



Certificat d'analyse

Produit

Clonidine (chlorhydrate de)

Clonidini hydrochloridum

N° Lot	2402006735	Date de fabrication	06/03/2024
CAS-Nr.	4205-91-8	Date de retest	05/03/2028

Paramètres	Spécifications Ph. Eur. 11.0	Résultats
Caractères		
*Aspect	Poudre cristalline blanche ou sensiblement blanche.	Conforme
Solubilité	Soluble dans l'eau et dans l'éthanol anhydre.	Conforme
Identité		
*B-Spectre IR	Conforme au standard	Conforme
*D-Réaction (a) des chlorures	Selon Ph. Eur.	Conforme
Pureté		
*Aspect de la solution	Limpide et pas plus fortement colorée que la solution témoin J ₇	Conforme
*pH	4.0 à 5.0	4.4
*Substances apparentées		
- Impuretés non spécifiées	≤ 0.10% par impureté	Non détecté
- Total des impuretés	≤ 0.2%	Non détecté
*Perte à la dessiccation	≤ 0.5%	0.0%
*Cendres sulfuriques	≤ 0.1%	0.1%
*Dosage	98.5 à 101.0% (substance desséchée)	100.9%
TSE/BSE	Conforme	Conforme
Fabricant d'origine	Alembic Pharmaceuticals Limited (Inde)	R1-CEP 2014-039-Rev 01

Stockage dans un récipient étanche fermé

Le produit a été contrôlé selon les procédures pharmaceutiques en vigueur,
il est conforme aux spécifications de la Ph. Eur. 11.0.

Analyses :

20/03/2024

Samadhan Chavan

Alembic Pharmaceuticals Limited

API Unit-I, P.O. Tajpura, Near Baska

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389 350 Panelav Village, Gujarat

Inde

Tél. : +91 (02676)-664200

*10/07/2024

Felix Heppeler

Responsable Contrôle Qualité

Untersuchungsinstitut Heppeler GmbH (sous-traitant INRESA)


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D-79539 Lörrach

Tél. : +49 (0)7621/93-45-0

Contrôle et libération le 26/08/2024

Emilie Grawey-Kling
Pharmacien INRESA



Alembic
Touching lives over 100

Certificate of Analysis

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Name of Product: Clonidine Hydrochloride Ph.Eur.		Quantity / Batch size: 44.9 kg
Product Code: 30000360	Insp. Lot No./A.R.No.: FP/A1/24/0635	
Batch No: 2402006735	Stage: API	
S.O.No.: 22027573	Release date: 20/03/2024	
Mfg. Date: 06/03/2024	Retest Date: 05/03/2028	

No.	Test	Result	Specification
1	Appearance	White, crystalline powder	White or almost white, crystalline powder
2	Solubility	Soluble in water and in anhydrous ethanol	Soluble in water and in anhydrous ethanol
3	Identification A. IR B. Chloride Test	IR absorption spectrum of test sample is concordant with that of Clonidine hydrochloride standard A curdy white precipitate is formed which is insoluble in nitric acid but is soluble in a slight excess of 6N Ammonium hydroxide	IR absorption spectrum of test sample should be concordant with that of Clonidine hydrochloride standard A curdy white precipitate is formed which is insoluble in nitric acid but is soluble in a slight excess of 6N Ammonium hydroxide
4	Loss on Drying (At 105°C for 3 hours)	0.18 % w/w	NMT 0.50% w/w
5	Sulfated Ash	0.05 % w/w	NMT 0.10% w/w

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ALEMBIC PHARMACEUTICALS LIMITED
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CIN:L24230GJ019PLC081123

Format No: CQC/SOP/0096-FD14-1.0



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Page 2 of 3

Name of Product: Clonidine Hydrochloride Ph.Eur.		Quantity / Batch size: 44.9 kg
Product Code: 30000360	Insp. Lot No./A.R.No.: FP/A1/24/0635	
Batch No: 2402006735	Stage: API	
S.O.No.: 22027573	Release date: 20/03/2024	
Mfg. Date: 06/03/2024	Retest Date: 05/03/2028	

No.	Test	Result	Specification
6	Appearance of solution	Solution S is clear and less intensely coloured than reference solution Y7	Solution S should be clear and not more intensely coloured than reference solution Y7
7	pH	4.43	4.0 to 5.0
8	Related Substances (By HPLC) Unspecified Impurities Total Impurities	BOL (LOQ 0.021 %) Below quantification limit	NMT 0.10% w/w NMT 0.20% w/w
9	Assay (By Chemical)	99.9 % w/w	98.5% w/w to 101.0% w/w (on dried basis)
10	Residual Solvent Dichloromethane Methanol Isopropyl alcohol	BOL (LOQ 16 ppm) BOL (LOQ 48 ppm) 48 ppm	NMT 300 ppm NMT 2000 ppm NMT 2000 ppm

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S.O.No.: 22027573	Stage: API
Mfg. Date: 06/03/2024	Release date: 20/03/2024
Retest Date: 05/03/2028	

No.	Test	Result	Specification
11	Ethylene Diamine (By HPLC)	BOL(LOQ 6 ppm)	NMT 250 ppm

Remark: Batch complies as per Specification No.-A11SPCI-API00099-1.0

Note: Storage Conditions: Keep the container tightly closed (Drug substance does not require any special storage condition)

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