ancona (AN), Italy

Tel.: +39/071/8091
Fax: +39/071/286 90 70